Appendix C: Importer Supporting Documentation

AdiraMedica

77 Brant Ave, Suite 325
Clark, NJ 07066
Tel: +1 908 654 8075
Fax: +1 908 654 0005
www.adiramedica.com

December 3, 2025

Center for Drug Evaluation and Research
Food and Drug Administration
10001 New Hampshire Avenue
Hillandale Building, 4th Floor
Silver Spring, MD 20993

RE: Name and Address of Importer, Contact Information for Responsible Individuals

Name of Importer: AdiraMedica, LLC

Address of Importer: 585 Turner Industrial Way, Aston Township, PA 19014

Responsible Individuals:

Name	**Contact Information**
Arvind Bhandari Co-Founder, President & CEO	Redacted
Doris Correa Senior Director, Quality Assurance	Redacted
Sharon Johnson Operations Manager	Redacted

Sincerely,

Arvind Bhandari MS, BPharm
Co-Founder, President & CEO

COLORADO
Department of Health Care Policy & Financing
303 East 17th Avenue
Denver, CO 80203

Colorado's Drug Importation Program

NON-CONFLICT OF INTEREST AND DISCLOSURE AGREEMENT

As an individual involved in the Colorado Drug Importation Program with the Department of Health Care Policy and Financing ("HCPF"), I understand that I will be responsible for parts of the program as defined in statute and the rule. By signing this document, I attest and agree that:

1. I have read this Non-Conflict of Interest and Disclosure Agreement in its entirety, and I have had the opportunity to consult with independent legal counsel regarding its contents, its meaning, the information I provide herein, and the legal significance of the Agreement and of my disclosure of any and information herein or related to it the Agreement.

2. I do not have any Actual Individual Conflicts of Interest, unmitigated Potential Individual Conflicts of Interest, or unmitigated Perceived or Apparent Conflicts of Interest, as described in Appendix A

3. I have disclosed all Potential Individual Conflicts of Interest related to this and any circumstances that could be perceived as creating bias.

4. I have provided a complete disclosure of any past criminal convictions or violations of State, Federal, or Canadian laws regarding drugs or devices as outlined by 21 Code of Federal Regulations Section 251.3(2) and shown in Appendix B.

5. I have listed below any Organization principal(s), any shareholder(s) who owns 10 percent or more of outstanding stock in the Organization, any Organization directors or officers, and any facility manager or designated representative of such a manager.

_____

_____

_____

6. Please list all disciplinary actions imposed against the Organization and any Workers of the Organization for the previous seven (7) years. Indicate 'N/A' if there are no disciplinary actions to report.

Date of Action	Party to any Action	Comments

I, FIRST MIDDLE LAST, have disclosed all affiliations with any person or organization that I have reason to believe may affect decisions related to this project or matter. I understand that I am not to participate on any matters relevant to my conflict(s) of interest as specified herein. I also further understand that if I fail to disclose any conflict(s) of interest, my participation in this project or matter will be terminated.

_____
Printed Name

_____
Signature

_____
Date

Appendix A

1. **Definitions.** For the purposes of this attestation, the following terms shall have the meanings ascribed to them below:
   a. **Actual Individual Conflict of Interest.** A situation where a financial, personal, or familial interest materially affects the Worker's duties to put the interest of the state first and compromises a Worker's objectivity, professional judgment, professional integrity, and/or ability to perform his or her duties.
   b. **Potential Individual Conflict of Interest.** A situation where a financial, personal, or familial interest could materially affect the Worker's duties to put the interest of the state first and may compromise a Worker's objectivity, professional judgment, professional integrity, and/or ability to perform his or her duties.
   c. **Perceived or Apparent Conflict of Interest** A situation where a financial, personal, or familial interest appears that it could materially affect the Worker's duties to put the interest of the state first and may appear to compromise a Worker's objectivity, professional judgment, professional integrity, and/or ability to perform his or her duties; even if no conflict of interest exists.
   d. **Organizational Conflict of Interest.** Organizational Conflict of Interest arises when an organization that receives funds from the State of Colorado, carries out part of a federal or state program as a Subrecipient, has a parent, affiliate, or subsidiary organization, and is unable or potentially unable to be impartial in conducting a procurement action involving a related organization.
   e. **Individual.** A natural person.
   f. **Organization.** Includes multiple individuals and includes all forms of legal organization.
   g. **Subrecipient.** An Individual or Organization that receives federal or state funds from the State of Colorado to carry out all or part of a federal or state program.
   h. **Worker.** Managers, supervisors, permanent full-time and part-time employees, temporary employees, contractors, applicants, volunteers, interns and for the purposes of this policy, include any individual whose close association with the employee is the equivalent of a family relationship.

2. **Applicability of this Agreement.** This agreement applies to all employees of registered partners of the State of Colorado State Importation Program. This applies and covers all Workers, and any individual who conducts business for and on behalf of the State of Colorado. Organizational Conflict of Interest: Any Subrecipient that receives federal or State funds from the State of Colorado State Importation Program shall be held to this agreement through their relationship with the partner.

3. **Consequences for Non-Compliance with this Agreement.** Any violation of this agreement will result in the immediate termination of a contract for the Partner (Organization)

Initials:_____

Appendix B

1. Include an attestation and information statement containing a complete disclosure of any past criminal convictions or violations of State, Federal, or Canadian laws regarding drugs or devices against or by the responsible individual(s), Foreign Seller, or Importer or an attestation that the responsible individual(s), Foreign Seller, or Importer has not been involved in, or convicted of, any such violations. Such attestation and information statement must include principals, any shareholder who owns 10 percent or more of outstanding stock in any non-publicly held corporation, directors, officers, and any facility manager or designated representative of such manager.

2. Include a list of all disciplinary actions, to include the date of and parties to any action imposed against the responsible individual(s), Foreign Seller, or Importer by State, Federal, or Canadian regulatory bodies, including any such actions against the principals, owners, directors, officers, quality unit, or any facility manager or designated representative of such manager for the previous 7 years prior to submission of the SIP Proposal.

H114-257 (rev. 01/19)

Commonwealth of Pennsylvania
Department of Health (DOH)
(717) 787-4779 FAX (717) 787-3188

Drug, Device, & Cosmetic Program
555 Walnut St, 7th Floor, Suite 701
Harrisburg, PA. 17101

DRUG, DEVICE, & COSMETIC COMPLIANCE INSPECTION REPORT

FIRM NAME: ADIRAMEDICA LLC	DATE: 1/14/2021	PA DOH REGISTRATION: 300009100	EXP. DATE: 11/30/2021
ADDRESS: 585 Turner Industrial Way	CHANGE ☐	PA DOH LICENSE: 800002567	EXP. DATE: 11/30/2021
CITY: Aston PA ZIP CODE: 19014	COUNTY: Delaware	FDA REGISTRATION	EXP. DATE
OWNER/PARENT (if different than above)	LEAD PERSON INTERVIEWED: Darcie Roberts	DEA REGISTRATION: RA0457603	EXP. DATE: 06/30/2021
PHONE: 610-485-5400	TITLE: MBR of QA	PA L&I LICENSE	EXP. DATE
HOURS OF OPERATION: 8-4:30 M-F	ID OF PERSON INTERVIEWED: PA 19882497	PA DOS LICENSE	EXP. DATE
TOTAL EMPLOYEES/ FACILITYSIZE: 5-7	INSPECTOR NAME:	OTHER REGISTRATION	EXP. DATE

Initial Inspection		Type of Action/Pursuant to:	X Controlled Substance, Drug, Device, & Cosmetic Act, Act 64 of 1972
Investigation/Compliance	X		X Wholesale Prescription Drug Distributors License Act, Act 145 of 1992
Follow-up			Noncontrolled Substance Registration & Reporting Act
Disaster			Other

TYPE of FIRM	PRODUCTS	SUBTYPE	MISC.
Manufacturer-Drugs	X Prescription Drugs (RX)	DME	comparators
Manufacturer-Devices	X Controlled Substances	Diagnostics	
Manufacturer-Cosmetics	List I Chemicals	Optical	
Transfiller-Medical Gases	X OTC Drugs/Medicinals	Dental	controlled substances
Relabeler/Repackager	Cosmetics/Cosmeceuticals	Orthotics	
X Distributor-Drugs	Veterinary-Prescription	Prosthetics	
Distributor-Medical Gases	Veterinary- OTC	Implants	
Distributor-Devices	Medical Gases	Assisted Hearing Devices	
Distributor-Cosmetics	RX Devices	Reprocessor/Reuser	
Retailer-Medical Gases	OTC Devices	Delivery Systems	
Retailer-Drugs, Medicinals,	X Biologics/Blood Products	Radiation Emitting Device	
Practitioner/Institution	Radiation Emitting Drug	Samples	
Medicated Feed Plant/Agri.	Medicated Feed	X Clinical Trial/Investigation	
X Research/Training	API (Active Pharm Ingred.)	X Foreign Import/Export	
Other:	Other:	Other:	

FACILITY, PHYSICAL CONTROLS, & STAFF	STOCK, RECORDS, & POLICIES	QUALITY CONTROL	KEY NOTES

"X" denotes firm meets standard in this area. "N" denotes deficiency in this area. " / " denotes not applicable

X	Physical Condition	X	Inventory control/Errors	X	Adulterated/Expired
X	Adequate Equipment	X	Suspect Product Policy	X	Misbranded
X	Physical Security	X	Recall Policy	X	Contraband
X	Staff Security/Limited Access	X	Return Goods Policy		*Manufacturing/Repack Only*
X	Temperature system/Logs	X	Emergency Policy/Reporting		Adherence to GMP
X	Ventilation/Humidity	X	Track and Trace System		Validation: Equipment
X	Running Water/Restroom	X	Receiving Records/Pedigree		Raw Materials
X	Cleanliness/Pest-Free	X	Distributing Records		Intermediaries
X	Quarantine/Hold Area	X	Authorized trading/transfer		Finished Prod.
X	Appropriate Storage	X	Disposal/Destruction Records		Sterile/X Contamination
X	Registration/Licenses	X	Controlled Substance Rec		Product Label/Identifiers
X	Perm. Site (deed/lease > 6m)	X	Labels/Prescription Order		Batch Record/Lot No.
X	Qualified Staff & Supervision		Other:		Other:
X	Name/ID/qualifications of manager:	PA 19882497, Darcie Roberts 10+ years			

Physical standards met. Personnel standards met.
Recordkeeping standards met. Policy/Procedure standards met

PASS / **FAIL** or **PASS-pending** (pending corrections made noted above & date corrections must be made)

Signature of Inspector

Darcie Roberts
Signature of Firm Representative

1/14/2021
Date

H114-257 (rev. 12/22)

Commonwealth of Pennsylvania
Department of Health (DOH)
(717) 787-4779 FAX (717)-231-4790

Drug, Device, & Cosmetic Program
2525 North 7th Street, Suite 210D
Harrisburg, PA. 17110

DRUG, DEVICE, & COSMETIC COMPLIANCE INSPECTION REPORT

FIRM NAME: ADIRAMEDICA LLC		DATE: 7/26/2024		PA DOH REGISTRATION: 30000091005	EXP. DATE: 11/30/24
ADDRESS: 585 Turner Industrial Way			CHANGE ☐	PA DOH LICENSE: 800060 2567	EXP. DATE: 11/30/24
CITY: Aston PA	ZIP CODE: 19014	COUNTY: Delaware		FDA REGISTRATION	EXP. DATE
OWNER/PARENT (if different than above)		LEAD PERSON INTERVIEWED: Darcie Roberts		DEA REGISTRATION: RA0457603	EXP. DATE: 06/30/25
PHONE: 610-485-5400		TITLE: MGR QA		PA L&I LICENSE	EXP. DATE
HOURS OF OPERATION: 8-4:30 M-F		ID OF PERSON INTERVIEWED: PA DL 19882497		PA DOS LICENSE	EXP. DATE
TOTAL EMPLOYEES/FACILITYSIZE: 10-15		INSPECTOR NAME: T. Ritchie		OTHER REGISTRATION	EXP. DATE

Initial Inspection		Type of Action/Pursuant to:	X	Controlled Substance, Drug, Device, & Cosmetic Act, Act 64 of 1972
Investigation/Compliance	X	Routine	X	Wholesale Prescription Drug Distributors License Act, Act 145 of 1992
Follow-up				Noncontrolled Substance Registration & Reporting Act
Disaster				Other

TYPE of FIRM		PRODUCTS		SUBTYPE		MISC.
	Manufacturer-Drugs	X	Prescription Drugs (RX)		Contract manufacturer	Mostly traditional
	Manufacturer-Devices	X	Controlled Substances	X	Wholesaler	wholesaler
	Manufacturer-Cosmetics		List I Chemicals		Intra-company transfers	
	Transfiller/Mfr. Medical Gases	X	OTC Drugs/Medicinals	X	3PL/Third Party logistics	some 3PL activity
	Relabeler/Repackager		Cosmetics/Cosmeceuticals		DME	
X	Distributor-Drugs	X	Veterinary-Prescription		Optical	
	Distributor-Medical Gases	X	Veterinary- OTC		Dental Lab	
	Distributor-Devices		Medical Gases		Prosthetics	
	Distributor-Cosmetics	X	RX Devices		Orthotics	
	Retailer-Medical Gases	X	OTC Devices		Assisted Hearing Devices	
	Retailer-Drugs, Medicinals,	X	Biologics/Blood Products		Reprocessor/Reuser	
	Practitioner/Institution		Radiation Emitting product		Samples	
	Medicated Feed Plant/Agri.		Medicated Feed	X	Clinical Trial/Investigation	
	Research/Training		API (Active Pharm Ingred.)	X	Foreign Import/Export	
	Other:		Other:		Other:	

FACILITY, PHYSICAL CONTROLS, & STAFF		STOCK, RECORDS, & POLICIES		QUALITY CONTROL		KEY NOTES
"X" denotes firm meets standard in this area. "N" denotes deficiency in this area. " / " denotes not applicable						
X	Physical Condition	X	Inventory control/Errors	X	Adulterated/Expired	
X	Adequate Equipment	X	Suspect Product Policy	X	Misbranded	
X	Physical Security	X	Recall Policy	X	Contraband	
X	Staff Security/Limited Access	X	Return Goods Policy		*Manufacturing/Repack Only*	
X	Temperature system/Logs	X	Emergency Policy/Reporting		Adherence to GMP	
X	Ventilation/Humidity	X	Track and Trace System		Validation: Equipment	
X	Running Water/Restroom	X	Receiving Records/Pedigree		Raw Materials	
X	Cleanliness/Pest-Free	X	Distributing Records		Intermediaries	
X	Quarantine/Hold Area	X	Authorized trading/transfer		Finished Prod.	
X	Appropriate Storage	X	Disposal/Destruction Records	X	Sterile/X Contamination	
X	Registration/Licenses	X	Controlled Substance Rec	X	Product Label/Identifiers	
X	Perm. Site (deed/lease > 6m)	/	Labels/Prescription Order	X	Batch Record/Lot No.	
X	Qualified Staff & Supervision		Other:		Other:	
X	Name/ID/qualifications of manager:	Jaclyn Fox 3+yrs experience PA DL 24744997				

Personnel standards met. Physical standards met. Policy/Procedure standards not. Track/Trace/Recordkeeping standards not

PASS / **FAIL** or **PASS-pending** (pending corrections made noted above & date corrections must be made _____)

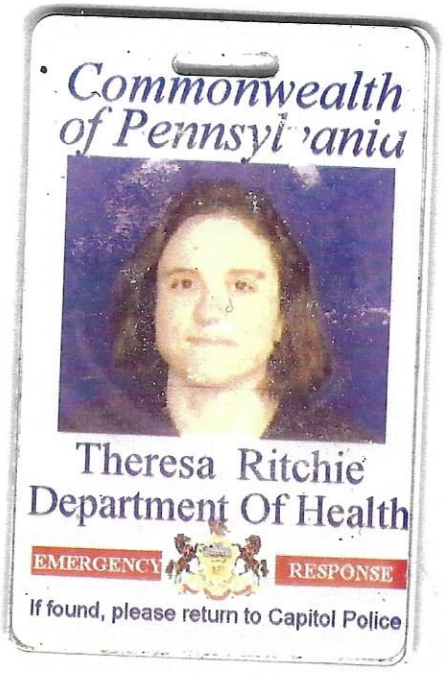
Signature of Inspector

Darcie Roberts

Signature of Firm Representative

7/26/24

Date


Commonwealth
of Pennsylvania
Theresa Ritchie
Department Of Health
EMERGENCY
RESPONSE
If found, please return to Capitol Police

Lookup Detail View

Licensee Information

This serves as primary source verification of the license.*

**Primary source verification: License information provided by the Colorado Division of Professions and Occupations, established by 24-34-102 C.R.S.*

Name	DBA	Public Address
AdiraMedica LLC		Aston, PA 19014

Credential Information

License Number	License Method	License Type	License Status	Original Issue Date	Effective Date	Expiration Date
WHO.0008393	Original	Wholesaler Out-of-State	Active	12/07/2018	11/01/2024	10/31/2026

Board/Program Actions

Discipline
There is no Discipline or Board Actions on file for this credential.

Generated on: 9/9/2025 1:34:20 PM

Wholesale Distributor and Third-Party Logistics Provider Reporting

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Search Results for *"Adira"*

Showing 1 to 17 of 17 entries Show 50 entries

Facility Name	Facility Type	License Number	License State	License Expiration Date	Reporting Year	Address	Facility Contact Name	Facility Contact Email
AdiraMedica LLC	WDD	OSD7698	US-CA	02-01-2026	2025	585 Turner Industrial Way Aston PA	Darcie Roberts	droberts@adiramedica.com
AdiraMedica LLC	WDD	WHO.0008393	US-CO	10-31-2026	2025	585 Turner Industrial Way Aston PA	Darcie Roberts	droberts@adiramedica.com
AdiraMedica LLC	WDD	CSW.0004517	US-CT	06-30-2025	2025	585 Turner Industrial Way Aston PA	Darcie Roberts	droberts@adiramedica.com
AdiraMedica LLC	WDD	A4-0012982	US-DE	09-30-2026	2025	585 Turner Industrial Way Aston PA	Darcie Roberts	droberts@adiramedica.com
AdiraMedica LLC	WDD	PHWH004558	US-GA	06-30-2025	2025	585 Turner Industrial Way Aston PA	Darcie Roberts	droberts@adiramedica.com
AdiraMedica LLC	WDD	004.004072	US-IL	12-31-2026	2025	585 Turner Industrial Way Aston PA	Darcie Roberts	droberts@adiramedica.com
AdiraMedica LLC	WDD	W04857	US-KY	09-30-2025	2025	585 Turner Industrial Way	Darcie Roberts	droberts@adiramedica.com

Facility Name	Facility Type	License Number	License State	License Expiration Date	Reporting Year	Address	Facility Contact Name	Facility Contact Email
						Aston PA		
AdiraMedica LLC	WDD	2019008246	US-MO	10-31-2025	2025	585 Turner Industrial Way Aston PA	Darcie Roberts	droberts@adiramedica.com
AdiraMedica LLC	WDD	17461/16.5a	US-MS	12-31-2025	2025	585 Turner Industrial Way Aston PA	Darcie Roberts	droberts@adiramedica.com
AdiraMedica LLC	WDD	1654	US-NC	12-31-2025	2025	585 Turner Industrial Way Aston PA	Darcie Roberts	droberts@adiramedica.com
AdiraMedica LLC	WDD	5003401	US-NJ	01-31-2026	2025	585 Turner Industrial Way Aston PA	Darcie Roberts	droberts@adiramedica.com
AdiraMedica LLC	WDD	034762	US-NY	05-31-2025	2025	585 Turner Industrial Way Aston PA	Darcie Roberts	droberts@adiramedica.com
AdiraMedica LLC	WDD	8000002567	US-PA	11-30-2025	2025	585 Turner Industrial Way Aston PA	Darcie Roberts	droberts@adiramedica.com
AdiraMedica LLC	WDD	1001687	US-TX	06-21-2025	2025	585 Turner Industrial Way Aston PA	Darcie Roberts	droberts@adiramedica.com
AdiraMedica LLC	WDD	PHWH.FX.61621981	US-WA	09-30-2025	2025	585 Turner Industrial Way Aston PA	Darcie Roberts	droberts@adiramedica.com
AdiraMedica LLC	WDD	9234-45	US-WI	05-31-2026	2025	585 Turner Industrial Way Aston PA	Darcie Roberts	droberts@adiramedica.com
AdiraMedica LLC	WDD	WD0560199	US-WV	06-30-2026	2025	585 Turner Industrial Way Aston PA	Darcie Roberts	droberts@adiramedica.com

Drug Establishments Current Registration Site

New Search (index.cfm)

Search Results for **AdiraMedica LLC**

CSVExcel
Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
ADIRAMEDICA LLC	3013310975	038202212	RELABEL;	585 TURNER INDUSTRIAL WAY, ASTON, Pennsylvania (PA) 19014, United States (USA)	12/31/2026

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Data Current through: Monday, Nov 24, 2025

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SUMMARY

(MMK) This was a GMP inspection of a contract testing laboratory. The inspection was conducted in accordance with CPGM 7356.002 Drug Manufacturing Inspections, CIN-DO FY25 workplan and operation ID 315216. Profiles LCP and LMN were covered during this inspection.

The previous inspection was conducted in November 2019. At the end of the inspection a one-item FDA 483 was issued. The inspection was classified as VAI. Firm management promised correction which was verified as corrected during the current inspection.

The current inspection found the firm to operate as a contract testing laboratory. The inspection covered the firm’s Quality and Laboratory Systems.

At the conclusion of the inspection a two-item FDA-483, Inspectional Observations was issued for the following: 1) Failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed; 2) Lack of laboratory records that include the initials or signature of a second person

showing that the original records have been reviewed for accuracy, completeness and compliance with established standards.

In addition, the following four verbal observations were discussed:

1) Insufficient trending and investigation of atypical results to determine the actual root cause and corrective actions.
2) Failure to update test procedures designed to assess the stability characteristics of drug products.
3) Voiding Out Of Specification investigations.
4) Non-Conformances resulting from Internal Audits and unplanned GMP walkthroughs were considered outside the scope of FDA inspection.

Firm Management stated they would respond to the district within 15 business days.

No samples were collected, and no refusals were encountered. The facility has a current drug registration.

ADMINISTRATIVE DATA

Inspected firm:	Q LABS, LLC
Location:	1930 Radcliff Dr Cincinnati, OH 45204-1823
Phone:	513-471-1300
FAX:	513-471-5600
Mailing address:	1930 Radcliff Dr Cincinnati, OH 45204-1823
Email address:	
Website:	www.qlaboratories.com
Dates of inspection:	4/16/2025-4/18/2025, 4/22/2025-4/23/2025, 4/25/2025
Days in the facility:	6
Participants:	**Rafeeq A Habeeb, Investigator** **Martin M Kimani, Investigator**

(MMK and RAH) Upon arrival at the firm, we presented our credentials and issued an FDA-482, Notice of Inspection, to Mr. Adam J. Morris, Chief Financial Officer. Mr. Morris stated he was the most responsible person available onsite. Also present were Mr. Jeff Knowles, Vice President of Quality, and Mr. August Smithmeyer, Vice President, Laboratory Operations. Mrs. Cathleen R Owen, Director of Regulatory and Tech support joined the meeting at a later time.

Cathleen Owen, Jeff Knowles, and August Smithmeyer accompanied RAH and MMK throughout the inspection.

At the conclusion of the inspection an FDA-483, Inspectional Observations was issued to Jayson B. Arling, President & CEO. Mr. Arling is the most responsible person at the firm.

The inspection report was written by Rafeeq A. Habeeb (RAH) and Martin M. Kimani (MMK). We have identified the section(s) we wrote with our names or initials. Throughout this report, we refer to Q LABS, LLC, as "the Firm" or "Q Labs".

*There were typographical errors on the FDA-483. The OOS numbers in Observation 1A were typed as "OOS-271, OOS-272, OOS-273" instead of "OOS 24-471, OOS 24-472, and OOS 24-473". The Non-Conformance number in Observation 1D was typed as "NC 24-242" instead of "NC 24-142".

HISTORY

(MMK) Q Labs was founded in 1966 by a Proctor & Gamble Scientist, Herbert Quinn. In 1988 analytical chemistry and GMP quality standards were added and implemented. The firm continues operations as a contract testing laboratory for food, drug, and cosmetics products. Chemistry and microbiology moved to its new location in May 2018 at 1911 Radcliff Dr Cincinnati, OH. In 2024, the firm initiated a capacity expansion dedicated to a water testing laboratory.

Previous regulatory action: None

Recalls since the previous inspection: None, only clients can initiate a recall.

Number of employees: ~151 (17 part-time)

Hours of operation: Monday thru Friday, 8:00 A.M. to 5:00 P.M. for main office, analytical chemistry and microbiology with limited weekend operation as needed.

Registration: The firm's registration is current for 2025

Firm size: 8

FMD-145 and future correspondence should be addressed to:

Jayson B. Arling, President & CEO

1930 Radcliff Dr

Cincinnati, OH 45204-1823

jarling@qlaboratories.com

INTERSTATE (I.S.) COMMERCE

(MMK) Q Laboratories Inc. is a contract laboratory for food, pharmaceutical, personal care products, cosmetic, food ingredients, and water treatment. Approximately [redacted] of Q Laboratories clients are from outside the state of Ohio. The top 30 list showing prescription drugs and personal care industry clients is attached as **Exhibit MMK 1.**

JURISDICTION (PRODUCTS MANUFACTURED AND/OR DISTRIBUTED)
(MMK) Q Laboratories Inc. performs contract testing for food, pharmaceutical, personal care products, cosmetics, and water treatment as such they are subject to the regulations of the FD&C Act. Drug testing includes but is not limited to microbial testing, Active Pharmaceutical Ingredients, excipients and finished products.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED
(RAH)
Jayson B. Arling, *President & CEO*: Mr. Arling is the most responsible person at the firm and his responsibilities include authorizing capital expenditure, strategy development and execution, and sales and marketing, and he is also responsible for equipment, capital, and personnel. Mr. Arling has the authority to hire and fire employees. Mr. Arling was present on the last day of the inspection, FDA 483, Inspectional Observations was issued to Mr. Arling.

August Smithmeyer, *Vice President of Lab Operations*: Mr. Smithmeyer has been with the firm for the past 15 years and is the most responsible person for the firm's operational areas. His roles and responsibilities include providing support to section supervisors of both analytical and microbiology divisions, continuous improvement, organizational development, and addressing client and employee needs. He reports to the Q Labs CEO, Mr. Jayson Arling. Mr. Smithmeyer's direct reports include the analytical lab managers, the GMP Micro lab manager, and the Media Prep Supervisor. Mr. Smithmeyer was present throughout the inspection.

Cathleen Owen, *Senior Director Regulatory and Technical Support*: Ms. Owen stated that she supports and facilitates regulatory compliance and assists clients with regulatory understanding of data and testing capability. Ms. Owen reports to VP of Scientific Consulting and she does not have any direct reports. Ms. Owen was present throughout the inspection and facilitated the inspection.

Jeffery Knowles, *VP of Quality Assurance*: Mr. Knowles is responsible for the quality assurance team, data review, OOS and NC investigations, and CAPAs. He leads weekly meetings for tracking OOSs, NCs, and CAPAs. Mr. Knowles has direct reports including the Microbiology Quality Assurance Supervisor, the QA Administrator, and the Chemistry QA Chemists and he reports directly to Mr. Arling, CEO Q Labs. Mr. Knowles was present throughout the inspection and facilitated the inspection.

Adam J. Morris, *Chief Financial Officer*: Mr. Morris is the CFO of Q Labs and reports to the Q Labs CEO, Jayson Arling. Mr. Morris was present during the start of the inspection and identified himself as the most responsible person available on site. An FDA-482, Notice of Inspection, was issued to Mr. Morris. Mr. Morris has 2 direct reports: the controller and the director of IT.

List all the employees from the firm that we interacted with as well as the topics discussed is included as **Exhibit MMK 2**.

FIRM'S TRAINING PROGRAM

(**MMK**) I reviewed the training SOP, QSOP-0362 previously known as SOP 20-ADMN-ISO-013K titled "Training" dated July 24, 2020. Employees receive initial orientation training and individualized training on methods and procedures specific to their job. Retraining is offered upon change/update of SOP or due to identified corrective actions. Employees receive cGMP and GLP training provided by the firm on a semi-annual basis. I reviewed the training records of 3 laboratory employees and 2 employees in the sample receipt section. I did not find any issues during my review of training records.

MANUFACTURING/DESIGN OPERATIONS

(MMK) The firm's facilities are located at 1911 and 1930 Radcliff Dr. Cincinnati Ohio. The facility at 1911 Radcliff Dr has two adjacent buildings. The first one houses microbiology R&D, stability chambers, quality department, sales, sample distribution and information technology. The second building is utilized for administrative offices, facilities/maintenance, and the receiving warehouse. The facility at 1930 Radcliff Dr consists of two levels primarily used for laboratory testing. The first level supports microbiological testing while the second handles all the analytical chemistry testing (**Exhibit MMK 3**).

QUALITY SYSTEM

(**MMK**) The firm's QSOP-0365 titled "Quality Assurance Unit" Version 7.3 outlines the roles and responsibilities of the quality unit. We reviewed the SOP and did not identify any issues.

Non-conformances- The firm's QSOP-0359 titled "Investigation of Nonconforming Work" dated January 14, 2022, provides guidance to describe the process for investigating departures from Q Laboratories Quality System policies and processes as well as those departures from regulatory/ organizational bodies held by the company. According to the firm's procedure the following items could lead to investigations on non-conforming work: audit findings (internal/external), Out of Specifications (OOS), customer complaints, internal observations, out of range proficiency test results, out of range daily verification samples, and out of tolerance equipment. A list of non-conformance reports for 2023 to 2025 are presented as **Exhibit MMK 4**. We reviewed the following non-conformances. NC 23-132, NC 23-142, NC 23-057, NC 24-100, NC 24-130, NC 24-142, NC 24-146, NC 24-147, NC 25-021, NC 25-031, and NC 24-242. There was failure to thoroughly review any unexplained discrepancies, please refer to **Observation 1** for additional information.

OSS Investigations - We reviewed the firm's OOSs SOP, QSOP-0120 titled "OOS Investigation" dated August 14, 2024, that provides guidance on how to investigate OOS test results, including the responsibilities of laboratory personnel, the decision to retest, and final evaluation of all test results. We selected and reviewed the following OOS investigations from 2023, 2024, and 2025: OOS 23-135, 23-136, 23-151, 23-158, 23-243, 24-038, 24-174, 24-312, 24-326, 24-340, 24-345, 24-422, 24-464, 24-471, 24-472, 24-473, 25-015, 25-036, 25-038, 25-068, and 25-095. Several of these OOS investigations were not thoroughly investigated, please refer to **Observation 1** for additional

information. Additionally, a total of 55 OOS investigations were voided in 2024 and 2025 (**Exhibit MMK 5**) due to a multitude of different reasons such as retest with passing results, updated protocol, incorrect calculations, and client submitted incorrect specifications or sample etc. The OOS SOP does not specify when and how to void an OOS. Please refer to **discussion Item 3** for additional information.

Atypical investigations - The firm's QSOP-0075 Version 10.0 titled "Handling Atypical Events and Observations in the Analytical Chemistry Laboratory" dated October 10, 2023, establishes the procedure for recognition of atypical data that could result in reanalyzing sample data or standard data during an analysis, as well as recording observations made during the lifetime of an analysis. An Atypical Event is defined as any unplanned deviation to a method that may have an impact on results. **Exhibit MMK 6** documents the atypical events logs from 2023 to 2025. We selected and reviewed the following 17 atypical events from 2024, and 2025: AT 23-132, AT 24-116, AT 24-142, AT 24-185, AT 24-367, AT 25-003, AT 25-031, AT 25-035, AT 25-042, AT 25-070, AT 25-083, AT 25-088, AT 25-090, AT 25-113, AT 25-125, AT 25-315, AT 25-418, AT 25-402, and AT 25-435. There were a total of 2569 atypical events from 2023 to 2025 and approximately 45.3% of these atypical events were attributed to human error. The large numbers of atypical events and high rates of human errors were not thoroughly investigated to determine the actual root causes and potential corrective actions. Please refer to **discussion Item 2** for additional information.

Observation events - The firm's QSOP-0075 Version 10.0 defines observation events as extra information or additional steps to the standard procedure observed during the experiment or sample lifetime which need to be recorded. They analyst must document the observation on Form (C1698), and enter into an Observation Log. **Exhibit MMK 7** documents the observation events log from 2023 to 2025. We reviewed the following observations: observation 24-360, 24-375, 24-380, and 25-116. No concerns were observed.

Change controls - The firm's QSOP-0360 Version 13.0 titled "Change Control" dated March 31, 2025, define how changes to equipment, facilities, compendial revisions, critical service providers and documents are initiated, reviewed, and approved by department supervisor, QAU and the VP of Quality of Q Laboratories, or designee, to ensure that systems remain suitable for their intended use. There are two different types of change controls:

- Document change control (DCC) - details changes such as creation of a new method, format, grammar, correction of typographic errors, rewording or adding wording for clarity, addition of quality control parameters or expansion of the scope of the document.
- Change controls (CC) - Include all categories of change control that are not document changes.

We reviewed the following seven change control documents from 2024 and 2025: CC 24-0025, CC 25-0106, CC 25-0235, 25-0263, CC-000026, DCC-0000057, DCC-0000063, and DCC-0000066. No concerns were observed. Please refer to **voluntary correction section** for additional information.

Corrective and Preventive Actions (CAPA) - The firm's QSOP-0363 Version 9.0 titled "Corrective and Preventive Actions" dated December 3, 2022, details the implementation of a CAPA (**Exhibit MMK 8**). **Exhibit MMK 4** documents the CAPA reports log from 2023 to 2025. We reviewed the following CAPAs: CAPA 23-035, CAPA 23-076, CAPA 23-132, CAPA 23-138, CAPA 23-171,

CAPA 24-017, CAPA 24-036, CAPA 24-045, CAPA 24-050, CAPA 24-085, CAPA 24-087, CAPA 24-130, CAPA 24-142, CAPA 24-155, CAPA 24-171, CAPA 24-186, and CAPA 25-029. No concerns were observed.

LABORATORY SYSTEM

(MMK) The facility at 1930 Radcliff Dr consists of two levels primarily used for laboratory testing. The first level supports microbiological testing while the second handles all the analytical chemistry testing. The microbiology section contains four sections: microbiology food lab, GMP microbiology lab, water testing, and microbiology R&D while the analytical testing section consists of wet chemistry, chromatography section, elemental analysis, and R&D. On the first day of inspection, we conducted a walkthrough of the laboratory accompanied by Mrs. Owen, Mr. Knowles and Mr. Smithmeyer. All samples are received at the facility on 1911 Radcliff Dr via FedEx, UPS, USPS or a courier service. The samples are logged on a sample submission form and assigned a six-digit QL number prior to delivery to the appropriate laboratory. We observed the transfer of samples and witnessed different employees working in the analytical and microbiology labs. The laboratories appeared clean and adequately equipped with the reagents, equipment, and instruments necessary to perform product and/or raw material testing.

During the walkthrough of the microbiology laboratory, we were joined by section supervisor Mr. Ben Uebel who stated that the lab conducts testing following USP <51>, <60>, <61>, and <62>. During the walkthrough we observed an employee conducting microbial colony count on finished product testing. We observed that the microbial test results (colony counts) were not verified and signed by a second person. Additionally, raw data (colony count) from other microbiological methods including growth promotion testing and environmental monitoring studies are not verified by a second person. Please refer to **Observation 2** for additional information.

Within the microbiology testing lab, we also observed the sample preparation and operation of the Bruker MALDI Biotyper System by analyst [redacted] that is intended to be used for the automated identification of bacteria and fungi. The system utilizes matrix assisted laser desorption/ionization time of flight (MALDI-TOF) mass spectrometry to identify the test organism. Highly abundant ribosomal proteins result in an organism specific mass spectrum with characteristic distribution and intensity. The mass spectra are transformed into peak lists by the MALDI Biotyper software and are compared to the patterns in the reference library. We reviewed the equipment QSOP-0237 titled “Bruker MALDI Biotyper Microbial Identification” as well as the IQ, OQ, and PQ for this instrument. We also reviewed the training records for [redacted] as well as data storage and audit trail of the MALDI Biotyper System. No concerns were observed.

During the walkthrough of the analytical lab, we were accompanied by laboratory manager Mrs. Erin Pachko and Technology development manager Mr. Brian Anderson. The analytical chromatography laboratory contains 8 HPLCs and 6 gas chromatography instruments that are serviced and qualified by Ohio Valley Scientific. **Exhibit MMK 9** lists all the equipments and instruments in the laboratory together with their last preventative maintenance completion date. Mrs. Meg Schlanser, Senior Chemist within R&D, provided demonstration of audit trail checks and reviews for quantitative and

qualitative data collected using HPLC and GC instruments that use the Openlab CDS software from Agilent technologies. The firm did not have an approved SOP that describes how to perform an audit trail check on high-performance liquid, gas chromatography, and Inductively Coupled Plasma Spectrophotometer with Mass Spectrometer instrumentations in the analytical laboratory during the start of the inspection. We also reviewed the calibration of exhaust fume hoods, lab balances, FT-IR spectrometer, and auto-titrator; all the equipment and instruments had current calibration stickers applied to them. No issues were noted.

According to Mrs. Owen, all methods (in-house and client) are either validated or verified prior to analysis. Validation involves determination that the method meets necessary performance criteria such as accuracy, precision, specificity, and detection limits. **Exhibit MMK 10** provides a list of all the test assay method verifications and transfers (non-USP) methods. Client validated methods undergo a method transfer protocol (similar to a method verification) where the firm collects a specific set data that is compared to data obtained by the client. We reviewed the validation reports for the following non-USP methods: PCMX method [redacted] (method transfer from [redacted], ethyl alcohol assay method [redacted], chloride determination method – QSOP-0421, analysis of BZK in hand sanitizers - QSOP-0068, levetiracetam [redacted] assay – [redacted] (method transfer from [redacted]), and LC method for phenoxyethanol – QSOP-0439. No discrepancies were noted.

Stability chambers – Mrs. Sonja E Boles, Stability Team Lead and Lilian Young, Stability Maintenance gave an overview of the stability chambers. The **Exhibit MMK 11** lists all the drug stability studies at the firm and the following five stability samples were pulled and inspected:

Project ID	Sample	Customer
01143	[redacted]	[redacted]
368996	[redacted]	[redacted]
00767	[redacted]	[redacted]
00446	[redacted]	[redacted]
01212	[redacted]	[redacted]

The firm's QSOP-0044 Version 17.0 titled "Stability Chambers and Stability Testing" dated February 21, 2025, describe the process for checking and retrieving temperature and humidity data from stability chambers and the data loggers within those chambers. There is a total of 23 stability chambers (**Exhibit MMK 12**) and all the chambers inspected were clean, had uniform loading of samples and had current calibration stickers applied to them. We reviewed the validation protocols/Reports, IQ/OQ/PQ, calibration records, mapping studies, maintenance logs, temperature and humidity excursions for stability chambers #QL366, QL1976, QL1228, and QL1636. We also reviewed the signed stability

study protocol agreement document between the firm and two different clients ([redacted]) as well as the last pull date, and a completed COA for client stability samples. Several stability samples were analyzed outside of the stability testing window. Please see **Observation 1C** for additional information.

MANUFACTURING CODES

(**MMK**) I reviewed the sample receipt SOP, QSOP-0389 titled "Operations Samples Receiving and Processing" dated October 24, 2023. This SOP details the assignment of QL numbers and sample ID numbers for all products received from clients.

QL Reference Number: A six-digit number assigned by the receiving staff that is unique to a specific sample or group of samples from the same location.

Sample ID Number: QL Reference Number with a numeric extension assigned by the receiving staff. For example, if a QL Reference Number is 123456, the Sample ID Number will be 123456 if there is only one sample, and if there is more than one sample in a group from the same location, then Sample ID Numbers will be 123456-1, 123456-2, 123456-3, 123456-4 and so on.

A complete set of samples designated for a stability study protocol is assigned a Project ID number. Once a specified set of that sample is pulled for a specific stability time study a Q Labs order number with a numeric extension is assigned. For example, if a Q Labs order number is 123456, the Q Labs Sample ID Number will be 123456-1001 if there is only one sample, and if there is more than one sample in a group from the same location, then Sample ID Numbers will be 123456-1002, 123456-1003, 123456-1004, 123456-1005 and so on.

COMPLAINTS

(MMK) The firm handles complaints per the firm's non-conformance SOP, QSOP-0359 titled "Investigation of Nonconforming Work" dated January 14, 2022. If a suspected nonconformance is found resulting from a customer complaint, an NC is initiated by the Q laboratories' staff member receiving the complaint or a member of the QAU. The following customer complaints were reviewed: NC 24-130, NC 24-146, and NC 24-147 and no issues were observed upon review.

RECALL PROCEDURES

(MMK) The firm has not been involved in any recalls since the previous inspection.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

Observations listed on form FDA 483

OBSERVATION 1
There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

Your firm is a contract testing laboratory performing microbial and analytical tests for firms (clients) manufacturing sterile, non-sterile, and OTC drug products.

A. Your investigations OOS-271, OOS-272, and OOS-273 dated 11/24/2024 for microbial out of specification (OOS) of finished drug products were inadequate. You identified likely contamination of the test samples by the laboratory analyst during sample processing as the root cause for the OOSs and therefore invalidated the results. However, the same analyst simultaneously prepared and tested multiple negative controls with passing results. In addition, as part of the investigation you did not include historical microbial test results for the drug product, total number of samples tested by the analyst on 11/24/2024 and the number of negative controls processed along with the test samples and their results.

B. Your investigations OOS 23-135, OOS 23-136, OOS 23-151, and OOS 23-158 dated 4/26/2023 and 5/2/2023 for microbial out of specification of multiple finished products were inadequate. You identified likely contamination of the test samples during processing as the root cause for the OOSs and therefore invalidated the results. However, multiple negative controls processed simultaneously along with the test samples had passing results. In addition, as part of the investigation you did not include total number of samples tested and the number of negative controls processed along with the test samples and their results.

C. Your non-conformance investigation NC 25-031 dated 3/4/2025 for stability testing of drug product (OTC hand sanitizer) outside of stability testing window is inadequate. The investigation did not include supporting information including the stability time-point, the dates the sample was pulled, the sample test date, test results, and any previous non-conformances.

D. Your non-conformance investigation, NC 24-242 dated 10/15/2024, classified failing results as atypical. Your firm performed a retesting of the samples without notifying the client which is inadequate per your QSOP-0075 “Handling Atypical Events and Observations in the Analytical Chemistry Laboratory”. Your firm did not thoroughly perform an investigation or risk assessment to retrospectively identify if there are other instances where failing results were considered atypical and rerun without notifying the client. Furthermore, your firm did not document if this practice is widespread or isolated to specific analysts, products, or methods.

Reference: 21 CFR 211.192

Supporting Evidence and Relevance:

A. Your investigations OOS-271, OOS-272, and OOS-273 dated 11/24/2024 for microbial out of specification (OOS) of finished drug products were inadequate. You identified likely contamination of the test samples by the laboratory analyst during sample processing as the root cause for the OOSs and therefore invalidated the results. However, the same analyst simultaneously prepared and tested multiple negative controls with passing results. In addition, as part of the investigation you did not include historical microbial test results for the drug product, total number of samples tested by the analyst on 11/24/2024 and the number of negative controls processed along with the test samples and their results.

*There were typographical errors on the FDA-483. The OOS numbers in Observation 1A were typed as "OOS-271, OOS-272, OOS-273" instead of "OOS 24-471, OOS 24-472, and OOS 24-473".

(RAH) During the inspection we reviewed the firm's list of OOS since January 2023. The firm has two separate lists one for Chemistry OOSs and the other for Micro OOSs. The lists of OOSs are attached as **Exhibit RAH 1 and Exhibit RAH 2**. We also reviewed the firm's SOP QSOP-0120 "OOS Investigations" dated 08/14/2024, Version 6.0 attached as **Exhibit RAH 3**. From the list of OOSs we selected approximately 21 OOSs for review.

We identified investigations for OOS 24-471, OOS 24-472, and OOS 24-473 and the associated CAPA 24-171 to be inadequate as they attribute human error for failing test samples when multiple negative controls processed simultaneously had passing results. (**Exhibit RAH 4, RAH 5, RAH 6, and RAH 7**). The 3 OOSs are for TAMC counts > 100 CFU/g for different packages of wipes including refill pouches, wet single wipes, and tall canister wipes. As shown in Table-1 there were 10 samples with TAMC counts above specification. The firm performed speciation on the colonies and identified multiple micro-organisms including Streptococcus sanguinis, Rothia aeria, Neisseria sicca, Rothia mucilaginosa, and Micrococcus lutes. The firm identified the microorganisms Rothia aeria, Rothia mucilaginosa, and Strepttococcus salivarius as typical human microflora. Table -1 below show microorganisms identified for each of the 10 samples.

The firm identified that the samples were initiated by and/or plated by analyst [redacted] and that lack of aseptic technique and insufficient PPE were the root cause. The firm identified that training records of the analyst [redacted] were up to date including training for aseptic technique and sample preparation. When asked, the management stated that the samples were run together as a batch along with 6 negative controls. Later, upon looking at the analytical records, the management stated that there were only two negative controls along with 50 test plates, and that the negative controls were plated at the start of the batch and at the end the batch. The management also stated that the none of the negative controls had any colonies, even though they were handled by the same analyst in a similar fashion. The firm did not document the information in the investigation report.

The management further stated that the microbes identified were human specific and that historically the product tested was never positive for any of the above microorganisms. When

asked the management provided records from tests subsequent to the OOS incident and were not able to provide the true historical data for the products. The management stated that they retested the failing samples and got passing results. The management failed to give a reasonable explanation for invalidating the failing results when the negative controls passed, and the samples failed microbial limits.

As a corrective action the firm implemented PPE (face masks) to be worn during sample preparation. The CAPA report is attached as **Exhibit RAH 7**. The management stated that following the implementation of the CAPA, no additional micro-OOS were observed.

Table: 1

OOS number and Date identified	Q Labs Sample number	TAMC count Specification < 100 CFU/g	Micro-organism Identified
OOS 24-471, 11/24/2024	0812120-1006	110 CFU/g	Streptococcus Sanguinis
OOS 24-472	0812121-1001	140 CFU/g	Rothia aeria
	0812121-1002	220 CFU/g	Neisseria sicca
	0812121-1003	160 CFU/g	Rothia mucilaginosa
	0812121-1004	190 CFU/g	Rothia aeria
OOS 24-473	0812433-1001	530 CFU/g	Rothia aeria, Steptococcus sanguinis
	0812433-1002	550 CFU/g	Micrococcus lutes, Rothia aeria
	0812433-1003	290 CFU/g	Rothia aeria
	0812433-1004	800 CFU/g	Micrococcus luteus
	0812433-1009	550 CFU/g	Micrococcus luteus, Rothia aeria, Steptococcus sanguinis

B. Your investigations OOS 23-135, OOS 23-136, OOS 23-151, and OOS 23-158 dated 4/26/2023 and 5/2/2023 for microbial out of specification of multiple finished products were inadequate. You identified likely contamination of the test samples during processing as the root cause for the OOSs and therefore invalidated the results. However, multiple negative controls processed simultaneously along with the test samples had passing results. In addition, as part of the investigation you did not include total number of samples tested and the number of negative controls processed along with the test samples and their results.

(RAH) This investigation is inadequate as it attributes human error for failing test samples, without considering multiple negative controls processed simultaneously had passing results. CAPA CA-23-076 is for OOS 23-135, OOS 23-136, OOS 23-151, and OOS 23-158 dated 4/26/2023 and 5/2/2023 for microbial out of specification of multiple finished products, with the same root cause.

The firm's Non Conformance and CAPA log for the years 2023, 2024, & 2025, is attached as **Exhibit RAH 14, RAH 15,** and **RAH 16**. The OOSs investigation reports for OOS 23-135,

OOS 23-136, OOS 23-151, and OOS 23-158 are included as **Exhibit RAH 8, 9, 10,** and **RAH 11** respectively. The associated CAPA CA-23-076 is included as **Exhibit RAH 12**.

The firm's OOS investigation identified multiple drug samples from different clients that were simultaneously processed and failed microbial specification (Table-2 and Table 3). One of the product testes was medicated toothpaste. The toothpaste tubes were packaged in a secondary box. The analyst sprayed and disinfected the outer box with 70% ethanol prior to entering it into the biological safety cabinet (BSC). In the BSC the toothpaste tubes were removed from the secondary container and sampled. The investigation identified that the primary containers (tubes) were not sprayed with 70% ethanol to disinfect before sampling. During the investigation, the firm recovered Micrococcus luteus on swabbing the primary toothpaste containers which was one of the microbes identified on the failing test samples (Table 2). In addition, the firm identified that the analyst infrequently changed the gloves and used the same gloves during weighing and plating multiple samples.

However, multiple negative controls were processed simultaneously along with the test samples, and all had passing results. We discussed with the firm that it is highly unlikely that the negative controls had 0 CFUs and the test samples had between 200 CFUs to > 7500 CFUs (Table-2), considering both negative controls and test samples were handled and processed simultaneously by the same analyst under the same conditions. The management stated that the negative controls are to confirm the sterility of the media and not the test procedure. We told the management that the negative controls, in addition to confirm the sterility of the media should also represent the test procedure.

As a corrective action the firm added requirement to ensure spraying/disinfecting with 70% ethanol on all sample containers including primary and secondary packaging, in addition to training to change gloves regularly especially while entering and exiting the BSC.

The firm invalidated the results and repeated the test without addressing the reliability of the negative control. The investigation and the CAPA is inadequate.

Table -2

OOS number and Date identified	Q Labs Sample number	Specification TAMC:<200 CFU/g TYMC: < 20 CFU/g	Micro-organism Identified
OOS 23-135 4/26/2023	0699103-1001	TAMC: 1700 CFU/g	Micrococcus lutes
	0699103-1002	TAMS: 1700 CFU/g	Micrococcus lutes
OOS 23-136, 4/26/2023	0698681-1001	TAMC: 750 CFU/g	Micrococcus lutes
	0698685-1001	TAMC: 410 CFU/g	Micrococcus lutes, Bacillus sp. and Bacillus Cereus
	0698936-1001	TAMC: 300 CFU/g TYMC: 45 CFU/g	Micrococcus lutes
	0698936-1002	TAMC: 380 CFU/g	Micrococcus lutes
	0698936-1003	TAMC: 430 CFU/g	Micrococcus lutes

		TYMC: 40 CFU/g	
	0698936-1004	TAMC: 400 CFU/g TYMC: 330 CFU/g	Micrococcus lutes
	0698936-1005	TAMC: 330 CFU/g TYMC: 180 CFU/g	Bacillus subtilis and Micrococcus luteus
	0698936-1006	TAMC: 480 CFU/g	
	0698936-1007	TAMC: 200 CFU/g	Micrococcus lutes
	0698936-1008	TAMC: 600 CFU/g	Micrococcus lutes
	0698936-1009	TAMC: 400 CFU/g	Micrococcus lutes
	0698939-1001	TAMC: 600 CFU/g	Micrococcus lutes
	0698939-1002	TAMC: 700 CFU/g	Micrococcus lutes
	0698939-1003	TAMC: 330 CFU/g	Micrococcus lutes
	0698940-1001	TAMC: 200 CFU/g	Micrococcus lutes
	0698940-1002	TAMC: 530 CFU/g	Micrococcus lutes
	0698941-1001	TAMC: 410 CFU/g	Micrococcus lutes
	0699217-1001	TAMC: 380 CFU/g	Micrococcus lutes
OOS 23-151 4/26/2023	0697977-1009	TAMC: >7500 CFU/g	Micrococcus lutes
	0697977-1010	TAMC: >7500 CFU/g	Micrococcus lutes
	0697977-1011	TAMC: >7500 CFU/g	Micrococcus lutes
	0697977-1012	TAMC: >7500 CFU/g	Micrococcus lutes
	0697977-1013	TAMC: >7500 CFU/g	Micrococcus lutes
	0697977-1014	TAMC: >7500 CFU/g	Micrococcus lutes
	0698186-1001	TAMC: 1600 CFU/g	Micrococcus lutes
	0698186-1002	TAMC: 940 CFU/g	Micrococcus lutes
	0698186-1001	TAMC: 1300 CFU/g	Micrococcus lutes
	0698186-1003	TAMC: 1100 CFU/g	Micrococcus lutes
	0698186-1004	TAMC: >7500 CFU/g	Micrococcus lutes
	0698186-1005	TAMC: >7500 CFU/g	Micrococcus lutes
	0698186-1006	TAMC: >7500 CFU/g	Micrococcus lutes
	0698186-1007	TAMC: >7500 CFU/g	Micrococcus lutes
	0698186-1008	TAMC: >7500 CFU/g	Micrococcus lutes
	0698186-1009	TAMC: >7500 CFU/g	Micrococcus lutes
	0698186-1010	TAMC: >7500 CFU/g	Micrococcus lutes
	0698186-1011	TAMC: >7500 CFU/g	Micrococcus lutes
	0698186-1012	TAMC: >7500 CFU/g	Micrococcus lutes
	0698186-1013	TAMC: >7500 CFU/g	Micrococcus lutes
	0698186-1014	TAMC: >7500 CFU/g	Micrococcus lutes
	0698186-1015	TAMC: >7500 CFU/g	Micrococcus lutes
	0698186-1016	TAMC: >7500 CFU/g	Micrococcus lutes
	0698186-1017	TAMC: 5000 CFU/g	Micrococcus lutes
	0698186-1018	TAMC: >7500 CFU/g	Micrococcus lutes

	0698186-1019	TAMC: 3000 CFU/g	Micrococcus lutes
OOS 23-158, 05/02/2023	06982031001	TAMC: 3000 CFU/g	Micrococcus lutes

Table: 3

OOS	Client	Product
OOS 23-135	[redacted]	Finished Pharmaceutical Products and Miscellaneous
OOS 23-136	[redacted]	Finished Pharmaceutical products
OOS 23-151	[redacted]	Unknown
OOS 23-158	[redacted]	Finished Pharmaceutical products - Tablets

C. Your non-conformance investigation NC 25-031 dated 3/4/2025 for stability testing of drug product (OTC hand sanitizer) outside of stability testing window is inadequate. The investigation did not include supporting information including the stability time-point, the dates the sample was pulled, the sample test date, test results, and any previous non-conformances.

(RAH) During the review of non-conformance investigation (NC 25-031) for stability testing of drug product BZK Hand Sanitizer we observed that the sample was tested outside the stability window. We identified the investigation is inadequate as it did not document information including the stability time-points, the sample pull and test dates, and any past stability tests done outside the stability window. The non-conformance investigation NC 25-031 is included as **Exhibit RAH 17**. The firm agreed to the observations and promised corrective actions.

D. Your non-conformance investigation, NC 24-242 dated 10/15/2024, classified failing results as atypical. Your firm performed a retesting of the samples without notifying the client which is inadequate per your QSOP-0075 "Handling Atypical Events and Observations in the Analytical Chemistry Laboratory". Your firm did not thoroughly perform an investigation or risk assessment to retrospectively identify if there are other instances where failing results were considered atypical and rerun without notifying the client. Furthermore, your firm did not document if this practice is widespread or isolated to specific analysts, products, or methods.

*There were typographical errors on the FDA-483. The Non-Conformance number in Observation 1D was typed as "NC 24-242" instead of "NC 24-142".

(RAH) The firm's non-conformance investigation, NC 24-142 dated 10/15/2024 is for classifying failing results as atypical. The analytical chemistry laboratory performed tests for 2 acetyl alcohol for [redacted] and obtained high OOS values (**Exhibit RAH 18**). The analyst did not inform QA about the OOS results, instead wrote an atypical event report and had it approved by a laboratory manger. The analyst reran the samples and obtained passing results. A failing result is not one of the acceptable reasons for an atypical, according to the QSOP-0075 "Handling Atypical Events and Observations in the Analytical Chemistry Laboratory" (**Exhibit RAH 19**). In addition, the firm performed retesting of the samples without notifying

the client as required by the QSOP-0075. The firm's CAPA was to update the Atypical Event form, specifically to add client notification for atypical events (**Exhibit RAH 20**). The firm did not thoroughly perform an investigation or risk assessment to retrospectively identify if there were other instances where failing results were considered atypical and rerun without notifying the client. Furthermore, the firm did not document if this practice is widespread or isolated to specific analysts, products, or methods.

Discussion with Management:
The deficiencies detailed under **Observation 1** were discussed during the inspection, daily wrap-up meeting and inspection closeout meeting on 25 April 2025. Management stated that the firm will respond in writing within 15 business days.

OBSERVATION 2
Laboratory records do not include the initials or signature of a second person showing that the original records have been reviewed for accuracy, completeness and compliance with established standards.

Specifically,
Your microbiology laboratory records do not include second person review of raw data for accuracy including for your clients performing environmental monitoring (EM) studies. Your clients include sterile manufacturers conducting EM of ISO areas with microbial action limit of less than one colony forming unit (CFU).
Reference: 21 CFR 211.194(a)(8)

Supporting Evidence and Relevance:
(RAH) During the walkthrough of the microbiology laboratory, we observed multiple analysts performing microbial plate count. The analyst after reading discarded the plates into a trash can. When asked we were told that only plates with colonies are kept for second person verification and that plates without colonies are discarded soon after reading. The firm performs microbial testing of drug products and environmental monitoring samples. One of the firm's top clients for EM sampling includes [redacted], [redacted] a sterile drug manufacturing facility. A recent sample submission form and test report for [redacted] shows multiple EM samples with action limit of >= 1 CFU indicating sampling from Grade A areas (**Exhibit RAH 21)**. Grade A area samples are critical as they are an indirect indicator of sterility of sterile drug products. The firm management stated that their clients do not share detailed information on the sample types. The list of tests performed for [redacted] is included as **Exhibit RAH 22**. The Quality Agreement between the firm and [redacted] is included as **Exhibit RAH 23**. The management also stated that they do not perform sterility testing of finished products and that the firm is not equipped to perform sterility testing. List of the firm's top 5 clients for drug sample testing is included as **Exhibit RAH 24**. The firm's top 5 clients for EM sample testing are included as **Exhibit RAH 25**. The firm's Quality Agreement with [redacted] is included as **Exhibit RAH 25**.

Discussion with Management:
The deficiencies detailed under **Observation 2** were discussed during the inspection, daily wrap-up meeting and inspection closeout meeting on 25 April 2025. Management stated that the firm will respond in writing within 15 business days.

REFUSALS
No refusals were encountered.

GENERAL DISCUSSION WITH MANAGEMENT
(RAH) At the conclusion of this inspection, a 2 item FDA-483 (Inspectional Observations) was issued to Mr. Jayson B. Arling, President & Chief Operating Officer, Q LABS, LLC. Mr. Arling identified himself as the most responsible person at the firm. Also in attendance were Mr. August Smithmeyer, Vice President of Lab Operations, Ms. Cathleen Owen, Senior Director Regulatory and Technical Support, Mr. Jeffery Knowles, VP of Quality Assurance, and Mr. Adam J. Morris, Chief Financial Officer.

During the inspection close-out I stated that it was the firm's responsibility to comply with the FD&C Act and that failure to do so could result in actions including seizure, injunction, and civil or criminal penalties. We also informed the firm that if a response to the FDA-483 was received within 15 business days that it may impact the FDA's final determination.
Firm management committed to correcting/evaluating the observations and stated they would be responding in writing to the observations within 15 days. In addition to the observations cited on the FDA-483, the following 4 observations were discussed verbally:

1. **(MMK)**. Insufficient trending and investigation of atypical results to determine the actual root cause and corrective actions.

   During the inspection of the contract testing laboratory, we reviewed a log of events identified as "Atypical Event". An Atypical Event can be defined as any unplanned deviation to a method. Unplanned deviations are defined as any departure from the standard methodology that may have an impact on results. There were a total of 2569 atypical events from 2023 to 2025 and approximately 45.3% of these atypical events were attributed to human error. The table below depicts the number of atypical events recorded from 2023 to 2025. Upon further investigation, the data revealed that human error accounted for 43 to 48% of all atypical events and a few (six out of 25) select analysts accounted for 47 to 57% of these errors (**Exhibit MMK 6**) for three consecutive years. The firm's atypical events SOP, QSOP-0075 Version 10.0 Section 6.0, states that any deviations from this SOP will be documented as a nonconformance and corrective action applied if warranted (**Exhibit MMK 13**). The firm did not conduct any investigations to determine why the same analysts continued to account for high human errors while conducting sample analysis for three consecutive years. MMK interviewed [redacted] regarding training, sample load, reporting of atypical events, and potential causes of the high rates of human errors. [redacted] indicated that high sample load is a contributing factor to the high rates of human errors. The large numbers of atypical events and high rates of human errors were not thoroughly investigated to determine the actual root causes and potential corrective actions.

Year	# of Atypical results	# of atypical results attributed to Human Error	% of human error due to top 6 analysts [redacted]
2025	408	175 (43%)	47%
2024	1244	607 (48%)	52%
2023	917	410 (45%)	57%

2. (**MMK**) Failure to update test procedures designed to assess the stability characteristics of drug products.

A). Specifically, the firm analyzed QL sample numbers 0811514, 0811515, 0811516, and 0811517 on 11/20/2024 and discovered an out of specification result (OOS) further identified as OOS 24-464 on 11/25/2024 (**Exhibit MMK 14**). Per OOS SOP, QSOP-0120 the client ([redacted]; Contacted individual - [redacted] was notified of this OOS on 11/27/2024. Ensuing investigation determined that the unspecified degradation product to be from the raw material miconazole nitrate. This investigation was closed on 2/10/2025 with a recommendation that for future stability time points studies the raw material will be run in sequence with samples alongside the fragrances and placebo to better identify potential impurities. Additionally, 29 samples were run without using an updated QMAST-2864 protocol on 3/21/2025 and 4/14/2025 for QL 0835716. A review of the audit trail revealed that the HPLC sample analysis protocol was updated prior to analysis of QL0835716 but the change control document and an updated QMAST-2864 protocol was missing. A change control to effect this change in QMAST-2864 was not initiated until MMK identified this discrepancy on 4/21/2025. This change control # DCC-0000066 detailing change of protocol for analysis of Miconazole Nitrate Topical Powder Impurities in QMAST-2864 was initiated and signed on 4/22/2025 (**Exhibit MMK 15**).

B). The firm did not update the sampling protocol for [redacted] lip balm as it relates to an OOS 24-345 investigation which resulted in CAPA 24-136 that was closed on 10/23/2024 (**Exhibit MMK 16**). The corrective actions from CAPA-24-136 were not documented via change control or update of the QMAST protocol until MMK observed this discrepancy during the inspection.

3. (**MMK**) Voiding out of specification investigations.

Your firm has voided 55 OOSs investigations in 2024 and 2025 (**Exhibit MMK 17; Sheet 1)**. Your OOS SOP, QSOP 0120 entitled "OOS Investigations" (**Exhibit RAH 3**) does not specify when and how to void an OOS. Table 2 below shows the number of OOSs recorded and voided in 2025.

Year	# OOS	# OOS voided
2024	142	45
2025	71	9

4. Non-Conformances resulting from Internal Audits and unplanned GMP walkthroughs were considered outside the scope of FDA inspection.
(RAH) We reviewed the firm's Non-Conformance (NC) and CAPA log for the years 2023, 2024, & 2025, attached as **Exhibit RAH 14, RAH 15,** and **RAH 16.** We identified that the sequence of NCs is not continuous, the firm mentioned that the non-conformances related to non-drugs are not included. We asked the firm to pull up the complete list of non-conformances and we identified many drug related non-conformances missing from the initial list. When asked the firm stated that the missing observations are related to internal observations following the firm's internal audit and/or vendor audit. We asked for the internal audit schedule (**Exhibit RAH 26**) and identified many of the internal observations related NCs were not during the same time as that of the internal audits. The firm explained that they also consider non-conformances resulting from routine GMP walkthrough as internal observations and outside the scope of FDA inspection. We did not agree with the firm's interpretation and stated that we would still review the non-conformance to identify if the investigations are adequate. The firm's complete list of Non-conformance from 2025 including internal audit NCs is included as **Exhibit RAH 13**.
The number of drug Non-conformances related to Internal observation in 2025 are 20 out of a total of 39 NCs. In addition, there were two NCs related to Internal/External Audit Findings. The internal observations were distributed in all months of the year and also include months where there were no internal audits as shown in the table below.

Month/Year	Internal Observation NCs	Internal/External Audit Findings	Total number
January 2025	3	0	3
February 2025	9	0	9
March 2025	6	1	7
April 2025	3	1	4

There were no internal audits during the months of January, March, and April 2025 (**Exhibit RAH 26**). The management stated that they considered the findings from unscheduled GMP/QA walkthrough of the facility as Internal Observations and therefore considered it outside the scope of FDA inspection.

ADDITIONAL INFORMATION
(RAH) The officially sealed original UBSs (Hardcopy **Exhibit RAH 27**) and unsealed working copy containing the electronic records provided by the firm during the inspection are filed with the unlabeled exhibits and attachments.

SAMPLES COLLECTED
(RAH) No samples were collected during this inspection.

VOLUNTARY CORRECTIONS

(RAH) The firm's last FDA inspection from 2019 resulted in a one item FDA 483, Inspectional Observation, for not closing OOS investigations within the allotted 30-day time limit. During the current inspection we did not identify any investigations open beyond the allotted time.

EXHIBITS COLLECTED

MMK EXHIBITS

Exhibit MMK 1: Top 30 prescription drugs and personal care clients – 2024
Exhibit MMK 2: List of employees interviewed and topics discussed
Exhibit MMK 3: Company overview presentation
Exhibit MMK 4: Non conformance report for 2023-2025
Exhibit MMK 5: 2023-2025 Chemistry OOS log
Exhibit MMK 6: Atypical events log
Exhibit MMK 7: Observations events log
Exhibit MMK 8: Non conformance CAPA report for 2023-2025
Exhibit MMK 9: Laboratory equipment and instruments list
Exhibit MMK 10: List of non-USP method validation and method transfers
Exhibit MMK 11: Lists all the drug stability studies at the firm
Exhibit MMK 12: List of stability chambers
Exhibit MMK 13: QSOP-0075 Version 10.0, Handling atypical events and observations
Exhibit MMK 14: OOS 24-464
Exhibit MMK 15: Protocol change for analysis of Miconazole Nitrate Topical Powder Impurities
Exhibit MMK 16: OOS 24-345
Exhibit MMK 17: Voided OOSs from 2025

RAH EXHIBITS

Exhibit RAH 1: List of Chemistry OOSs
Exhibit RAH 2: List of Microbiology OOSs
Exhibit RAH 3: SOP OOS Investigations QSOP-0120
Exhibit RAH 4: OOS Investigation OOS 24-471
Exhibit RAH 5: OOS Investigation OOS 24-472
Exhibit RAH 6: OOS Investigation OOS 24-473
Exhibit RAH 7: CAPA 24-171
Exhibit RAH 8: OOS Investigation OOS 23-135
Exhibit RAH 9: OOS Investigation OOS 23-136
Exhibit RAH 10: OOS Investigation OOS 23-151
Exhibit RAH 11: OOS Investigation OOS 23-158
Exhibit RAH 12: CAPA 23-076
Exhibit RAH 13: List of Non-Conformances/CAPAs 2025
Exhibit RAH 14: List of Non-Conformances/CAPAs 2023
Exhibit RAH 15: List of Non-Conformances/CAPAs 2024

Exhibit RAH 16: List of Non-Conformances/CAPAs 2025
Exhibit RAH 17: Non-Conformance Investigation NC 25-031
Exhibit RAH 18: Non-Conformance Investigation NC 24-142
Exhibit RAH 19: SOP Handling Atypical Events and Observations in the Chemistry Laboratory
Exhibit RAH 20: CAPA 24-142
Exhibit RAH 21: [redacted] sample submission and data
Exhibit RAH 22: List of tests performed for [redacted] QL 0842197
Exhibit RAH 23: Quality Agreement between [redacted]
Exhibit RAH 24: List of the firm's top 5 clients
Exhibit RAH 25: List of the firm's clients testing EM samples
Exhibit RAH 26: The firm's Internal Audit Schedule
Exhibit RAH 27: USB Drive submitted as Hard Copy to CIN-DO

ATTACHMENTS
1(RAH) Issued 483, 4 pages
2(RAH) Issued 482, 3 pages

RAFEEQ HABEEB -S
Digitally signed by RAFEEQ HABEEB -S
Date: 2025.06.02 11:18:36 -04'00'

Rafeeq A. Habeeb
Investigator

Martin M. Kimani -S
Digitally signed by Martin M. Kimani -S
Date: 2025.06.02 11:22:56 -04'00'

Martin M Kimani
Investigator

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513)322-0700 Fax:(513)679-2772	4/16/2025-4/25/2025* FEI NUMBER 1527260

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jayson B. Arling, President and CEO

FIRM NAME	STREET ADDRESS
Q LABS, LLC	1930 Radcliff Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Cincinnati, OH 45204-1823	Laboratory

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

Your firm is a contract testing laboratory performing microbial and analytical tests for firms (clients) manufacturing sterile, non-sterile, and OTC drug products.

A. Your investigations OOS-271, OOS-272, and OOS-273 dated 11/24/2024 for microbial out of specification (OOS) of finished drug products were inadequate. You identified likely contamination of the test samples by the laboratory analyst during sample processing as the root cause for the OOSs and therefore invalidated the results. However, the same analyst simultaneously prepared and tested multiple negative controls with passing results. In addition, as part of the investigation you did not include historical microbial test results for the drug product, total number of samples tested by the analyst on 11/24/2024 and the number of negative controls processed along with the test samples and their results.

B. Your investigations OOS 23-135, OOS 23-136, OOS 23-151, and OOS 23-158 dated 4/26/2023 and 5/2/2023 for microbial out of specification of multiple finished products were inadequate. You identified likely contamination of the test samples during processing as the root cause for the OOSs and therefore invalidated the results. However, multiple negative controls processed simultaneously along with the test samples had passing results. In addition, as part of the

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Rafeeq A Habeeb, Investigator Martin M Kimani, Chemist/Biologist X Rafeeq A Habeeb Investigator Signed By: 2002600695 Date Signed: 04-25-2025 14:13:50	4/25/2025

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513)322-0700 Fax:(513)679-2772	4/16/2025-4/25/2025* FEI NUMBER 1527260

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Jayson B. Arling, President and CEO	
FIRM NAME Q LABS, LLC	STREET ADDRESS 1930 Radcliff Dr
CITY, STATE, ZIP CODE, COUNTRY Cincinnati, OH 45204-1823	TYPE ESTABLISHMENT INSPECTED Laboratory

investigation you did not include total number of samples tested and the number of negative controls processed along with the test samples and their results.

C. Your non-conformance investigation NC 25-031 dated 3/4/2025 for stability testing of drug product (OTC hand sanitizer) outside of stability testing window is inadequate. The investigation did not include supporting information including the stability time-point, the dates the sample was pulled, the sample test date, test results, and any previous non-conformances.

D. Your non-conformance investigation, NC 24-242 dated 10/15/2024, classified failing results as atypical. Your firm performed a retesting of the samples without notifying the client which is inadequate per your QSOP-0075 "Handling Atypical Events and Observations in the Analytical Chemistry Laboratory". Your firm did not thoroughly perform an investigation or risk assessment to retrospectively identify if there are other instances where failing results were considered atypical and rerun without notifying the client. Furthermore, your firm did not document if this practice is widespread or isolated to specific analysts, products, or methods.

OBSERVATION 2

Laboratory records do not include the initials or signature of a second person showing that the original records have been reviewed for accuracy, completeness and compliance with established standards.

Specifically,
Your microbiology laboratory records do not include second person review of raw data for accuracy including for your clients performing environmental monitoring (EM) studies. Your clients include sterile manufacturers conducting EM of ISO areas with microbial action limit of less than one colony forming unit (CFU).

***DATES OF INSPECTION**

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Rafeeq A Habeeb, Investigator Martin M Kimani, Chemist/Biologist	X Rafeeq A Habeeb Investigator Signed By: 2002600695 Date Signed: 04-25-2025 14:13:50	4/25/2025

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513)322-0700 Fax:(513)679-2772	4/16/2025-4/25/2025* FEI NUMBER 1527260

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jayson B. Arling, President and CEO

FIRM NAME	STREET ADDRESS
Q LABS, LLC	1930 Radcliff Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Cincinnati, OH 45204-1823	Laboratory

4/16/2025(Wed), 4/17/2025(Thu), 4/18/2025(Fri), 4/22/2025(Tue), 4/23/2025(Wed), 4/25/2025(Fri)

X Martin M Kimani
Chemist/Biologist
Signed By: Martin M. Kimani -S
Date Signed: 04-25-2025 14:14:25

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Rafeeq A Habeeb, Investigator
Martin M Kimani, Chemist/Biologist

X Rafeeq A Habeeb
Investigator
Signed By: 2002600695
Date Signed: 04-25-2025
14:13:50

DATE ISSUED
4/25/2025

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."

May 16th, 2025

Via Email (CDER-OC-OMQ-Domestic483Response@fda.hhs.gov)

RE: Response to Form 483 – Q Labs, LLC (FEI 1527260)

Please accept this response to the FDA Form 483 issued on April 25, 2025, following the on-site inspection of Q labs, LLC which occurred from April 16th through April 25th, 2025, at 1930 Radcliff Drive, Cincinnati, Ohio by consumer safety officers Rafeeq A Habeeb and Martin M Kimani from the Office of Pharmaceutical Quality Operations Pharma Division 3.

Q Labs, LLC takes the FDA inspection seriously and maintains a commitment to correcting all observations and responding to the verbal discussions that took place during the inspection. Executive management is committed to supporting all efforts to ensure the responses and corrective actions are appropriate and effective.

The company is committed to following up on this response with documents or records as they are completed, to further demonstrate our commitment to accountability and continuous improvement in support of a mature corporate quality culture.

Attached you will find the observations as written on Form 483 and discussed during the closing meeting with Q Labs' response. We welcome any feedback to support our understanding of the observations.

Respectfully Submitted,

Jayson Arling
President & CEO
Q Labs, LLC
jarling@qlaboratories.com

Observation 1:

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

Your firm is a contract testing laboratory performing microbial and analytical tests for firms (clients) manufacturing sterile, non-sterile, and OTC drug products.

A. *Your investigations OOS-271, OOS-272, and OOS-273 dated 11/24/2024 for microbial out of specification (OOS) of finished drug products were inadequate. You identified likely contamination of the test samples by laboratory analyst during sample processing as the root cause for the OOSs and tested multiple negative controls with passing results. In addition, as part of the investigation you did not include historical microbial test results for the drug product, total number of samples tested by the analyst on 11/24/2024 and the number of negative controls processed along with the test samples and their results*

B. *Your investigations OOS 23-135, OOS 23-136, OOS 23-151, and OOS 23-158 dated 4/26/2023 and 5/2/2023 for microbial out of specification of multiple finished products were inadequate. You identified likely contamination of the test samples during processing as the root cause for the OOSs and therefore invalidated the results. However, multiple negative controls processed simultaneously along with the test samples had passing results. In addition, as part of the investigation you did not include the total samples tested and the number of negative controls processed along with the test samples and their results.*

Please note that there appears to be a typo in observation 1 A. OOS-271, OOS-272, and OOS-273 should be OOS 24-471, OOS 24-472, and OOS 24-473.

Response:

We have determined that our existing investigations did not consistently document all aspects of the Out of Specification (OOS) process. Specifically, total negative control data, review of historical results, total number of samples tested by the analyst, and information from related and unrelated in-process samples are not consistently documented as reviewed as part of the OOS investigation. While these aspects are part of the investigation process, they weren't documented in the investigation report.

To address this observation, we will revise our OOS Investigation procedure, QSOP-0120, and the OOS Investigation Form, QFORM-0111, to ensure comprehensive documentation of information collected during the investigation process. Specifically, a new summary of findings will be added to section 2E of QFORM-0111 to serve as a visual reminder to document the review of parallel unrelated samples. These updates are captured in change control DCC-0000123 (see attachment 1) and are targeted to be complete with training by 6/30/2025.

We are implementing a new procedure that clearly defines the required number and scope of negative controls during testing events. This enhanced control framework will support the reliability of microbiological testing and better assist the associated OOS investigations. This new procedure with training will be completed by 6/30/2025. Responses to Observation 1A and 1B are addressed in CAPA 25-064 (see attachment 2)

C. Your non-conformance investigation NC 25-031 dated 3/4/2025 for stability testing of drug product (OTC hand sanitizer) outside of stability testing window is inadequate. The investigation did not include supporting information including the stability time-point, the dates the sample was pulled, the sample test date, test results, and any previous non-conformances.

Response:

To address this observation, we will:

- Update procedure QSOP-0359, Investigation of Nonconforming Work, to require the inclusion of the stability time-point, the dates the sample was pulled, the sample initiation test date, test results and any previous non-conformances. The update will include additional details of the investigation so that the report is a standalone document. This update is on change control DCC-0000121 (see attachment 3) and is targeted to be complete by 6/30/2025.
- Update QFORM-0015, Nonconformance Form, will be updated to include a new field that requires the documentation of stability time-point, the dates the sample was pulled, the sample test initiation date, test results and any previous non-conformances. This update is on change control DCC-0000121 and is targeted to be complete by 6/30/2025.
- Conduct training for all applicable employees on the changes to QSOP-0359, Investigation of Nonconforming Work, and QFORM-0015, Nonconformance Form. This training will occur prior to the change control DCC-0000121 becoming effective and is targeted to be complete by 6/30/2025.
- QSOP-0044, Stability Chambers and Stability Testing, requires stability testing to be initiated within 2 weeks of the pull date. The assay and ID testing of the stability samples noted in NC 25-031 (QLs 0822836 and 0819950) were delayed by 1 and 3 weeks, respectively. All other testing was completed within the 2-week stability window. The client was notified of the delay.

The steps taken to address Observation 1 C are documented on CAPA 25-065 (see attachment 4).

D. Your non-conformance investigation, NC 24-242 dated 10/15/2024, classified failing results as atypical. Your firm performed a retesting of the samples without notifying the client which is inadequate per your QSOP-0075 "Handling Atypical Events and Observations in the Analytical Chemistry Laboratory". Your firm did not thoroughly perform an investigation or risk assessment to retrospectively identify if there are other instances where failing results were considered atypical and rerun without notifying the client. Furthermore, your firm did not document if this practice is widespread or isolated to specific analysts, products, or methods.

Please note that there appears to be a typo in observation 1 D. The nonconformance dated 10/15/24 is 24-142 not 24-242. We did not issue a nonconformance 24-242.

Response:

To address this observation, we will:

- Update procedure QSOP-0359, Investigation of Nonconforming Work, to require a retrospective review for additional instances of the nonconformance and the documentation of whether the nonconformance is widespread or isolated to a specific analyst, product, or method. This update is on change control DCC-0000121 and is targeted to be complete by 6/30/2025.
- Update QFORM-0015, Nonconformance Form, to include a new field that requires a retrospective review for additional instances of the nonconformance and the documentation of whether the nonconformance is widespread or isolated to a specific analyst, product, or method. This update is on change control DCC-0000121 and is targeted to be complete by 6/30/2025.
- Conduct training for all nonconformance investigators on the changes to QSOP-0359, Investigation of Nonconforming Work, and QFORM-0015, Nonconformance Form.
- It should be noted that in NC 24-142 the client was notified but at the time of the nonconformance there wasn't a requirement to document the notification on the form. The resulting CAPA updated QFORM-0069, Atypical Event (see attachment 5), to include a field for improved visibility and to document the client notification.

The current atypical procedure, Handling Atypical Events and Observations in the Analytical Chemistry Laboratory, QSOP-0075, requires clients to be notified if any atypical event results in an OOS result. QSOP-0075 is attached as evidence (see attachment 6).

The steps taken to address Observation 1 D are documented on CAPA 25-066 (see attachment 7).

Observation 2:

Laboratory records do not include the initials or signature of a second person showing that the original records have been reviewed for accuracy, completeness and compliance with established standards.

Specifically,

Your microbiology laboratory records do not include second person review of raw data for accuracy including for your clients performing environmental monitoring (EM) studies. Your clients include sterile manufacturing conducting EM of ISO areas with microbial action limit [sic] of less than one colony forming unit (CFU).

Response:

Q Labs appreciates any observations or recommendations to improve its operations. Unfortunately, we are currently unable to provide a thorough response to Observation 2, as we require additional clarification regarding the scope and nature of the FDA's concern.

This topic was discussed daily and at length with the inspectors throughout the inspection. To assist the FDA in providing additional clarity regarding this observation, we have summarized relevant details of our discussions with the inspectors below. We have also provided copies of relevant documents that were reviewed. It is important to note that no new information is being shared with this response. Each of these points were presented and discussed with the inspectors. All referenced procedures were reviewed, and copies of each were taken by the inspectors. Where applicable, these processes and procedures were demonstrated in the laboratory. We request that the FDA consider our points below and provide clarification regarding the nature and scope of the observation. We would welcome any feedback to assist us in providing a thorough and appropriate response.

Q Labs Procedure for Secondary Verification of Plate Counts

The observation, as written, may give the mistaken impression that Q Labs conducts no secondary verification of microbiological data. This is not the case. It is critical to understand that current Q Labs procedures require that all microbial plate counts be contemporaneously recorded by the analyst at the conclusion of incubation. We submit that this plate count, as recorded, represents the original record. Per Q Labs procedure QSOP-0369, Reporting and Reviewing Test Results, section 5.4 (see attachment 8), the original data (plate count), along with all other data including subsequent calculations is reviewed by a second qualified analyst (a member of Q Labs' Quality Assurance Unit) prior to data release.

This review process was demonstrated during the inspection. FDA Investigator, Rafeeq A Habeeb, asserted that the agar plate itself (not the plate count) constitutes the original record, and as such requires secondary review as prescribed in 21 CFR 211.194. Mr. Habeeb insisted that each individual agar plate must be counted by a second analyst to confirm the count of the first analyst.

We respectfully request clarity as to whether this is indeed the case, as it is inconsistent with Q Labs' current understanding of the meaning and intent of 21 CFR 211.194.

21 CFR 211.194 Laboratory Records

"(a) Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays…(a)(4) A complete record of all data secured in the course of each test …(a)(5) A record of all calculations performed in connection with the test, including units of measure, conversion factors, and equivalency factors…(a)(8) The initials or signature of a second person showing that the original records have been reviewed for accuracy, completeness, and compliance with established standards."

Q Labs suggested to Mr. Habeeb, that the plate ***count***, not the agar plate itself, represents the "original record" as it represents the number of colonies forming units identified at the completion of the incubation period dictated by the validated method.

Moreover, we submit that the agar plate should not, and more importantly cannot represent the "original record". This is because the agar plate is not immutable. Given additional time, the plate count should reasonably be expected to change. Slow-growing organisms may form colonies which would increase the plate count. Conversely, colonies may grow together or spread which would, in effect, decrease the observed plate count. These "higher" or "lower" plate counts, while no less real, would not represent the result of the method as validated and would therefore not be themselves "valid".

This is directly spoken to in USP <1117>, Microbiological Best Laboratory Practices.

USP <1117>, Data Integrity of Microbiological Data

"Counts from Petri plates are considered original data on the day that the method requires the plates to be read and recorded. After reading, if these same plates are subsequently stored at room temperature or under refrigeration, it is not possible to confirm the original results because the microbial counts may increase during storage. Many microbial colonies continue to grow during refrigeration but at a slower rate. The colony counts derived from conducting a microbe test using a compendial method depend on adherence to the incubation time and temperature stated in the prescribed method (i.e., <61>)."

In summary, based on Q Labs' current understanding of the intent of 21 CFR 211.194, we maintain that the plate count represents the original record, and that existing Q Labs procedures (e.g., QSOP-0369, Reporting and Reviewing Test Results) regarding reviewing of recorded plate counts, and confirmation of calculation accuracy meets the intent of the record review requirements outlined in 21 CFR 211.194.

1. Secondary Review of Agar Plates is Not Best Practice

Beyond the point that agar plates should not be considered "original records" within the meaning of 21 CFR 211.194, universal secondary review of agar plates is not a best practice. On the contrary, USP specifically recommends ***against*** this practice.

USP <1117>, Data Integrity of Microbiological Data

"For the compendial sterility test that combines criticality of the test and higher risk of misinterpretation of results, it is now a standard practice to have a second analyst perform a contemporaneous evaluation of the sample (in test media) for microbial growth. Nonetheless, applying uncritically a contemporaneous reading by a second analyst (four-eyes principle) for all samples and microbiological tests is not recommended."

Q Labs is not aware of any current guidance document that does recommend or require that agar plates be contemporaneously counted by a second analyst. Specifically, this practice is not spoken to in any of the following standards/guidance documents that Q Labs adheres to and/or is accredited to:

- ICH Q7, Good Manufacturing Practice for Active Pharmaceutical Ingredients
- ICH Q10, Pharmaceutical Quality System
- ISO/IEC 17025, General Requirements for the Competence of Testing and Calibration Laboratories
- FDA Office of Regulatory Science, Pharmaceutical Microbiology Manual
- FDA Draft Guidance, Microbiological Quality Considerations in Non-sterile Drug Manufacturing

Q Labs welcomes the opportunity to review any regulatory reference or industry guidance document that universally suggests or recommends that agar plates be counted by two analysts.

2. Q Labs' Procedures to Ensure Counting Accuracy

Given that secondary review of agar plates is not recommended, Mr. Habeeb expressed concern over ensuring accuracy of the plate count. USP <1117> also addresses this concern acknowledging that classic cultural microbiology has a ***predictably*** higher level of variation even under optimal circumstances, but that this variation is acceptable given the context of this testing.

USP <1117>, Data Integrity of Microbiological Data

"Precision in counts may vary from one analyst to another (even if they are trained and qualified) as colonies may overlap, swarm over media, etc., allowing for misinterpretation. Microbiology is a "logarithmic science" (<u>(1223)</u>); sample size is statistically weak and testing procedures have inherent variability. By tolerating no differences in counts, a high number of non-critical deviations will be generated, thus consuming resources unreasonably."

The samples being tested at Q Labs are of a non-sterile, but low bioburden, nature. In practice what this means is that the majority of plates have no growth. In instances where there is growth, it is typically low (few

colonies; often below the typical countable range of 25 CFU). As such, the practical risk of "miscounting" plates is quite low. However, in an effort to minimize any variability as much as possible, Q Labs employs multiple procedures that go beyond industry standards.

i. ***All plates must be read under illuminated magnification.***

QSOP-0252, Calculating and Reporting Plate Count Results for Quantitative Microbiological Analyses (see attachment 9), requires that all agar plates be read under illuminated magnification (i.e., utilizing a Quebec darkfield colony counter or equivalent). Such colony counters have background grids which help ensure counting accuracy, particularly when counts are high. Additionally, examining plates under illumination and magnification minimizes the risks of missing even a single colony when counts are low (or zero). While darkfield colony counters are common tools in microbiology laboratories, the requirement that all plates be examined under illuminated magnification is a best practice required by Q Labs procedures that goes beyond industry standard (or USP requirements/guidance).

ii. ***Analysts must pass monthly plate counting accuracy verification checks.***

QSOP-0222, Monthly Plate Count Comparison (see attachment 10), requires that all microbiology analysts responsible for counting plates perform a monthly counting accuracy verification. This involves a Senior Microbiologist (part of laboratory management) first either selecting a plate with growth that is currently in place in the laboratory or preparing an artificially inoculated plate. The plate is then counted by the Senior Microbiologist to establish the "true count". Then every analyst in the laboratory must count the same plate and report their plate count on an individual reporting sheet. The Senior Microbiologist collects all of the individual count reports and compares the counts statistically. Any analyst falling outside the acceptable range will be immediately disqualified from counting plates, the failure would be investigated, and the analyst would not be permitted to count plates again until minimally they were retrained and obtained passing monthly plate count comparison verification results.

This procedure ensures that counting accuracy is continuously monitored across all analysts in the laboratory. It is a best practice that goes well beyond industry standard (or USP requirements/guidance).

iii. ***All plates with growth are retained for 30 days.***

Any plate with any growth observed is maintained under refrigerated conditions for 30 days. This allows the client time to determine if any additional testing (e.g., microbial identification/characterization, creation of a stock culture, etc.) is warranted or necessary. Maintenance of all growth works in concert with Q Labs' out-of-specification (OOS) procedure

whereby laboratory supervision, and subsequently the client, is immediately notified of any OOS growth.

3. Q Labs Does Not Perform Sterility Testing

While secondary review of agar plates is not required, it is not an especially uncommon practice in sterile drug manufacturing (as mentioned in USP <1117>). However, it is explicitly stated that the reason for this is due to the "…criticality of the test and higher risk of misinterpretation of results…".

Specifically, compendial sterility tests (i.e., USP <71>) involve general enrichment(s) and an analysis of the sample preparations for an increase in turbidity of the test media. In the context of sterility testing, a secondary review of the sample preparation may be warranted. This is for two main reasons:

i. ***Higher risk of misinterpretation of results.***
Analysis of compendial sterility testing (i.e., USP <71>) ultimately rely on a visual determination of an increase in turbidity of the test media. Depending on the level of contamination, nature of the product being tested, and other confounding factors, this analysis may be more likely to lead to subjective misinterpretation than standard quantitative microbiological analyses such as USP <61>.

ii. ***Misinterpretation of results in sterility testing poses higher risk to patients.***
Drugs required to be sterile are required to be so because the route of drug administration and/or the risk profile of the intended patient are such that any microbial contamination would lead to a high risk of infection. As such, it is critical that the risk of subjective misinterpretation described above be minimized. While not the only mechanism to minimize this risk, one common practice is to employ the "four eyes" approach.

USP <1117> explicitly states that an uncritical application of the "four eyes" approach is not recommended and so suggests that alternative approaches involving contemporaneous confirmation by a second qualified analyst that the method was performed correctly may be appropriate for these "higher risk tests".

USP <1117>, Data Integrity of Microbiological Data

"As an alternative to a contemporaneous enumeration, a contemporaneous verification by a second person that the testing activity is performed correctly may be executed for higher risk tests. A second person could verify, for instance, if the reading of results is correctly executed according to the procedure, if the result on the Petri plate is correctly transcribed onto the GMP recording sheet (i.e., if growth is observed this is captured in the GMP sheet), and if the description of the sample corresponds to the description on the GMP recording sheet. An assessment of the risk due to a misinterpreted result and its impact on patient safety is performed to determine the high risk test outlined above."

Regardless, Q Labs ***does not*** perform sterility testing for any clients. This was explained and demonstrated to the investigators. However, Mr. Habeeb stated that the "four eyes" approach must be applied to

environmental monitoring samples from sterile manufacturers. While we understand and appreciate Mr. Habeeb's concern regarding the low tolerances employed in environmental monitoring programs in sterile manufacturing, we ask that the FDA consider that it is for precisely this reason that the "four eyes" approach in evaluating environmental monitoring plates is redundant.

In sterile manufacturing suites, the acceptable limit provided by Q Labs' sterile manufacturing clients is typically <1 CFU/plate. Mr. Habeeb indicated concern that lack of a secondary verification may allow plates to be reported as "<1 CFU/plate" (zero colonies observed) when there was in fact a single colony. Q Labs would respectfully suggest that the procedures in place at Q Labs make this risk extremely low. As outlined in Section 2i above, all plates are examined under illuminated magnification. This magnification greatly reduces the risk of inadvertently "missing" even a single colony when counting plates. It should be noted that the investigators did not find any instances of plates that were miscounted during their review of the laboratory.

Summary

Ultimately, as with any manual test in microbiology or chemistry, there is a point at which we must rely on the training and competence of individual analysts. Q Labs believes its training and laboratory procedures deliver the highest standard of microbiological data integrity. Moreover, we believe that our ongoing monthly plate count verification of our microbiology analysts demonstrates the efficacy of our procedures. Q Labs is committed to new learnings and to continuously improving our Quality Culture. To that end, we ask that the FDA review the information provided and provide additional feedback on any compliance concern.

Verbal Observation 1:

There are opportunities to better utilize quality metric trends to rapidly identify opportunities for improvement.

Response:

We agree that better trending our data will provide opportunities for improvement. To address this observation, we will:

- Review quality metrics (i.e. NCs/CAPAs/OOS/atypicals) for trends at weekly meetings between lab management and quality personnel.
- Review of quality metrics (i.e. NCs/CAPAs/OOS/atypicals) for trends at the annual Management Review.
- The increased focus in weekly meetings on concerted review of quality metric data will allow for more rapid identification of actionable trends and timely improvements via the nonconformance/CAPA process as appropriate.

This improved process began on 5/16/2025.

Verbal Observation 2:

Opportunity to more rapidly update test procedures with explanative details that were not included in the originally issued document – two examples:

Miconazole nitrate impurities testing requires submission and testing of raw material active.

Sample lip balm sticks 2/3 down the side of stick.

Response:

Both examples provided were outputs of our atypical process. The current atypical process can be improved by documenting follow-up and closure. To address this observation, we will:

- Update QFORM-0069, Atypical Event, to more clearly identify and facilitate follow-up and closure.
- Update QSOP-0075, Handling Atypical Events and Observations in the Analytical Chemistry Laboratory, to more clearly identify and facilitate follow-up and closure.
- All applicable employees will be trained in the new process.

The concerted focus on review of atypical data as described in our response to Verbal Observation 1 will help improve this process immediately. The systemic solution, including updating the forms and SOPs listed above, will be completed by 7/31/2025.

Verbal Observation 3:

QSOP-0129, OOS Investigations does not explain the process for voiding OOS

Response:

To address this observation, we will:

- Update QSOP-0129, OOS Investigations, to include the process to void OOS investigations.
- Conduct training for all applicable employees on the changes to QSOP-0129, OOS Investigations.

These updates are targeted to be complete by 7/31/2025.

U.S. FOOD & DRUG ADMINISTRATION

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
www.fda.gov

Via Email
Return Receipt Requested

July 28, 2025

Jayson Arling, President & CEO
Q Labs, LLC
1930 Radcliff Drive
Cincinnati, OH 45204
jarling@qlaboratories.com

Dear Mr. Arling:

We have reviewed the Establishment Inspection Report (EIR) for the inspection conducted at your contract testing laboratory Q Labs, LLC, FEI 1527260, located at 1930 Radcliff Drive, Cincinnati, Ohio, from April 16 to April 25, 2025. We have also reviewed your response to the Form FDA 483, Inspectional Observations issued at the conclusion of the inspection.

Based on our review, we have the following comment:

In your response to observation 2, your firm requested clarity about the reading of microbiological plates. Specifically, whether each individual agar plate must be counted by a second analyst in order to comply with the intent of Title 21 Code of Federal Regulations (CFR), part 211.194 (21 CFR Part 211.194).

We agree that each individual agar plate does not need to be counted by a second analyst when testing non-critical, lower risk samples. For example, a single analyst reading a plate for total aerobic microbial count (TAMC) testing of a non-sterile, over-the-counter topical drug would comply with Current Good Manufacturing Practice (CGMP) regulations.

However, when testing critical, higher risk samples, contemporaneous reading by a second analyst (i.e., 'four-eyes principle') is recommended. The United States Pharmaceopeia (USP) general chapter <1117> "*MICROBIOLOGICAL BEST LABORATORY PRACTICES*" mentions compendial sterility testing as an example where it is considered standard practice to have a second analyst perform a contemporaneous reading. It notes that this is due to the criticality of the test and higher risk of misinterpretation of results. While we acknowledge that your firm does not perform sterility testing, your firm does appear to perform critical tests at higher risk of misinterpretation of results. For example, environmental samples from one of your clients indicates an action limit of greater than or equal to one.

We recommend that your firm conduct a risk assessment to determine when contemporaneous reading of a microbiological plate by a second analyst (i.e., 'four-eyes principle') is appropriate to mitigate the risk of a misinterpreted result.

This assessment, any associated corrective action, and the effectiveness of your corrective actions will be reviewed during a subsequent inspection. These comments are not intended as an all-inclusive list. Failure to take corrective actions may result in regulatory action by FDA without further notice.

If you have any questions regarding this letter, contact CDER-OC-OMQ-Communications@fda.hhs.gov.

Sincerely,

Ernest Bizjak, Team Leader
Office of Manufacturing Quality
Office of Compliance
Center for Drug Evaluation and Research

Drug Establishments Current Registration Site

New Search (index.cfm)

Search Results for **Q labs**

CSVExcel
Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Q Labs, LLC	1527260	080737501	ANALYSIS;	1930 Radcliff Dr, Cincinnati, Ohio (OH) 45204, United States (USA)	12/31/2026

Showing 1 to 1 of 1 entries
Previous1Next
Data Current through: Monday, Nov 3, 2025

Return to Drug Firm Annual Registration Status Home Page (default.cfm)

Q Laboratories

Quality Agreement

Q Laboratories
1930 Radcliff Dr.
Cincinnati, OH 45204
(also referred to as Contractor)

Authorization
Q Laboratories

DocuSigned by:
Jayson Arling
2F297F14561B46D...
Jayson Arling – President and CEO — 12/2/2025 Date

DocuSigned by:
Jeff Knowles
621748E7B186493...
Jeff Knowles – Vice President, Quality — 12/2/2025 Date

Buyer Company Name – AdiraMedica LLC

Signed by:
Arvind Bhandari
B33CADE480AE46F...
Arvind Bhandari – President and CEO — 12/2/2025 Date

DocuSigned by:
Doris B. Correa
D3AA79569AA6413...
Doris B. Correa Senior Director – Quality Assurance — 12/2/2025 Date

The action of approving this document indicates that the appropriate parties have reviewed the agreement to the complete content of this document.

THIS DOCUMENT WILL BECOME EFFECTIVE FROM THE DATE FINAL APPROVAL IS GIVEN BY THE BUYER AND CONTRACTOR.

Q Laboratories

TABLE OF CONTENTS **Pages**

1.0 Scope of the Quality Agreement:

a) Q Laboratories has been appointed by AdiraMedica LLC to perform monographed and/or method validated testing, physicochemical testing, microbiological testing, and stability storage under cGMP or GLP conditions as appropriate.

b) This Quality Agreement is not intended to supersede, modify or amend the Confidentiality Agreement in any respect.

c) This Quality Agreement is subject to US law and if it is translated into a language other than English, this version in English shall be controlling on all questions of interpretation.

2.0 Revision History:

Issued 11-21-25

3.0 DEFINITIONS:
Except as otherwise defined below, the terms in this agreement shall have the meaning, if any, as defined within the US GMP Regulations.

a) "Q Labs" Q Laboratories referred to as Contractor- approved contract testing laboratory.

b) AdiraMedica LLC referred to as Buyer, a cGMP regulated company.

c) "Competent Authority" means the applicable competent authority referred to by US and European cGMP Regulations.

d) "Parties" means Q Laboratories and Buyer and their permitted assigns and "Party" means any one of them or their permitted assigns, as the context requires.

e) "Quality Investigation" means any unplanned deviations that are raised during the laboratory testing for the product.

f) "Reference Sample" means a sample, stored for identification purposes, of a fully packaged unit from a batch of Finished Product.

g) "Primary Responsibilities" are defined between the Parties within the quality matrix, section 4, by the designators (R, I, C and NA) listed at the top of each section table, in the appropriate company column. NA delineates a responsibility as not applicable.

h) "Retention Sample" or "Retain sample" means a sample which is stored for the purpose of being analyzed should the need arise.

i) "Specifications" means those specifications for each Product provided to Contractor used to manufacture and test the Product.

j) Under General requirements and responsibility **(R)** = Responsible will be used to indicate which party would be responsible for performing or completing the task, likewise **(I)** = Inform will indicate which party would need to be informed, **(C)** = Consult would indicate that the party would act in consultation, and **(N/A)** = not applicable indicates that the activity does not apply to the designated party.

4.0 RESPONSIBILITIES

GENERAL REQUIREMENTS AND RESPONSIBILITIES
(R = responsible, I = inform, C = consult, N/A = not applicable)

Ref	Activity	Contractor	Buyer	Clarification of Responsibility
4.1	Preparation and update of Quality Agreement	R	R	Q Laboratories and Buyer are responsible for the preparation and regular review of this Quality Agreement.
		R	R	Except as otherwise expressly stated, the terms and conditions of the Quality Agreement remain in full force and effect.
		R	R	Contractor and Buyer have agreed to the Quality Agreement as a free-standing document and either company can propose changes to it. The change initiator shall communicate the change in writing prior to implementation. The initiator shall generate a draft revision. The draft revision will then be routed and approved without undue delay by the Buyer and the Contractor according to each Party's procedure. Upon completion of the review, Buyer will send Contractor two signed originals of the revised Agreement for Contractor's approval. Upon Contractor's approval, the Buyer will return one signed original to Contractor and retain the other.
		R	R	No change shall be made without written agreement of both parties, except as required by law or regulatory action.
		R	R	This Quality Agreement will be periodically reviewed and updated in accordance with each party's Standard Operating Procedures.
4.2	US cGMP / GLP and other applicable Health Authorities	R	R	Testing of Products shall be in accordance with the "The Rules Governing Medicinal Products" in the Good Manufacturing Practice provisions set forth in 21 CFR 58, 210, 211, 820 and Part 11, and other applicable regulatory or health authorities' provisions as amended from time to time. The generation and reporting of test data shall be in accordance with the Good Laboratory Practice and Good Manufacturing Practices provisions set forth in 21 CFR 58, 210, 211, 820 and Part 11, as appropriate
4.3	Subcontracting	R	C	The Contractor reserves the right to subcontract testing or other laboratory analysis to outside laboratories, provided that these outside testing laboratories are qualified using internal procedures. The Buyer must be notified and approve the subcontractor.

4.4	Documentation requirements	R	C	Contractor will prepare, provide and maintain Buyer's standard documentation requirements according to standard operating procedures and document control systems. Additional required documentation shall be provided by Contractor as agreed between Buyer and Contractor.
4.5	Key contacts/Buyer Visitation	I	I	See Appendix 2 to this Quality Agreement. The Buyer will be afforded the right on a limited basis and with a minimum of 7 days advanced notice, to have representatives present at Contractor premises whenever work is being conducted on behalf of the Buyer**,** *as long as presence does not violate confidentiality of other* Contractor *clients,* to assess compliance with quality requirements of the Buyer.
4.6	Electronic Records/Signatures	R	N/A	Electronic Records / Signatures: Contractor shall comply with 21 CFR Part 11 requirements regarding the use of electronic records / signatures involved in data generation.
4.7	Validation	R C	C R	Method validations will be performed, data compiled and documented as agreed between the Buyer and the Contractor. Buyer requests for additional qualifications and/or validations will be at Buyer's expense.
4.8	Dispute resolution	R	R	Every attempt will be made to amicably resolve any dispute arising out of or relating to this Quality Agreement by escalating such disputes to senior members of each organization's Quality Team.

LABORATORY TESTING AND CONTROL

(R = responsible, I = inform, C = consult, N/A = not applicable)

Ref	Activity	Contractor	Buyer	Clarification of Responsibility
4.9	Site	R	I	Address(es) of approved site(s) of operation as Contractor: Q Laboratories, 1911 Radcliff Dr, Cincinnati OH, 45204 Q Laboratories, 1930 Radcliff Dr. Cincinnati OH, 45204
4.10	Documentation – Preparation	R	I	The contractor is responsible for the preparation and approval of laboratory documents.
4.11	Documentation – Retention	R	I	Contractor shall retain original documents in accordance with cGMP and local Standard Operating Procedures.
4.12	Specifications and Test methods for Starting Materials	I I	R R	The Buyer is responsible for the provision of specifications and test methods for samples. The Buyer is responsible for communicating any

				changes to specifications.
4.13	Specification and Test methods for Product	N/A	R	The Buyer is responsible for the approval of Finished Product Specifications and test methods for Product release.
4.14	Reference standards for Drug(s)	R	I	The Contractor is responsible for the supply of appropriate Reference standards, at cost to the Buyer, but will inform Buyer on any changes of supply or Reference standards.
4.15	Sampling and release for use of Bulk Product	I	R	Buyer is responsible for sampling and release of Bulk Product.
4.16	Warehousing	R	N/A	All samples provided to Contractor by Buyer are to be stored in accordance with the appropriate labeled storage conditions and in compliance with cGMP requirements or as otherwise agreed provided it is in accordance with US cGMP.
4.17	Waste management	R	N/A	Contractor shall comply with the current US Applicable Laws on waste management and waste disposal, and/or European legislation as appropriate.

QUALITY ASSURANCE

(R = responsible, I = inform, C = consult, N/A = not applicable)

Ref	Activity	Contractor	Buyer	Clarification of Responsibility
4.18	Inspection by a Competent Authority	R R	I I	Contractor will inform Buyer as soon as possible, not to exceed two consecutive business days, of any findings arising from routine inspections conducted by Competent Authorities of Contractor's facility, which may affect Buyer's Product. Contractor shall provide copies of inspection reports upon request by Buyer, which result in a finding that indicates a possible cGMP violation that affects or may affect the Products. Contractor will inform Buyer as soon as possible, not to exceed 2 business days, of any inspection by a Competent Authority of Contractor that may give rise to inspection of Buyer's facility.
4.19	Regulatory Inspections of Buyer	I C	R R	In the case of a request for an audit/inspection of Buyer's Facility from a Competent Authority having jurisdiction over the Product, Buyer shall permit representatives of the regulatory authority to enter Buyer's premises for inspection in relation to cGMP regulations. During an inspection the Buyer may contact the Contractor for assistance in addressing a question from the regulatory authority to include obtaining

				additional documentation of past testing that is within normal document retention periods.
4.20	Handling of cGMP Out Of Specification (OOS).	R R R R	I C I R	In the event of a cGMP out of specification (OOS), Contractor will notify Buyer as soon as possible, but within a timeframe not to exceed two (2) business days. Contractor shall have primary responsibility for the investigation with respect to laboratory analyses conducted, in accordance with agreed procedures with a target completion date of 30 calendar days. Contractor will consult with Buyer during the course of the investigation. Contractor will notify Buyer of extensions beyond the 30-day target completion. The Buyer will be notified if an OOS investigation determines that retesting is warranted. The Buyer has two business days to respond to the retest request. A lack of response from the Buyer is considered an authorization to move forward with retesting.
4.21	Deviations (from the agreed processes or methods)	R	R	Contractor shall notify Buyer and obtain its prior approval for any planned deviations, which may affect the quality of the product.

REGULATORY

(R = responsible, I = inform, C = consult, N/A = not applicable)

Ref	Activity	Contractor	Buyer	Clarification of Responsibility
4.22	Technical Documentation	N/A N/A	N/A N/A	If applicable, Contractor or its agent is responsible for compiling and submitted all Technical Documentation to notify bodies and competent authorities for registrations outside the U.S. If applicable, Buyer will provide Contractor with all needed technical information to be able to complete the Dossier and international registrations, as appropriate and per Supply Agreement Drug substance characterization
4.23	Post inspection notification if Product quality is affected	R	I	Contractor will inform Buyer within two business days of any findings arising from routine inspections conducted by any recognized regulatory authority, including but not limited to, inspection by the FDA, which may affect Contractor's testing.
4.24	Regulatory Filing	I	R	Buyer will notify Contractor prior to listing Contractor on any type of regulatory filing with the FDA or other regulatory bodies.

APPENDIX 1 – REQUIRED DOCUMENTS

Q Laboratories

DOCUMENT	FUNCTION
Purchase Order Request	Buyer includes with submitted sample(s) for identification, required testing and test method(s) to be performed by Contractor.
Sample Submission Form	Document used internally by Contractor to log incoming samples.
Final Report	Issued to Buyer by Contractor when testing has been completed, quality reviewed and accepted. Each report is identifiable by a "Q Labs Reference No.".

APPENDIX 2 – KEY CONTACTS

CONTRACTOR QUALITY MANAGEMENT

Name	Jeff Knowles
Phone	
Email	

CONTRACTOR OPERATIONS MANAGEMENT

Name	August Smithmeyer
Phone	
Email	

BUYER QUALITY ASSURANCE MANAGEMENT

Name	Doris B. Correa
Phone	
Email	

BUYER QUALITY MANAGERCONTACT

Name	Jaclyn Fox
Phone	
Email	j

BUYER OPERATIONS MANAGER

Name	Sharon Johnson
Phone	
Email	

QUALITY AGREEMENT

SUPPLY OF PRODUCT UNDER THE SECTION 804 IMPORTATION PROGRAM (SIP).

R.00

AdiraMedica LLC
77 Brant Ave Suite 325
Clark, NJ 07066, USA

hereinafter referred to as "SIP Importer", Contract Giver (CG)

and

AdiraMedica Inc.
2233 Argentia Rd,
Suite #302, Unit #306
Mississauga, Ontario, L5N 2X7, Canada

hereinafter referred to as "Foreign Seller", Contract Acceptor (CA)

1 SCOPE

This Quality Agreement ("Agreement") is made by and between AdiraMedica LLC Contract Giver (CG) located at 585 Turner Industrial Way Aston, PA, USA and AdiraMedica Inc. the Contract Acceptor (AC) Contract Acceptor (CA)., located at 2233 Argentia Rd, Suite #302, Unit #306, Mississauga, Ontario, L5N 2X7, Canada.

This Agreement is for **CA** to act as the Foreign Seller and Drug Establishment License holder of the drug products listed in Attachment I and **CG** to act as the Importer as defined under the Section 804 Importation Program (SIP) of drug products listed in Attachment I.

As the Importer, **CG** has primary responsibility for all quality management over importation into the United States of America related to the products listed in Attachment I on behalf of the SIP Sponsor.

CA will be the Foreign Seller for the drug products listed in Attachment I, Current Product Listing**.**

For purposes of regulatory compliance, **Contract Acceptor (CA)** and **Contract Giver (CG)** enter into this Agreement to confirm that the CA will carry out all quality obligations in Canada that may be relevant hereunder, and **Contract Acceptor (CA)** acknowledges those quality obligations.

The purpose of this Agreement is to set forth the obligations of the parties regarding quality matters, related to the products imported by **Contract Giver (CG)** under the requirements of SIP.

The responsibility for ensuring this agreement is implemented, reviewed and revised as needed rests with the Quality Management of **Contract Acceptor (CA)** and **Contract Giver (CG)**.

Both parties have agreed to cooperate to ensure that the activities and responsibilities contemplated hereunder are carried out in full compliance with the relevant guidelines, policies and regulations set forth by the authorities in Canada and in the USA. In particular the current Good Manufacturing Practices, as set forth and amended from time to time by Health Canada and Federal Drug Administration (FDA).

2 DEFINITIONS

For purposes of this agreement, the following terms were used in this agreement and any Schedules to it, and shall, unless the context otherwise requires have the meanings herein ascribed:

Certificate of Analysis (CoA): A Certificate of Analysis is a document containing the name and address of the laboratory performing the test(s), name and specifications of the product(s), test(s) performed, test method(s) used, actual numerical results, approval date(s), signature of approver, and any other technical information deemed necessary for its proper use.

Certificate of Manufacture (CoM): Also referred to as a Certificate of Compliance (CoC). is a document issued by a Manufacturer or Marketing Authorization Holder to a distributor or importer that attests that a specific lot or batch of drug has been produced in accordance with its master production documents. Such certificates include a detailed summary of current batch documentation, with reference to respective dates of revision, manufacture, and packaging, and are signed and dated by the Manufacturer or Marketing Authorization Holder quality control department.

Drug Identification Number (DIN): An eight (8) digit numerical code assigned to each drug product marketed under the Canadian Food and Drugs Act and Regulations. The DIN identifies the following product characteristics: manufacturer, brand name, medicinal ingredient(s), strength of medicinal ingredient(s), pharmaceutical form, and route of product marketed under the Food and Drugs Act and Regulations.

cGMP: means the current edition of Code of Federal Regulations (FDA) and Health Canada's Health Products & Food Branch Inspectorate (HPFBI) Good Manufacturing Practices Guidelines.

Import: Means to import into USA a drug for the purpose of reprocessing and sale under the requirements of the SIP.

Manufacturer: The entity from where the Foreign Seller will source the drugs on behalf of the SIP Sponsor.

Marketing Authorization Holder (MAH): The DIN Product owner authorized to market the product in Canada.

Products: Drug products listed in Attachment I, Current Product Listing.

Package/Label: means to put a drug into its immediate container or to affix the inner or outer label of the drug under the requirement of the SIP.

QA: Quality Assurance department responsible for executing the quality systems to ensure product quality and regulatory compliance.

Record/Document Retention: An administrative program outlined in a standard operating procedure as required by regulations and by which an organization manages the retention periods of its records both paper and digital based on the guidelines provided in FDA or Health Canada regulations.

SIP & SIP Sponsor: Section 804 Importation Program. The SIP Sponsor is the entity which has applied and has been approved for the importation of DIN products.

Stability Program: This is typically a procedure which outlines the requirements to carry out the stability studies for each of the product sizes, dose forms and the various conditions to which they are exposed to. The requirements are based on the guidelines by FDA, Health Canada or other recognized entities such as ICH (The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use).

Stability Study: A stability study is an examination of a substance or product over a specified period of time to examine the effects under defined storage conditions monitoring the characteristics of this substance or product. This test essentially generates data to support the product's shelf life.

Test: Means to perform the tests, including any examinations, evaluations, and assessments, as specified in the Code of Federal Regulations of the FDA and the SIP requirements.

3PL: Third Party Logistics. (i.e. warehousing and distribution) providing services to the Foreign Seller (CA) and the SIP Sponsor.

3 CONFIDENTIALITY

CA and CG have addressed confidentiality in the separate Confidentiality Agreement. Excluded are disclosures of information necessary for regulatory authorities during inspections covered by this Agreement.

4 REGULATORY AFFAIRS INFORMATION

4.1 ESTABLISHMENT LICENSING

CA is responsible for all drug establishment licensing (DEL) requirements with Health Canada, including amendments, annual renewals for the purpose of wholesale activities.

CG is responsible for all drug establishment licensing requirements with the FDA, including amendments and annual renewals for the purpose of importation activities. This includes the necessary **drug establishment registration** for relabeling and repackaging activities, as well as any applicable **Wholesale Drug Distributor (WDD) licenses** and other state and local licenses required for distribution or importation.

5 GMP INSPECTION

CA shall notify **CG** of any regulatory inspections, including inspections that may impact products supplied to **CG**.

CG shall notify **CA** of any regulatory inspections, and their outcomes that may impact products supplied by **CA.**

On reasonable advance notice, and to the extent legally possible, **CG** and **SIP Sponsor** may audit **CA** every 2 years to ensure compliance to the SIP requirements. CG reserves the right to perform a *for cause* audit with reasonable notice.

Regulatory inspections shall take precedence over scheduled audits by either party.

6 GMP QUALITY SYSTEMS

CA shall ensure that all activities related to the SSI Labeling, storage, transportation and release of products listed in this Agreement follow Health Canada regulations for maintaining the marketing authorization (i.e. Drug Identification Numbers (DIN)) issued by Health Canada as well as the SIP requirements.

CG shall ensure that activities related to the importation and further processing of products supplied by **CA** will be in accordance with the **CG** Procedures and regulatory and SIP requirements.

CA personnel and any contractors and consultants used by **CA responsible** for wholesale activities of products shall have suitable education, training and experience.

CAs individual in charge of quality shall meet the Health Canada GMP requirements for wholesaled products.

The Delegation of Quality Responsibilities in listed in Attachment IV: *Delegation of Quality Responsibilities*.

6.1 PROCEDURES

CA shall have procedures documenting the GMP quality system that include the following (if applicable to the activity):

- Receiving, Inspecting and Disposition
- Change Control
- Product Complaints
- Recalls

- Deviations and Corrective Preventative (CAPA)
- Document Control
- Record Retention

6.2 GMP DOCUMENTATION

CA agrees to ensure a Certificate of Manufacturing and Certificate of Analysis is generated and supplied for each supplied batch when permitted by the manufacturer or MAH.

CA shall prepare and maintain quality documentation required for disposition of product supplied to **CG.**

6.3 DATA INTEGRITY

CG and **CA** are responsible to ensure that all data recorded is accurate, controlled and safe from manipulation or loss, intentional or unintentional.

If electronic records and/or electronic signatures are used by **CA** and **CG,** they shall ensure that they to comply with the applicable Good Documentation Practice by U.S. FDA and Health Canada regulations and guidance documents.

6.4 RECORD RETENTION

CA and **CG** shall ensure that they retain the documents for at least the retention time specified in their applicable record retention procedures ensuring at a minimum 6 years for documents listed in Attachment V. **Change Control**

CG shall notify **CA** regarding changes to products that may affect the Product marketing authorizations (e.g., manufacturer or MAH).

CG and CA agree to inform each other about any major changes that require a compliance, validation and/or regulatory review, that may interfere with the quality of the product.

CA shall ensure a formalized change control procedure to ensure that changes occur in a controlled and timely manner, including, but not limited to changes affecting:

- Storage requirements
- SSI Labelling
- Transportation

- Changes to packaging components.

CG shall have a formalized change control procedure to ensure that changes to importing processes/responsibilities occur in a controlled and timely manner.

6.5 SSI LABELLING

CA shall be responsible for the SSI labelling of the drug products supplied to **CG.**

CA shall ensure the drug products are labelled in accordance with GMPs and Procedural requirements.

CG undertakes to ensure that all packaging/labeling, testing and release processes shall meet the applicable cGMPs (US).

7 PRODUCT DISPOSITION

CA is responsible for the release of product for sale to **CG**, as the Importer. **CG** is responsible for the release of product for sale in the USA.

8 RETURNED PRODUCTS

CA is responsible to ensure that there is a written procedure describing the receipt, interim storage and final disposition of Products that are returned from customers

CA and their 3PL Provider are responsible to ensure that Products which have been returned from the market or are damaged at the 3PL Provider must be identified, clearly labelled and placed in an adequately segregated storage area (e.g. a secured quarantine cage) to avoid confusion with other Products and to prevent re-distribution or re-processing until a decision has been reached as to their disposition.

CG is responsible for managing product returns from the US market and is solely responsible for investigating and dispositioning the cause of the return. **CG** will ensure that returned products are not sent or returned to **CA**.

9 SECURITY AND COUNTERFEITING / THEFT

CG and CA are responsible to use their best efforts to prevent the theft or any non-authorized (re-)use of Product bearing applicable logo or brand name occurs. **CG and CA** shall take any necessary action to secure the product supply.

CA shall notify **CG** within five (5) business days in writing, after having received the appropriate information of any known incident or any suspicion of counterfeit or theft of product and shall help in any necessary investigation requested by **CG**.

10 STORAGE AND TRANSPORT CONDITIONS

CA agrees to ensure that all packaging components and finished product are received and stored under labeled storage conditions that do not interfere with the quality characteristics of the material or finished product.

CG shall ensure that products are shipped as per labeled storage conditions (i.e. temperature monitoring as required). This is to ensure that product quality is maintained and not exposed to conditions that may have an adverse effect on quality or stability of the product.

11 COMPLAINTS AND ADVERSE EVENTS

11.1 COMPLAINTS

CG shall establish a procedure that describes the communicating in writing of any product complaints for products supplied by **CA** within three (3) business days for any batches supplied to **CG**.

CA shall summarize and communicate in writing any product complaints requiring an investigation to **CG** within three (3) business days.

CG shall ensure that all product complaints are investigated for products supplied by **CA**. **CA** shall provide **CG** with a written report within thirty (30) business days after receiving complaint notification from **CG** If the final report is not available from **CA** within thirty (30) business days, an interim report will be provided to **CG** by **CA.**

11.2 ADVERSE EVENTS

CG will follow-up with FDA and the MAH or Manufacturer on adverse events and report them as required by the MAH or FDA.

12 RECALL

CA agrees to inform **CG** immediately of any decisions to recall a product supplied to **CG** or while in transit to **CG**. **CG** shall not proceed with any further processing of the recalled product unless notified by the SIP Sponsor.

CG agrees to inform **CA**, MAH or Manufacturer of any decision to recall a product supplied to **CG** within 2 working days.

Each party shall provide all supporting documentation related to the (potential) recalled product in a timely manner.

CA will support the MAH or Manufacturer's final decision whether to initiate a recall or a product withdrawal within in Canada.

It will be the responsibility of th**e CG** to contact the FDA for the product recall for all products in USA.

CG and **CA** shall mutually agree on all communications concerning the recall or product withdrawal with FDA, as applicable.

CG and **CA** shall be responsible for coordinating all the necessary activities in connection with such recall or product withdrawal.

13 DESTRUCTION AND DISPOSAL

CG shall be responsible for coordinating and documenting all the necessary activities associated with destruction and disposal of rejected, returned, recalled or damaged product in USA.

CA shall be responsible for coordinating and documenting all the necessary activities associated with destruction and disposal of rejected, returned, recalled or damaged product in Canada.

CG and **CA** will maintain al**l** destruction and disposal records and all other applicable documentation as required.

14 THIRD PARTY CONTRACTING

CA & CG shall notify **each other** if there are any changes to the 3PL Provider. **CA & CG** will maintain compliance evidence for any third-party contractors.

15 COMMUNICATION

CG and **CA** have identified key contact personnel, listed in Attachment II, *Key Contacts,* to ensure responsible individuals are fully informed and involved. Changes to key personnel or their designate shall be confirmed in writing and Attachment II, *Key Contacts* revised as necessary.

All communication shall be in writing as set forth below. To be effective, any verbal communication must be followed up in writing. Any notice or other communication shall be deemed sufficiently given if delivered by personal delivery or sent by confirmed email, acknowledged fax subsequently followed by a hard copy, or by courier or registered mail (return receipt requested), postage prepaid, addressed to:

In the case of **Contract Acceptor (CA), AdiraMedica Inc.:**

Mr. Cal Bains
2233 Argentia Rd,
Suite #302, Unit #306
Mississauga,
Ontario, L5N 2X7,
Canada

and in the case of **Contract Giver (CG), AdiraMedica LLC**.

Arvind Bhandari MS, BPharm
President and CEO

AdiraMedica LLC
77 Brant Ave, Suite 325
Clark, NJ 07066
United States

16 QUALITY AGREEMENT REVISIONS

This Agreement may be revised as new products and/or requirements are added or deleted.

Any revisions to this document, excluding the Attachment I, *Current Product Listing***,** shall be made in writing to the other party stating the reason for the revision and shall be agreed to by both parties prior to implementation of the revision.

17 TERMINATION OF QUALITY AGREEMENT

This Quality Agreement may be terminated in the event of any of the following:

- By either party for convenience by giving at least ninety (90) days prior written notice to the other party;
- With the mutual agreement of the parties. Such agreement will include a termination date, transition plan and financial considerations, if any, under the parties' separate agreements.

This Quality Agreement will also terminate automatically upon the termination or expiration of the parties' business relationship.

The terms and conditions of this Quality Agreement which by their nature or meaning survive termination of this Quality Agreement, including but not limited to provisions relating to Product Complaints, Product Returns and Product Recalls, shall so survive.

Attachments to this Agreement can be updated by agreement between **CA** and **CG**, independently of a revision of the overall Quality Agreement document.

Attachment I – Current Product Listing

Attachment II – Key Contacts.

Attachment III – Current Sub-Contracting List of Suppliers, outlines the sub-contracting partners.

Attachment IV – Delegation of Quality Responsibilities

Attachment V –- Record Retention Responsibilities

Attachment VI – Revision History, outlines the revision history of this agreement

18 CONCLUDING PROVISIONS

The agreement comes into force when signed by the contracting parties.

In witness, whereof the parties have executed this agreement on the date and year first above written.

AdiraMedica LLC, Contract Giver (CG)	
Name: Arvind Bhandari	**Position:** President and CEO
Signature: Signed by: Arvind Bhandari Signer Name: Arvind Bhandari Signing Reason: I approve this document Signing Time: 12/2/2025 | 8:33:17 PM PST 2902661CCFAE4DB499FC8A2547F21F55	**Date:** 12/2/2025 | 8:33:25 PM PST

AdiraMedica LLC, Contract Giver (CG)	
Name: Doris B. Correa	**Position:** Sr. Director, Quality Assurance
Signature: Signed by: Doris B. Correa Signer Name: Doris Correa Signing Reason: I approve this document Signing Time: 12/3/2025 | 4:47:57 AM PST D3AA79569AA6413296FEB3F2E593C263	**Date:** 12/3/2025 | 4:49:23 AM PST

Adira Medica Inc., Contract Acceptor (CA)	
Name: Cal Bains	**Position:** Director, Business & Operations
Signature: Signed by: Cal Bains Signer Name: Cal Bains Signing Reason: I have reviewed this document Signing Time: 12/2/2025 | 1:51:41 PM PST B9858B33A1674032A6CAE7A5A7D02814	**Date:** 12/2/2025 | 1:51:44 PM PST

Adira Medica Inc., Contract Acceptor (CA)	
Name: Ashwin Narotam	**Position:** Director, QA & RA
Signature: Signed by: Ashwin Narotam Signer Name: Ashwin Narotam Signing Reason: I approve this document Signing Time: 12/2/2025 | 1:53:12 PM PST 1A3733570C6D4BCA89A32289A6DAF226	**Date:** 12/2/2025 | 1:55:32 PM PST

19 ATTACHMENT I: TEMPLATE CURRENT PRODUCT LISTING

Product Name	DIN	Dose Form	Strength	Size	MAH
Biktarvy			n/a		
Eliquis			2.5		
Erleada			60		
Janumet			50-500		
Janumet			50-1000		
Januvia			25		
Januvia			50		
Januvia			100		
Odefsey			200-25-25		
Otezla			30		
Ozempic			0.68mg/mL		
Ozempic			1.34mg/mL		
Prezcobix			800-150mg		
Rinvoq			15mg		
Sprycel			100mg		
Symtuza			800-150-200-10		
Tivicay			50mg		
Trikafta			100/50/75/150mg		
Triumeq			600-50-300		
Victoza			18mg/3mL		

Approved by:	Name	Signatures/Date
AdiraMedica LLC (CG)	**Doris B. Correa**	Signed by: Doris B. Correa 12/3/2025 | 4:49:23 AM PST Signer Name: Doris Correa Signing Reason: I approve this document Signing Time: 12/3/2025 | 4:48:10 AM PST D3AA79569AA6413296FEB3F2E593C263

Approved by:	Name	Signatures/Date
AdiraMedica Inc. (CA)	**Ashwin Narotam**	Signed by: Ashwin Narotam 12/2/2025 | 1:55:32 PM PST Signer Name: Ashwin Narotam Signing Reason: I approve this document Signing Time: 12/2/2025 | 1:53:36 PM PST 1A3733570C6D4BCA89A32289A6DAF226

20 ATTACHMENT II: KEY CONTACTS

CA – AdiraMedica Inc.

Name	Position	Areas of Responsibility	E Mail address & Telephone
Cal Bain	Director	Business & Operations	Redacted
Ashwin Narotam	Director	QA & RA	Redacted

CG- AdiraMedica LLC

Name	Position	Areas of Responsibility	E Mail address & Telephone
Arvind Bhandari	President and CEO	Global	Redacted
Alexander Santos	VP, Global Clinical Trial Supply Services	Global	Redacted
Doris B. Correa	Sr, Director	Quality Assurance	Redacted

Approved by:	Name	Signatures/Date
AdiraMedica LLC (CG)	**Doris B. Correa**	Signed by: Doris B. Correa 12/3/2025 | 4:49:23 AM PST Signer Name: Doris Correa Signing Reason: I approve this document Signing Time: 12/3/2025 | 4:48:25 AM PST D3AA79569AA6413296FEB3F2E593C263
AdiraMedica Inc. (CA)	**Ashwin Narotam**	Signed by: Ashwin Narotam 12/2/2025 | 1:55:32 PM PST Signer Name: Ashwin Narotam Signing Reason: I approve this document Signing Time: 12/2/2025 | 1:53:55 PM PST 1A3733570C6D4BCA89A32289A6DAF226

21 ATTACHMENT III: CURRENT SUB-CONTRACTING LIST

Oversight	Supplier	Activity
CA	*BioScript Logistics Inc.*	Warehousing and Storage.

Approved by:	Name	Signatures/Date
AdiraMedica LLC (CG)	**Doris B. Correa**	Signed by: 12/3/2025 | 4:49:23 AM PST Doris B. Correa Signer Name: Doris Correa Signing Reason: I approve this document Signing Time: 12/3/2025 | 4:48:41 AM PST D3AA79569AA6413296FEB3F2E593C263
AdiraMedica Inc. (CA)	**Ashwin Narotam**	Signed by: 12/2/2025 | 1:55:32 PM PST Ashwin Narotam Signer Name: Ashwin Narotam Signing Reason: I approve this document Signing Time: 12/2/2025 | 1:54:18 PM PST 1A3733570C6D4BCA89A32289A6DAF226

22 ATTACHMENT IV: DELEGATION OF QUALITY RESPONSIBILITIES

a) License to Provide the Specified Service

Responsibility	Contract Giver (CG)	Contract Acceptor (CA)
Maintain relevant licences and authorisations for importation of the Product contained in this Quality Agreement.	X	X
Maintain and provide relevant GMP compliance evidence to perform the obligations specified in this Quality Agreement.	X	X
CA will ensure that the Foreign Seller registration is reviewed and updated annually and that any changes are handled within 30 calendar days.		X

b) Testing and Specifications

Responsibility	Contract Giver (CG)	Contract Acceptor (CA)
Provide Certificate of Analysis or equivalent for each Product lot if available.		X
Provide Certificate of Manufacture for each Product lot if available.		X

c) Documentation

Responsibility	Contract Giver (CG)	Contract Acceptor (CA)
Ensure that the documentation for the Product SSI labelling complies with the GMP/cGMP and other relevant requirements for documentation control.	X	X
Ensure that the documentation for the Product storage, and distribution complies with the GMP / cGMP relevant requirements for documentation control.	X	X
Ensure that all records relating to **Contract Giver (CG)** and Contract Acceptor (CA) business are appropriate, stored in a secure location and are maintained for a period of: Product expiry plus 2 years or 6 years, whichever is greater.	X	X

Responsibility	Contract Giver (CG)	Contract Acceptor (CA)
On a quarterly basis CA will initiate a written report pertaining to the SIP activities and submit to CG upon request. (1) Documentation specifying the manufacturer of each eligible prescription drug and the quantity of each lot of the eligible prescription drug(s) received by the CA from that manufacturer; (2) Documentation demonstrating that the eligible prescription drug was received by the CA from the manufacturer and subsequently picked up and shipped by the CG from CA warehouse to CG warehouse;		X
Prepare and complete SIP Pre-Import Request (Form 907A and FORM-907B) and forward to **CG**		X
CG will provide the pre-import request form electronically to FDA	X	

d) Batch Release

Responsibility	Contract Giver (CG)	Contract Acceptor (CA)
Releasing of SSI labels and drug product supplied to **CA.**		X
QA Release of the final SSI labelled products to **CG**.		X
QA Release of Products after importation to USA.	X	
QA Release: Completed, Receiving & Inspection, SSI Labelling Batch Documents, list of deviations, major changes and OOS results provided to **CA by CA's 3PL** for each lot of Product supplied		X

e) Drug Supply Chain Security

Responsibility	Contract Giver (CG)	Contract Acceptor (CA)
Quarantine the illegitimate or suspect product upon determination that a product within its possession or control or due to a request for verification by the FDA.	X	X
Inform the CG, Manufacturer or MAH on the receipt of any suspect products.		X
Inform the CG, FDA or other involved parties the outcome of investigations pertaining to illegitimate products.		X

f) Sub-Contracting

Responsibility	Contract Giver (CG)	Contract Acceptor (CA)
Ensure that both parties notify each other of any changes or addition of third-party service providers (as listed in Attachment III) are used.	X	X
Provide evidence of qualification of sub-contractors.	X	X

g) Warehousing and Transportation

Responsibility	Contract Giver (CG)	Contract Acceptor (CA)
Storage of the Product under labelled storage conditions in approved and secure location in the warehouse.	X	X
Notifications of temperature excursions upon receipt of Product.	X	X
Investigation of temperature excursions and decision on disposition of affected product without any unnecessary delay.	X	X

h) Quality Audits

Responsibility	Contract Giver (CG)	Contract Acceptor (CA)
Contract Giver (CG) may audit **Contract Acceptor (CA)**and will announce with reasonable notice, taking into consideration the reason for the audit and its potential consequences.	**X**	
Provide the audit report within the agreed timeline (i.e.,30 calendar days).	X	
Provide the audit response indicating the corrective action plan for deficiencies (if any) noted during the audit within the agreed timeline (30 calendar days).		X

i) Complaints, Recalls and Returns

Responsibility	Contract Giver (CG)	Contract Acceptor (CA)
Report quality complaints relating to the Products in writing to **CA and CG** Quality Assurance within one (1) business day.	X	X

Responsibility	Contract Giver (CG)	Contract Acceptor (CA)
Ensure customer/patient can send any available complaint sample to CG QA representative and forwarded to **Contract Acceptor (CA)**, if applicable.	X	
Conduct investigation of product quality complaints relating to the Products and communication of the outcome to **CA** within 30 calendar days from date of receipt.	X	
Return of product quality complaints to CA.	X	
Investigate complaints and returns, provide report to CG within 30 calendar days of receipt		X
Injectables returned will not be restocked for resale.	X	X
Notification of recalls and market withdrawals relating to the Products.	X	X
Recalls and market withdrawals relating to the Products are to be concluded within the timeframes provided by the market authorization holder.	X	X

j) Regulatory Requirements

Responsibility	Contract Giver (CG)	Contract Acceptor (CA)
Notification of changes which impacts product registration or licences to the regulatory authority as applicable.	X	X
Provide information to support regulatory submissions, as required.		X
Communication of regulatory authority approval/outcome.	X	X
Follow up and action conditions of approval.		X
Compliance with conditions of registration at all times.	X	X

k) Deviation Management

Responsibility	Contract Giver (CG)	Contract Acceptor (CA)
Have established written procedures for planned and unplanned deviations.	X	X

l) Change Control

Responsibility	Contract Giver (CG)	Contract Acceptor (CA)
Have established written procedures for Change control.	X	X

Approved by:	Name	Signatures/Date
AdiraMedica LLC (CG)	**Doris B. Correa**	Signed by: 12/3/2025 | 4:49:23 AM PST Doris B. Correa Signer Name: Doris Correa Signing Reason: I approve this document Signing Time: 12/3/2025 | 4:48:53 AM PST D3AA79569AA6413296FEB3F2E593C263
AdiraMedica Inc. (CA)	**Ashwin Narotam**	Signed by: 12/2/2025 | 1:55:32 PM PST Ashwin Narotam Signer Name: Ashwin Narotam Signing Reason: I approve this document Signing Time: 12/2/2025 | 1:54:39 PM PST 1A3733570C6D4BCA89A32289A6DAF226

23 ATTACHMENT V: RECORD RETENTION RESPONSIBILITIES

The following outlines the documents to be retained by each party. The length of time for retention is according to the internal Retention procedures of each party or at a minimum of 6 years as per Section 804 Importation Program requirements.

Responsibility	Contract Giver (CG)	Contract Acceptor (CA)
	Provide and Approve	Review and maintain on file
Product Release • Executed Batch Records • Associated Deviations, Investigations, CAPA, • CofC, CofA, CofM	X	X
Complaints • Investigations and follow-up	X	X
Deviations • Deviation Report including root cause, risk assessment and complete investigation	X	X
Recalls • Recall Records and associated Investigations, Risk Assessment • Inventory Records	X	X
Change Controls • Change Control Records and supporting documentation	X	X
GMP Compliance Evidence • Regulatory Agency Inspection Report • Corrective Actions • Supporting SOPs • Quality Agreements	X	X

Approved by:	Name	Signatures/Date
AdiraMedica LLC (CG)	**Doris B. Correa**	Signed by: Doris B. Correa 12/3/2025 | 4:49:23 AM PST Signer Name: Doris Correa Signing Reason: I approve this document Signing Time: 12/3/2025 | 4:49:05 AM PST D3AA79569AA6413296FEB3F2E593C263
AdiraMedica Inc. (CA)	**Ashwin Narotam**	Signed by: Ashwin Narotam 12/2/2025 | 1:55:32 PM PST Signer Name: Ashwin Narotam Signing Reason: I approve this document Signing Time: 12/2/2025 | 1:54:56 PM PST 1A3733570C6D4BCA89A32289A6DAF226

24 ATTACHMENT VI: REVISION HISTORY

Revision Number	Date Prepared	Reason for Change
0	1***2/02/2025***	New QA agreement.

MASTER SERVICE AGREEMENT

THIS MASTER SERVICE AGREEMENT ("Agreement") is made and entered into this 2nd day of December, 2025, (the, "Effective Date") by and between **DENVER HEALTH AND HOSPITAL AUTHORITY**, a body corporate and political subdivision of the State of Colorado, with offices located at 601 Broadway, Denver, Colorado 80204 ("DHHA"), on behalf of its division, **Rocky Mountain Poison & Drug Safety**, with a mailing address of 777 Bannock Street, Mail Code 0180, Denver, Colorado 80204 ("RMPDS") and; collectively known herein as (the "Provider") and **ADIRAMEDICA LLC,** having a place of business at 77 Brant Ave. Suite #325, Clark, NJ 07066 ("Company"). Each may be referred to as a "Party" and collectively the "Parties".

RECITALS:

WHEREAS, Provider provides contact center services, and other related services, including but not limited to medical information, safety reporting (adverse events and product quality complaints), clinical trials support, technical support and administrative support, medical writing, and pharmacovigilance and safety surveillance services (the, "Services"); and

WHEREAS, Provider has expert staff including nurses, pharmacists, physicians, scientists, and other non-medical program specialists (the, "Contact Center Providers") who provide both emergent and non-emergent services in a professional manner and Provider will use its best efforts to ensure that the individuals providing Services exercise their best judgment in performing the Services; and

WHEREAS, Company desires to receive Services from the Provider; and

WHEREAS Provider, desires to provide Company with these Services as described in this Agreement.

NOW, THEREFORE, in consideration of the mutual agreements hereinafter contained and subject to the terms and conditions herein stated, the parties agree as follows:

ARTICLE I
SERVICES, WORK ORDERS & CHANGE ORDERS

1.1 Services**.** Provider hereby agrees to provide to Company the Services identified and described in the Services section of each Work Order, as further defined below.

Provider shall perform the Services set forth in the applicable Work Order in compliance with (i) the provisions of this Agreement; and (ii) pursuant to the terms and conditions of the Work Order; and (iii) in accordance with Provider's policies and standard operating procedures mutually agreed upon by the Parties; and (iv) pursuant to the applicable federal, state and local laws, statutes, ordinances, guidelines and regulations, including but not limited to, the Federal Food, Drug and Cosmetic Act as amended, and the regulations of the United States Food and Drug Administration (the "FDA"), and ICH Good Clinical Practices (the, "Applicable Law"); and (v) Services shall be performed with due diligence and in a good and workmanlike manner in accordance with recognized industry standards. Each Work Order shall also be conducted in accordance with Applicable Law and applicable medical privacy laws and regulations including those pertaining to the protection of personal and protected health information.

1.2 Work Order. If the Parties reach an agreement to add new Services, Provider and Company shall execute a Work Order evidencing such Services. Each Work Order shall set forth in detail the responsibilities and obligations of the Parties, the fees and payment schedule, and as applicable, any deliverables, with respect to the Services to be provided by Provider. The Work Order, along with any applicable quality agreement, attachments, and exhibits, and this Agreement shall constitute the entire agreement for the Services. To the extent any terms set forth in a Work Order, unless otherwise stated, conflict with the terms set forth in this Agreement, the terms of the Work Order shall govern.

1.3 Change Orders. If Company requests any change to the Services for a particular Work Order that the Parties mutually agree upon and are not specifically provided for in the applicable Work Order, including without limitation, any change to the related protocol, it shall notify Provider in writing of such requested change.

Provider shall prepare an amendment to reflect the agreed upon change(s) to the Work Order, to include but not limited to, an estimate of any resulting adjustment to the timeline for the

performance of the Services under the amended Work Order and to the payment schedule (whether an increase, decrease or no effect). After an amendment change to the Work Order is fully executed, such action shall constitute an amendment to the applicable Work Order and the Services therein.

ARTICLE II
DATA COLLECTION AND REPORTING

2.1 Services will be conducted and reported to Company in a manner and time frame as mutually agreed upon by the Parties.

2.2 Case information will be entered into Provider's data base as outlined in applicable Standard Operating Procedure ("SOP"). Case information and any source documents will be forwarded to Company in a manner and frequency as mutually agreed upon by the Parties and as further detailed in the subsequent Work Order.

ARTICLE III
OBLIGATIONS OF COMPANY

3.1 Company must provide:

(i) Current list of Company product(s). The product list should be organized, if applicable, alphabetically by Company's divisions or product groupings.

(ii) Company shall provide updates to the product list as required.

(iii) Company shall ensure Provider has current Company contact information, to include: names, addresses, phone numbers, email addresses for telecommunications, technology, finance, operations, and other appropriate individuals.

(iv) As applicable, Company shall provide Provider with appropriate software licenses and access to Company databases, systems, and information necessary to provide Services.

ARTICLE IV
OBLIGATIONS OF PROVIDER

4.1 Provider must provide:

(i) Qualified staff to provide the Services to the Company pursuant to this Agreement.

(ii) Provider shall identify, develop, and maintain appropriate SOPs, SOW's, and other control documentation as applicable, regarding the Services under the Work Order. All SOPs will be reviewed and approved by Company prior to dissemination for training.

(iii) Provider will deliver operational performance metrics as mutually agreed upon by the Parties. Ad hoc or custom reports are available at an additional cost upon the request of Company and mutual agreement of the Parties.

(iv) Provider shall ensure Company has current Provider contact information, to include: names, addresses, phone numbers, email addresses for telecommunications, technology, and other appropriate individuals.

ARTICLE V
CONFIDENTIALITY

5.1 Definition. As used in this Agreement, the term "Confidential Information" means (a) either Party's technical, marketing, product, business affairs information, including, without limitation, customers, prospects, pricing, clinical or other research, patent applications, regulatory data or plans, clinical data or plans, products, product plans, product candidates, markets, inventions, manufacturing processes, compounds, formulas and formulations, technology, designs, forecasts, market research, litigation matters, strategies, vendor agreements, equipment, finance or capitalization, and other proprietary and trade secret information, whether oral, graphic, written, electronic, or in machine readable form, and (b) all data, record formats, computer programs (and source code therefor), proposals, plans, programs, analysis, compilations, forecasts, studies, agreements or other documents prepared by a Party, or by the Parties jointly, related to any subject matter in this Agreement, including, without limitation, the terms of this Agreement.

5.2 Limitations. The term "Confidential Information" shall not include any information that: (i) is or becomes known or publicly available through no fault of the "Receiving Party"; (ii) is known by the Receiving Party at the time of disclosure, not subject to restriction; (iii) is independently developed by the Receiving Party without use of, reference to or reliance on the "Disclosing Party's" Confidential Information; or (iv) is lawfully obtained from a third party who has the right to make such disclosure.

5.3 Third-Party. Except as specifically permitted in this Agreement, neither Party will use or disclose Confidential Information of the other to any third party, except for the purpose described herein and only to those persons within the Disclosing Party and the Receiving Party

and their necessary consultants, subcontractors, agents, and affiliates with a need to know. The Receiving Party agrees that if it receives a subpoena or other government process that purports to require the production of any of the Confidential Information for use in an action or proceeding, the Receiving Party: (1) shall promptly inform the other Party or entity issuing such subpoena or other government process of the existence of this Agreement; (2) shall promptly inform the Disclosing Party of the receipt of such subpoena or other government process; and (3) shall not oppose any effort by the Disclosing Party to seek a protective order or to quash any such subpoena or other government process. If the Disclosing Party fails to intervene to seek a protective order or to quash said subpoena or other government process after being given notice and a reasonable opportunity to do so, or if such motion is denied by a court of competent jurisdiction, the Confidential Information may be produced, notwithstanding anything in this Agreement to the contrary. If any Confidential Information is ordered produced in an action or proceeding, it shall not lose its confidential status through such use, and the Receiving Party shall take all reasonable and necessary steps to protect its confidentiality during such use, to the extent possible.

5.4 Intellectual Property. If the Disclosing Party's intellectual property is or is threatened to be disclosed, the Disclosing Party will be entitled, if it so elects and without limitation of any other available remedy, to seek injunctive relief in any court of competent jurisdiction to enjoin or restrain such disclosure.

5.5 Ownership of Materials. Each Receiving Party agrees that all Confidential Information received is and will remain the property of the Disclosing Party and that such shall not be copied or reproduced without the express permission of the Disclosing Party, except for such copies as may be reasonably necessary to accomplish the purpose of this Agreement. Upon written request of the Disclosing Party, the Receiving Party shall immediately discontinue all use of all Confidential Information of the Disclosing Party, and shall, at the Disclosing Party's option, either destroy or return to the Disclosing Party all hard copies in its possession of such Confidential Information and any derivatives thereof (including all hard copies of any translation, modification, compilation, abridgement or other form in which the Confidential Information has been recast, transformed or adapted), and to delete all online electronic copies thereof; provided, however, that the Receiving Party may retain one (1) archival copy of the Confidential Information, which shall be used only in case of a dispute concerning this Agreement. Notwithstanding the foregoing, neither Party shall be required to destroy or alter any computer-based back-up files generated in

the normal course of its business, provided that such files are maintained confidential in accordance with the terms of this Agreement.

5.6 The Receiving Party agrees that it will maintain in confidence all Confidential Information. The Receiving Party shall take necessary and reasonable precautions to prevent such information from being disclosed to any unauthorized person, firm, or company. Upon disclosing Confidential Information to its officers and employees, necessary consultants, subcontractors, affiliates or agents, the Receiving Party shall advise same of the confidential nature thereof and shall take necessary and reasonable precautions to prevent the unauthorized disclosure of such information by such parties. The terms and obligations of this section shall survive the termination of this Agreement.

ARTICLE VI
TERM AND TERMINATION

6.1 Term. The term of this Agreement shall commence on the aforementioned Effective Date and shall continue in full force and effect for three (3) years (the, "Initial Term") and shall automatically renew for a successive term of three (3) years (the, "Renewal Term) until either Party elects not to renew, or terminates this Agreement and provides to the other Party a written notice of nonrenewal (the, "Termination Notice") ninety (90) days prior to the date of the expiration date of the then current term (the, "Termination"). If this Agreement is terminated, any and all Work Orders pursuant and subsequent to this Agreement shall also terminate at the Termination of this Agreement.

6.2 Termination. Unless otherwise specified in the applicable Work Order, this Agreement and/or any Work Order may be terminated: (i) by either Party at any time if one Party commits a material breach of its obligations hereunder (including Work Orders, amendments, attachments and exhibits), and the breaching Party fails to cure such breach within thirty (30) days of receipt of written notice of the alleged breach; or (ii) immediately by Provider in the event of a disclosure of any Confidential Information directly or indirectly to a third party other than as permitted by this Agreement or the applicable Work Order; or (iii) as additionally permitted in the applicable Work Order. Expiration or termination of any Work Order pursuant to this Section shall constitute the expiration or the termination of such Work Order only and shall not affect this

Agreement or any other Work Order under this Agreement. In the event of termination, Company shall pay Provider for Services performed through the termination date.

6.3 Wind Down. Upon the Notice of Termination or Termination of this Agreement, Provider shall cooperate with Company to provide for an orderly wind-down of all Services provided by Provider hereunder. In the case of termination of a Work Order, Provider shall cooperate with Company to provide for an orderly wind-down of all Services provided by Provider under such Work Order.

ARTICLE VII
PAYMENT OF SERVICES AND PASS-THROUGH COSTS

7.1 Charges for Services. Company shall pay Provider for all Services performed under this Agreement in accordance with the rates for Services and the payment schedule set forth in the applicable Work Order. Company shall also reimburse Provider for all out-of-pocket expenses incurred by Provider that are mutually agreed upon by the Parties and are incurred in connection with the performance of the Services (the, "Pass Through Costs").

Except as otherwise expressly provided in a Work Order, Provider shall submit to Company for each Work Order a monthly invoice describing in detail the charges for the Services and all Pass-Through Costs paid by Provider during the "Invoice Period".

7.2 Payments Company shall pay each monthly invoice within thirty (30) days of receipt thereof, unless otherwise specified in the applicable Work Order. Each payment shall reference the Provider's invoice number for which the Company is remitting payment. Payments received by Provider that do not reference Provider's invoice number shall be applied to any past due amounts in the order of the invoice date. All payments must be made payable to Denver Health and Hospital Authority, RMPDS and remitted to the following address:

Denver Health and Hospital Authority, RMPDS
P.O. Box 17093
Denver, Colorado
80217-0093
Tax ID# 84-1343242

7.3 Late Payment. If Company fails to timely pay any amount due pursuant to this Agreement and in accordance with the applicable Work Order within the Invoice Period other than those amounts that are the subject of a good faith dispute by Company, Company shall also pay a

late fee equal to one and one half percent (1.5%) per month (18% per annum) or the maximum charge permitted by applicable law, whichever is less, and all reasonable costs of collection, including, without limitation, reasonable attorneys' fees.

ARTICLE VIII
WARRANTIES, REPRESENTATIONS AND LIMITATIONS OF LIABILITY

8.1 No Inconsistent Obligations or Constraints upon Provider. Provider represents and warrants that it is qualified and permitted to enter into this Agreement and that the terms of this Agreement are not inconsistent with its other contractual arrangements. Provider warrants that it is not constrained by any existing agreement in providing the Services to be performed under this Agreement.

8.2 No Impairment; No Conflict. During the term of this Agreement, Provider warrants that it will not enter into any agreement to provide services that would in any way materially impair its ability to complete the Services in a timely fashion.

8.3 Disclaimer of Warranties. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER COMPANY NOR PROVIDER MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED, INCLUDING ANY EXPRESSED OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

8.4 Limitations of Liability. Each party hereto agrees to be responsible and assume liability for its own negligent or wrongful acts or omissions or those of its officers, employees or agents arising out of this Agreement to the full extent allowed by law and adjudicated by a court of competent jurisdiction; and in no event shall either Party be liable to the other Party for any indirect, incidental, special, or consequential damages, including, but not limited to, lost profits, or revenue, lost savings, loss of use of the licensed products, business interruption, or cost of substituted facilities, equipment, or services, whether or not such Party has been advised of the possibility of such damages, and whether any claim for recovery is based on theories of contract, negligence, or tort (including strict liability).

8.5 The Parties acknowledge that Provider is covered and self-insured under the *Colorado Governmental Immunity Act (CGIA) § 24-10-101, C.R.S. et seq.,* as applicable now or hereafter amended.

Notwithstanding any other provisions to the contrary, no term or condition of this contract shall be construed or interpreted as a waiver, express or implied, of any of the immunities, rights, benefits, protection or other provisions of the *Colorado Governmental immunity Act, CRS § 24-10-101 et. seq.*, as now or hereafter amended. The parties understand that liability for claims is controlled and limited by the provisions of *Colorado Governmental immunity Act, CRS §24-10-101 et. seq.*, as now or hereafter amended.

8.6 Company Liability - International Calls. With regard, and as applicable, to contacts which originate outside the United States, Company agrees to be responsible for and assume all liability for all such contacts and shall defend, indemnify and hold harmless Provider, its employees, officers, directors and agents from and against any and all claims, demands, causes of actions, proceedings, damages, losses and expenses resulting from Services provided as a result of any such call (collectively, the "Claims"), provided that such assumption of liability or indemnification shall not extend to Claims resulting directly or indirectly from the negligence, willful misconduct or fraud of, or from a breach of this Agreement committed by Provider. This indemnification shall survive the termination of this Agreement.

ARTICLE IX
DEBARMENT

9.1 Provider represents to the best of its knowledge that none of its directors, officers or employees providing services under this Agreement is a person debarred under *Code of Federal Regulations, Title 21, 1.284, Volume I Food and Drugs, Ch. I Food and Drug Administration Department of Health and Human Services, Subchapter A, Subpart A-C § 11.1-11.300, (Revised as of April 1, 2019)*. Provider further agrees to notify Company immediately should any of its directors, officers or employees providing services under this Agreement become a debarred person during the term of this Agreement.

ARTICLE X
INTELLECTUAL PROPERTY

10.1 No License. Neither the operation of this Agreement, nor the delivery of any information to a Party hereto, shall be deemed to grant the receiving Party any right or license under any copyright, trademark right, patent right or any other proprietary right or to any know-how, technology or inventions of the disclosing Party, except as specifically provided herein.

10.2 Company Property. Provider will promptly disclose to Company all improvements, inventions, formulae, on behalf of its employees, agents or subcontractors, solely or jointly with Company, as a result of the performance of the Services under this Agreement that relates to the product that is the subject of any Work Order, is made using or incorporates Company's Confidential Information, or directly results from Provider's provision of the Services.

10.3 Provider Property. Company acknowledges that Provider may possess certain inventions, processes, technology, know-how, trade secrets, improvements, other intellectual property and other assets, including, without limitation, those related to data collection processes, data management processes, analytical methods, procedures and techniques, computer technical expertise and software (including codes) which have been independently developed by or for the Provider prior to the Effective Date without the benefit of, or access to, any information or materials provided by Company and do not relate to the composition of matter, method of using or method of administering any product that is the subject of a Work Order (collectively, the "Provider Property"). All Provider Property and improvements thereto, which are not specific to any Work Order, are the sole and exclusive property of Provider, and Company shall have no right, title, or interest therein.

Notwithstanding anything to the contrary, if applicable, Provider shall be the owner of any written materials produced pursuant to this Agreement and shall therefore also hold and/or own any copyright, trademark, registration, or other legal rights that may be obtained regarding, or associated with, such materials.

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ARTICLE XI
INDEMNIFICATION

11.1 Company will defend, indemnify and hold harmless the Provider and its employees, officers, directors and agents from and against any and all claims, demands, causes of actions, proceedings, damages, losses and expenses resulting from the negligent or willful acts or omissions

of the Company, including the Company's employees, officers and agents. Company need not indemnify or hold the Provider harmless for damages or claims caused by sole negligence of the Provider or the Provider's employees or officers. This indemnification shall survive the termination of this Agreement. Provider cannot and by this Agreement does not agree to indemnify, hold harmless, exonerate, or assume the defense of Company or any other person or entity whatsoever, for any purpose whatsoever.

ARTICLE XII
PUBLICATION

12.1 Provider may not publish any articles or make any presentations relating to the Services provided to Company with respect to this Agreement or any Work Order, or referring to data, information or materials generated as part of the Services without the prior written consent of Company.

ARTICLE XIII
INSURANCE

13.1 Insurance. Each Party shall maintain, for the duration of this Agreement, insurance in an amount that is commercially reasonable to cover its obligations hereunder and, upon request, each Party will provide to the other Party a certificate of insurance showing that such insurance is in effect.

ARTICLE XIV
HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 (HIPPA)

14.1 Provider may receive or create from or on behalf of the Company, certain health or medical information Protected Health Information or "PHI" in connection with the performance of Services under this Agreement. Use or disclosure of PHI is subject to protection under state and federal law, including the *Health Insurance Portability and Accountability Act of 1996 and its corresponding privacy regulations (the "Privacy Rule"), as amended from time to time, as codified at 45 C.F.R. Parts 160 and 164* (the "Identifiable Data") and regulations promulgated thereunder by the U.S. Department of Health and Human Services ("Regulations").

14.2 As applicable, Provider shall (i) not use or further disclose information other than as permitted or required by this Agreement; (ii) not use or further disclose information in a manner that would violate the requirements of the HIPAA regulations; (iii) use appropriate safeguards to prevent use or disclosure other than as provided in the Agreement; (iv) report to the Company any use or disclosure not provided by this Agreement; (v) ensure that any subcontractors and agents to which Provider may provide PHI agree to the same restrictions and conditions as apply to Provider; (vi) make appropriate health information available upon individual request as appropriate; (vii) make its practices, book and records relating to the use and disclosure of PHI available to the U.S. Department of Health and Human Services; (viii) if feasible, return or destroy all PHI at the termination of the Agreement; and (ix) authorize Company to terminate this Agreement if Provider has violated a material term.

ARTICLE XV
RECORDS STORAGE

15.1 Record Maintenance. During the term of this Agreement, Provider shall maintain all materials and all other data obtained or generated by Provider in the course of providing the Services hereunder, including all computerized records and files as may be required by this Agreement and all Applicable Law. Provider shall cooperate with any reasonable internal review or audit by Company and promptly make available (at Provider's facilities, wherever Services are performed, or other mutually acceptable locations) to Company, the FDA or other regulatory agencies, for examination and duplication, during normal business hours and at mutually agreeable times, all documentation, data and information relating to this Agreement or subsequent Work Order(s). Provider shall maintain all materials and all other data obtained, generated, or collected by Provider in the course of providing the Services, including all computerized records and files, in a secure area, reasonably protected from fire, theft and destruction. Provider agrees to take reasonable steps that are requested by Company as a result of an audit to cure deficiencies in all documentation related to the Services. Audits conducted under this Article 15 shall be at the expense of Company.

15.2 Record Maintenance after Expiration or Termination. Upon the termination of this Agreement, all materials and all other data and information obtained or generated by Provider and its employees, officers, directors and agents in the course of providing the Services hereunder (the "Records") shall, at Company's option and unless stated otherwise in the applicable Work Order,

be (i) delivered to Company at its expense and risk to its offices identified herein in such form as is then currently in the possession of Provider, (ii) retained by Provider for Company for a period of three (3) years, or (iii) disposed of at Company' expense, as directed by written request of Company, unless the Records are otherwise required to be stored or maintained by Provider under Applicable Law. If Provider is required or requested to maintain and/or store the Records for a period beyond three (3) years after the termination or expiration of this Agreement, Company shall reimburse Provider for its maintenance and storage costs, which shall be no more than a commercially reasonable cost. In no event shall Provider dispose of Records without first giving Company sixty (60) days' prior written notice of its intent to dispose of the Records. Provider shall be entitled at its expense to retain copies of the Records reasonably necessary for regulatory purposes or to demonstrate the satisfaction of its obligations hereunder, all subject to the confidentiality obligations set forth in Article 5 above.

ARTICLE XVI
INSPECTIONS / AUDITS

16.1 Provider agrees to maintain financial records and other records documenting the Services provided under this Agreement. Provider also agrees to allow reasonable access to those records by the Company. Company may upon written request and mutual agreement of the Parties, conduct periodic audits of Provider to ensure compliance with the terms and conditions of this Agreement and subsequent Work Order(s).

16.2 Audits will be conducted per an agreed-upon Audit Standard Operating Procedure and audit agenda with a closing audit meeting conducted following completion of the audit by both the auditor and Provider to review any findings. In order for Provider to continue to improve Services, Company shall provide a copy of the final audit report to Provider.

16.3 Should Company opt to use a third-party auditor or contracted consultant to conduct an audit or review, Provider reserves the right to approve all third-party auditors or contracted consultants in advance to determine if any conflicts of interest exist and to secure a signed confidentiality non-disclosure agreement between Provider and the third-party auditor or contracted consultant.

16.4 At least ten (10) days prior to the audit, Company will provide Provider with the name, contact information and business information and/or website for the third-party auditor or

contracted consultant and a signed authorization that will allow Provider to disclose to this individual, Company's information relative to the Agreement. If Provider identifies a conflict of interest with the proposed third-party auditor or contracted consultant, Provider reserves the right to notify the Company and deny access to its files and systems by the third-party auditor or contracted consultant. Company and Provider will work together to agree upon an alternative third-party auditor or contracted consultant.

16.5 Company will be responsible for payment of the cost of any audit or subpoena, requiring information from Provider that is directly related to the Services to be provided hereunder. Provider staff and management time directly related to the audit or subpoena will be invoiced to the Company based on the hourly rates of the personnel involved in the audit or subpoena including pre and post audit or subpoena activity. The terms and provisions of this Article 16 shall survive the Termination or expiration of this Agreement.

ARTICLE XVII
EXAMINATION OF RECORDS

17.1 Company shall have the right at any time to review and inspect all such records, as referred to herein, maintained by Company. Company shall keep and maintain all such records for a period of at least three (3) years after the Termination of this Agreement.

ARTICLE XVIII
ANTI-KICKBACK

18.1 Provider and Company each agrees that the fees to be paid by Company to Provider hereunder reflects the fair market value for the Services and has been negotiated at arm's length and has not been determined in a manner which considers the volume or value of any referrals or other business otherwise generated between the Parties for which payment may be made in whole or in part. Provider is being compensated solely for the performance of the Services described in this Agreement, and nothing in this Agreement is intended, or should be construed as, a reward for past or an incentive for future decisions regarding the prescription, use, purchase or recommendation of Company's products or services. Company expects Provider and its employees, agents, and contractors to exercise their best and independent professional judgment regarding the care and treatment of individual patients.

ARTICLE XIX
GENERAL

19.1 Relationship of Parties. The Parties expressly acknowledge and agree that each Party's legal relationship to the other under this Agreement is as an independent contractor. Nothing in this Agreement shall be construed to place the Parties in the relations of partners or joint venturers, and neither Party shall have the power to obligate or bind the other in any manner whatsoever, except as specifically provided for herein.

19.2 Conflict of Interest. The Parties agree that no employee of Provider shall have any personal or beneficial interest whatsoever in the Services or property described herein during the Term of this Agreement. Company agrees not to directly solicit for hire or directly contract the services of any employee or officer of Provider without first obtaining prior written consent from the Provider.

19.3 No Waiver of Rights. No assent expressed or implied, to any breach of any one or more covenants, provisions, or conditions of the Agreement shall be construed as a waiver of any succeeding or other breach.

19.4 No Third-Party Beneficiaries. It is expressly understood and agreed that enforcement of the terms and conditions of this Agreement, and all rights of action relating to such enforcement shall be strictly reserved to the Parties and nothing contained in this Agreement shall give or allow any such claim or right of action by any other entity or third person. It is the express intention of the Parties that any person other than a Party to this Agreement receiving services or benefits under this Agreement shall be an incidental beneficiary only.

19.5 Assignment and Subcontracting. Company and Provider each agree not to assign, pledge, transfer, or subcontract their duties and rights in this Agreement, in whole or in part without first obtaining the prior written consent of the other Party. Any attempt by Company or Provider to assign, transfer, or subcontract their rights hereunder without such prior written consent shall, at the option of the non-assigning Party, terminate this Agreement and all rights of the assigning Party. Such prior written consent may be granted or denied at the sole and absolute discretion the Party whose consent is sought.

19.6 No Discrimination in Employment. In connection with the performance or work under this Agreement, each Party agrees to comply with laws applicable to hiring, discharge, promoting, demoting and discrimination in matters of compensation relating to any person otherwise qualified, solely because of race, color, religion, national origin, gender, gender identity or expression, age, military status, sexual orientation, marital status, or physical or mental disability.

19.7 General Data Protection Regulation and The California Consumer Privacy Act.

Each Party shall, and as applicable to either Party: (a) at its own costs, take all necessary measures to be compliant with the provisions of the *Regulation (EU) 2016/679 (General Data Protection Regulation) in the current version of the OJ L 119, 04.05.2016; cor. OJ L 127, 23.5.2018, GDPR* and *Title 1.81.5, The California Consumer Privacy Act of 2018, CCPA;* and (b) each Party is to be regarded as an independent data controller or data processor within the meaning of the GDPR and CCPA when it processes personal data for its own purposes in the field of its activities. This applies to the exchange of personal data from one Party to the other Party in the performance of this Agreement.

Each Party acknowledges the importance of complying with the GDPR and CCPA and each Party represents it has: (i) carefully assessed whether and to what extent the provisions of the GDPR and CCPA apply to its operations; and (ii) each Party has taken all necessary steps to comply with the provisions of the GDPR and CCPA where required.

In any event, national and international laws which are applicable under the GDPR and CCPA shall apply to this Agreement and each Party agrees to remain compliant with such laws.

19.8 Publicity. Each Party shall keep the terms of this Agreement confidential, provided that either Party may disclose the terms of this Agreement to the extent required by applicable law or any government regulatory agency or with the prior written consent of the other Party. Neither Party may issue a press release or otherwise make a public announcement upon execution of the Agreement stating the general nature of the relationship between the Parties and the assignment and transfers provided for herein, without the prior written consent of the other Party.

19.9 Severability. In the event any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction to be invalid, void or unenforceable, the remainder of the terms, provisions, covenants or restrictions of this Agreement shall remain in full

force and effect and shall in no way be affected, impaired or invalidated, and to the extent possible, the term, provision, covenant or restriction held to be invalid, void or unenforceable shall be amended or revised so as to make it valid and enforceable and give effect to the original intent of the Parties.

19.10 Notices. All notices, requests, claims, demands and other communications hereunder shall be in writing and shall be delivered to the respective Party as follows:

If to Provider:

Denver Health and Hospital Authority
Office of General Counsel
777 Bannock Street, M.C. 1919
Denver, Colorado 80204
Fax: 303-436-5073

With a copy to:

Rocky Mountain Poison & Drug Safety
777 Bannock Street, Mail Code 0180
Denver, Colorado 80204
Attn: Contracts Manager
Fax: 303-739-1446

If to Company:

AdiraMedica LLC
77 Brant Ave., Suite #325
Clark, NJ 07066
Attn: ___Arvind S Bhandari_____

Said notice shall be delivered personally during normal business hours to the appropriate office, above, or by prepaid U.S. mail or other commercial mail service. Mailed notice shall be deemed effective three (3) days after deposit with the U.S. Postal Service or other commercial carrier with a tracking mechanism. The Parties may from time-to-time designate substitute addresses or persons where and to whom such notices are to be mailed or delivered but such substitutions shall not be effective until actual receipt of written notification.

19.11 Force Majeure. If any Party to this Agreement is rendered unable, wholly or in part, by an event of force majeure or any other cause not reasonably within its control, to perform

or comply with any material obligation or condition of this Agreement, such Party shall, upon giving notice and reasonably full particulars to the other Party, be relieved of such obligation or condition during the continuance of such inability. The term "force majeure" shall include acts of God, pandemics, the elements, fire, accidents, breakdowns, strikes and any other industrial, civil or public disturbance, inability to obtain or maintain telephonic communications because of power failure or failure by the telephone company, inability to obtain materials, supplies, permits or labor, and any laws, orders, rules, regulations, acts or restraints of any government or governmental body or authority, civil or military.

19.12 Non-Solicitation. During the term of this Agreement and for one (1) year thereafter, the Company shall not knowingly solicit or recruit for employment or hire any of Provider's employees. To "knowingly" solicit, recruit or hire within the meaning of this provision does not include, and therefore does not prohibit, solicitation, recruitment or hiring of a Provider employee by Company if the Provider employee was identified by Company solely because of the Provider employee's response to a general advertisement placed in the public domain.

19.13 Governing Law. This Agreement shall be construed and enforced in accordance with the laws of the State of Colorado, without regard to the choice of law thereof. Venue for any action arising hereunder shall lie in a court of competent jurisdiction in Denver, Colorado. This provision shall survive the termination of this Agreement.

19.14 Successors in Interest. This Agreement and the rights, interest and obligations hereunder shall be binding upon, inure to the benefit of, and be enforceable by the Parties and their respective successors and permitted assigns.

19.15 Dispute Resolution/Non-Binding Mediation. The Parties shall endeavor to resolve any dispute or claim arising out of or relating to this Agreement or to a breach, termination, or validity of this Agreement as follows: the Executive Officers or their designees, of each Party will meet to attempt to resolve such dispute by good faith negotiations. If the Executive Officers cannot resolve the dispute within thirty (30) days after a Party requests such a meeting, then each Party will attempt in good faith to settle the dispute by mediation pursuant to this Section. The mediation of any dispute is to be administered by The Mediation Association of Colorado, JAMS or such other mediator as may be mutually agreed to by the Parties. The Parties shall share the direct costs

of the mediator equally, but each Party shall be responsible for its own costs and expenses, including attorneys' fees, if any, relating to its participation in mediation. If mediation is unsuccessful within thirty (30) days after the Parties complete the mediation process pursuant to this Section, the Parties may then have recourse to the state and federal courts located within the State of Colorado.

19.16 Agreement as Complete Integration – Amendments. This Agreement contains the entire understanding between the Parties with respect to the subject matter and supersedes all prior and contemporaneous agreements, negotiations, correspondence, undertakings, and understandings, oral or written, relating to such subject matter. No amendment to or modification of this Agreement shall be effective unless it shall be in writing and signed by both Parties. No Party may waive any term, provision, covenant, or restriction of this Agreement except by duly signed writing referring to the specific provision to be waived.

19.17 Paragraph Headings. The captions set forth are for convenience of reference only and shall not be construed to define or limit the terms and provisions hereof.

19.18 Legal Authority. The Parties assure and guarantee that each of them possesses the legal authority, pursuant to any proper, appropriate, and official motion, resolution or action passed or taken, to enter into this Agreement. Additionally, the Parties assure and guarantee that the person or persons signing and executing this Agreement on behalf of such Party, has been fully authorized to execute this Agreement on its behalf and to bind the Party validly and legally to all terms, performance and provisions herein.

19.19 Execution of Agreement. This Agreement is expressly subject to and shall not become effective or binding on any Party hereto until it has been fully executed by all Parties.

19.20 Counterparts of Agreement. This Agreement may be executed in multiple, identical counterparts, each of which shall be deemed to be an original, and all of which, taken together, shall constitute one and the same instrument. Signatures to this Agreement transmitted by facsimile transmission, by electronic mail in "portable document format" (".pdf") form, or by any other electronic means intended to preserve the original graphic and pictorial appearance of the Agreement, shall have the same effect as physical delivery of the paper Agreement bearing the original signature.

19.21 Survival of Certain Agreement Provisions. The Parties agree that all terms, conditions and covenants of this Agreement, together with the exhibits and attachments hereto, which reasonably contemplate continued performance or compliance beyond the termination of this Agreement, and referred to, shall survive termination and shall continue to be enforceable as provided herein.

19.22 Capitalized Terms. All capitalized terms used herein and not otherwise defined in this Agreement will have the meanings set forth in the Agreement.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the Effective Date shown above.

ADIRAMEDICA LLC

By _____

Name: Arvind Bhandari
Title: President and CEO

"COMPANY"

DENVER HEALTH AND HOSPITAL AUTHORITY
Employer Identification # 84-1343242

By _____

Brandon Ensign
Title: Chief Operating Officer
RMPDS
Contract # CLX 1073

"PROVIDER"

SAFETY DATA EXCHANGE AGREEMENT

THIS SAFETY DATA EXCHANGE AGREEMENT ("SDEA") is entered into this2nd day of December, 2025 between **Denver Health and Hospital Authority,** a body corporate and political subdivision of the State of Colorado ("DHHA"), on behalf of its division, Rocky Mountain Poison & Drug Safety ("RMPDS"), and the **State of Colorado**, **Department of Health Care Policy and Financing, ("SIP SPONSOR" or "HCPF")** and **AdiraMedica LLC ("IMPORTER")** (hereinafter and may sometimes be referred to as the "Party" in the singular and "Parties" in the plural).

This SDEA shall be effective as of the date executed after the approval for Colorado's Drug Importation Program by FDA.

PROCEDURES FOR ADVERSE EVENT AND OTHER SAFETY DATA EXCHANGE NOTIFICATION AND REPORTING

BACKGROUND

The purpose of this SDEA is to outline the roles and responsibilities of Parties in the distribution of the Products imported under Colorado's Drug Importation Program and confirming compliance with applicable regulatory requirements regarding the reporting of Adverse Events.

PROCEDURES FOR ADVERSE EVENT NOTIFICATION AND REPORTING

1.0 DEFINITIONS AND PURPOSE

Whenever used in this SDEA, the words and terms set forth on Attachment 1 shall have the respective meanings set forth thereon.

The purpose of this SDEA is to set forth the procedures and define the responsibilities which SIP SPONSOR and IMPORTER and their Affiliates, will employ RMPDS to ensure that Adverse Event notification and reporting requirements for the Product shall comply with all applicable federal, state, local laws, and regulations (the, "Laws"). Should changes in Laws occur wherein Services could potentially be impacted, the Parties shall review this SDEA and implement a mutually agreed upon amendment(s) as necessary to address such changes.

All Parties understand and agree that these procedures are intended to comply with relevant Laws and guidelines, including, but not limited to the following, as applicable and such guidelines and regulations form the basis of the information to be exchanged between the parties:

- *Code of Federal Regulations* ("CFR") *Title 21* as amplified by relevant United States Food and Drug Administration Guidances, Compliance Program Guides, and other relevant

regulatory materials, will be adhered to in relation to any applicable reporting requirements in the United States.

2.0 REVIEW AND REVISIONS

The procedures set forth in this SDEA may be amended by the Parties at any time, at the request of either Party, to ensure that they fully and accurately reflect the procedures in place for surveillance, receipt, evaluation and reporting of Adverse Events or Adverse Experiences by the Parties, and comply with applicable Laws.

The Parties agree that:

- The terms of this SDEA shall supersede and take precedence over any conflicting terms and conditions of any other agreements between the parties regarding the exchange of safety reporting data and the duties which are addressed herein and obligations of each with respect to such activities.

- Any modification to this SDEA, with the exception of any updating of the assigned company contacts designated in Appendix 2, shall be completed by a written amendment signed by all Parties. Once the amended SDEA is signed by all parties, verification of the updated amendment can be sent via a transmittal as defined by the administrative requirements exhibits in the executed contracts between HCPF and Denver Health, and HCPF and AdiraMedica.

- All terms used in this document will be consistent with the definitions in the FDA regulations and guidelines, *CFR Title 21*.

3.0 EXCHANGE OF ADVERSE EVENT INFORMATION

Exchange of Adverse Event information between the Parties will be performed as outlined in Sections 3.1, and 3.2, below to ensure that regulatory requirements for expedited and periodic reporting can be met. The following general guidelines will apply in connection with the reporting of Adverse Event information and compliance with applicable Laws:

RMPDS on behalf of the IMPORTER will provide Adverse Event processing, including but not limited to, regulatory reporting for the Products, maintenance of the safety database, regulatory report submissions to their applicable regulatory authorities.

SIP SPONSOR will be responsible for all costs associated with Adverse Event processing.

The language of all exchanges of Adverse Event information shall be in English. Should translation of Adverse Event information be required, costs associated with translation will be the responsibility of the SIP SPONSOR.

Adverse Event information timeframes, pursuant to CFR Title 21, will apply to all Parties of this SDEA. Adverse Event information which meets the Minimum Standard of Information ("MSI"), will be exchanged even though there may be clarification required.

For purposes of this SDEA, the First Contact Date is regarded as day 0 in accordance with applicable Laws.

In the case of Literature, the First Contact Date is the calendar day when an English language copy of the article has been obtained, with the Minimum Standard of Information. If the Literature articles contain only the abstract but have included therein the MSI for reporting, this shall be regarded as day 0.

3.1 Spontaneous Reports

a) RMPDS will provide both the FDA and the Market Authorization Holder pursuant to *21 CFR Part 251§804 Importation Program* with a written report or electronic submission of: (i) Serious Adverse Events within fifteen (15) calendar days of First Contact Date: and (ii) Non-Serious Adverse Events within ninety (90) calendar days of First Contact Date.

b) On a Quarterly basis, RMPDS will initiate a reconciliation of all Serious and Non-Serious Adverse Event reports received. RMPDS will provide the date the report was sent to Market Authorization Holder as required by *21 CFR Part 251§ 804 Importation Program* and the submission date to the FDA. If the report was not submitted, RMPDS will indicate that a submission was not required. SIP SPONSOR and IMPORTER will review the reconciliation form and provide confirmation to RMPDS no later than two (2) weeks from the date of receipt. The reconciliation form will be sent to relevant Parties electronically, and the delivery confirmation will be filed in RMPDS's case folder.

c) Upon receipt of Adverse Event reports, RMPDS will provide receipt confirmation to the sending Party. The required confirmation may be communicated electronically.

3.2 Combination Product Reports

a) RMPDS will provide both the FDA and the Market Authorization Holder pursuant to *21 CFR Part 251§804 Importation Program* with a written report or electronic submission as required by 251.18 (c).

3.3 Follow-up Information

a) The Party receiving the initial report is responsible for forwarding to RMPDS and RMPDS will obtain any follow-up or additional information, as required or as appropriate.

b) RMPDS may request additional follow up information on any safety case provided by any Party.

3.4 Contacts

Contact information for each Party can be found in Appendix 2 attached hereto. The Parties shall provide updated contact information to the other in writing as appropriate.

3.5 Lack of Drug Effect Reports

Lack of drug effect is considered both, an Adverse Event, and Product Complaint. Information regarding the lack of drug effect will be classified and reported as provided under Section 3.1.

3.6 Product Complaints

If an Adverse Event is connected to a Product Complaint, all available information on the Product Complaint will be included in the case report exchanged between the Parties in accordance with Section 3.1.

3.7 Pregnancy Reports

Each Party shall be required to follow-up on all of their Pregnancy Reports for which, the outcome is not yet known, to obtain comprehensive information where available, irrespective of whether an Adverse Event occurred.

3.8 Overdose, Abuse and Misuse Reports

Reports of Overdose, Abuse and Misuse will be exchanged between the Parties as provided under Section 3.1. Each Party shall collect any available information on overdose, abuse and misuse related to the Product.

3.9 Transmission of Infectious Agents

Reports on the transmission of infectious agents will be exchanged between the Parties as provided under Section 3.1.

3.10 Medication Errors

Reports containing medication errors (including reports of near misses) irrespective of whether associated with Serious Adverse Drug Reactions will be exchanged between the Parties as provided under Section 3.1.

3.11 Off-Label Use

Reports on off label use including off-label pediatric use will be exchanged between the Parties as provided under Section 3.1.

3.12 Reports of Resistance

Any reports which may suggest that the Product was not resolving the patient's condition for an approved indication or was taking longer than normal from Statistical Process Control ("SPC") to resolve will be investigated as a possible resistance to treatment. Such a situation is normally reserved to vaccines, medicines for infections or in oncology situations.

4.0 REPORTING RESPONSIBILITIES

4.1 Spontaneous Reports-Marketed Product

RMPDS on behalf of the IMPORTER will be responsible for submitting to the FDA expedited reports, defined as spontaneous ICSRs containing serious, unexpected adverse events or as requested by FDA where IMPORTER has the responsibility for distributing the Product, directly or through an Affiliate. SIP SPONSOR shall be responsible for all costs for such submissions.

RMPDS on behalf of the IMPORTER will be responsible for submitting to the FDA and the manufacturer an ICSR for each domestic adverse event not meeting the serious/unexpected criteria for expedited reporting within 90 calendar days from the date any partner receives a valid ICSR.

5.0 QUESTIONS FROM REGULATORY AUTHORITIES

IMPORTER and RMPDS will communicate with SIP SPONSOR prior to providing any response to regulatory authority and await a response from SIP SPONSOR. All Parties each agree to fully assist the other Parties in responding to requests pertaining to specific cases initially reported to them. All Parties will collaborate to provide a joint response including but not limited to providing the other Parties with a copy of the documentation pertaining to the request.

6.0 LITERATURE REVIEW

Literature review is not required per 21 CFR §251. Literature review will not be performed by RMPDS on any imported product.

7.0 SIGNAL DETECTION and RISK MANAGEMENT

Signals, risk, and crisis management activities are not required per 21 CFR §251 and therefore these activities will not be performed by RMPDS on any imported product.

8.0 MANAGEMENT OF PRESCRIBING INFORMATION AND CORE SAFETY DATA

8.1 Labeling Changes

IMPORTER will notify the other Parties in writing prior to submission of any changes in labeling documents.

Each Party will notify the other Party immediately of any regulatory actions or pending actions that might result in a change in labeling or market restriction due to signals including but not limited to the following:

- Importation program authorization withdrawal, adjustments and/or revisions or program suspension
- Restrictions on distribution
- Original Market Authorization holder label update and approved by FDA

9.0 COOPERATION

9.1 Audit

Each Party agrees to maintain accurate and complete records of all Adverse Events relating to the Product and submissions to regulatory authorities relating thereto (collectively, "Records"). Each Party agrees to permit representatives of the other Party to examine and audit the Records, and Standard Operating Procedures (SOPs) during normal business hours, upon reasonable written notice at a time that is mutually agreed upon between the Parties. Provided, however, that such audit must be reasonable in scope and in relationship to the Adverse Events for the Product and both Parties shall have the opportunity to participate in any post-audit meeting and receive a copy of any audit report relating to that Party. Provided further that, if either Party seeks to use the services of a third party in such an audit, the third party must be acceptable to both Parties and be willing to comply with reasonable requirements of the Party being audited, such as signing a confidentiality agreement.

Any corrective actions from such an audit must be provided to RMPDS along with timeframes for resolution.

9.2 Regulatory Authority Correspondence

RMPDS agrees to provide, to the SIP SPONSOR a copy of any correspondence or notices received from any regulatory authority relating to Adverse Event notification and reporting compliance issues, safety related regulatory actions, product recalls, or which otherwise may affect or be relevant to the duties and obligations under this Agreement, within three (3) business days of receipt and a copy of any response to any such correspondence or notices with three (3) business days of making a response.

9.3 Database Reconciliation

RMPDS shall have in place a tracking system for incoming Adverse Event reports such that they may reconcile at least quarterly and to ascertain that all qualifying Adverse Events were followed up and exchanged with all applicable Parties other.

9.4 Clarifications

All Parties agree to answer in a reasonably exhaustive manner all questions that the other Party might raise that affect case evaluation or regulatory reporting with regard to exchanged Adverse Event cases.

9.5 Language

All correspondence and communications between the Parties will be in English. If necessary, timely translations will be provided by the Party sending a communication at the expense of the Party.

Documents from regulators must be translated to English, and any costs associated with such translation will be the responsibility of SIP SPONSORS.

9.6 Safety Cases Not Reaching Minimum Information

Safety cases that RMPDS receives that do not have Minimum Standards of Information (MSI), despite RMPDS' attempt to obtain the follow up information, shall be documented within the database as outlined in Section 3.0.

10.0 Termination

If the Colorado Drug Importation Program terminated, this SDEA will also terminate. In the event a Party is no longer a party to this SDEA; by way of termination of its agreement between said Party, the remaining Parties to this SDEA mutually agree to amend this SDEA as required.

Upon termination of this SDEA, Parties shall cooperate to provide for disposition of all documents and records and an orderly wind-down of all services provided by this SDEA.

11.0 ROUTINE REVISION OF SDEA

This SDEA will be reviewed every two (2) years to ensure compliance with regulations and business processes.

12.0 LOCAL or FEDERAL LEGISLATION CHANGES

SIP SPONSOR shall inform RMPDS of any legislative changes pertinent to Colorado's Drug Importation Program.

13.0 AVAILABILITY

RMPDS agrees to provide intake coverage 24 hours/day, 7 days/week. Any reported Adverse Events or Medical Inquiries will be addressed as referenced in this SDEA.

Denver Health & Hospital Authority

By: 

Name: Brandon Ensign
Title: Chief Operating Officer, RMPDS

AdiraMedica LLC, Importer

By: 

Name: Arvind Bhandari
Title: President and CEO

State of Colorado, SIP Sponsor

By: 

Name: Kelly Swartzendruber
Title: Drug Importation Program Manager (Responsible Individual)

APPENDIX 1

DEFINITIONS

A. “Adverse Event” Any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related, including the following: An adverse event occurring in the course of the use of a drug product in a professional practice; an adverse event occurring from drug overdose whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any failure of expected pharmacological action. Provider will only capture adverse events related to Company’s product(s), unless otherwise requested by Company.

B. "Affiliates” shall mean any company or business entity directly or indirectly controlling, controlled by or under common control with either of the parties)

C. “Associated With the Use of the Drug (i.e., drug-related)” shall mean a reasonable possibility that the experience may have been caused by the drug.

D. “Combination Product” shall mean:

(1) A product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity;

(2) Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products;

E. “Company Core Data Sheet” shall mean the document prepared by the marketing authorization holder containing in addition to safety information, material relating to indications, dosing, pharmacology and other information concerning the product.

F. “Company Core Safety Information” shall mean the set of facts and recommendations prepared by the pharmaceutical manufacturer containing all relevant safety information, such as adverse drug reaction, warnings, precautions, contraindications, use in pregnancy, etc., which the manufacturer believes should be listed (minimum core safety information) for the drug in all countries where it is marketed. This information is used for assessing labeledness or expectedness unless the local regulatory authority requires a modification.

G. "First Contact Date” will be considered to be the calendar day when the initial report containing the Minimum Standard of Information necessary for transmission of a case has been received by either Party. This date will be considered day 0 for the purposes of reporting timelines.

H. “Importer” shall mean the contracted company that performs the roles and responsibilities of the Importer as required by 21 CFR Part 251. An Importer is a State-licensed pharmacist, or a State- or FDA-licensed wholesale distributor, who is the U.S. owner of an eligible prescription drug at the time of entry into the United States.

I. “Individual case safety report” (ICSR) means a description of an adverse event related to an individual patient or subject.

J. “ICSR attachments” means any document related to the adverse event described in an ICSR, such as medical records, hospital discharge summaries, or other documentation.

K. “Life-threatening adverse event” means any adverse event that places the patient, in the view of the initial reporter, at immediate risk of death from the adverse event as it occurred, i.e., it does not include an adverse event that, had it occurred in a more severe form, might have caused death.

L. “Literature” shall mean published articles/abstracts in scientific journals, medical journals, and unpublished manuscripts involving case reports or clinical studies in which there is an identifiable patient.

M. “Manufacturer” means an applicant or a person who owns or operates an establishment that manufactures an eligible prescription drug. Manufacturer also means a holder of a drug master file containing information necessary to conduct the Statutory Testing, prepare the manufacturer’s attestation and information statement, or otherwise comply with section 804 of the FD&C Act or this part.

N. “Marketing Authorization Holder” The MAH is the legal entity that holds the marketing authorization for a medicinal product. The MAH may be a pharmaceutical company, a hospital or other institution authorized to market medicines, or an individual person.

O. “Minimum Standard of Information” (MSI) shall mean an identifiable patient, a suspect medicinal product, and identifiable reporting source and an event or fatal outcome.

P. “Minimum data set for an adverse event” means the minimum four elements required for reporting an ICSR of an adverse event: An identifiable patient, an identifiable reporter, a suspect drug product, and an adverse event.

Q. “Non-serious Adverse Event” shall mean any Adverse Event which does not meet the criteria for being classified as a Serious Adverse Event.

R. “Product” shall mean the imported eligible prescription drug.

S. “Product Quality Complaint” shall mean any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability or reliability of a medicinal product drug after it is released for distribution. This includes components distributed with the drug, such as packaging, drug containers, labeling and inserts. Product Quality Complaints can be related to the following, but not limited to damage to the packaging, damaged, discolored, malodorous, broken or chipped tablets/capsules or tablets/capsules stuck together, missing products/wrong quantity on packaging, missing or opened/broken seal on bottle, foreign tablet/capsule or foreign substance or item in bottle or packaging, suspected product tampering or product labeling error or missing lot code or expiration date.

T. “Pregnancy Report” shall mean a case report related to an administration of the Product to the mother at conception, during pregnancy, or delivery.

U. “Serious Adverse Event” shall mean any adverse drug experience occurring at any dose that results in any of the following outcomes: Death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

V. “Unexpected Adverse Event” means an adverse event that is not included in the current U.S. labeling for the drug product. Events that may be symptomatically or pathophysiologically related to an adverse event included in the labeling but differ from the labeled event because of greater severity or specificity would be considered unexpected. “Unexpected,” as used in this definition, also refers to adverse events that are mentioned in the product labeling as occurring with a class of products or anticipated from the pharmacological properties of the product but are not specifically mentioned as occurring with the particular product.

(1) Example of greater severity. Under this definition, hepatic necrosis would be unexpected if the labeling referred only to elevated hepatic enzymes or hepatitis.

(2) Example of greater specificity. Cerebral thromboembolism and cerebral hemorrhage would be unexpected if the labeling included only cerebrovascular accidents.

W. “Section 804 Importation Program Sponsor (“SIP Sponsor”) means a State or Indian Tribe that regulates wholesale drug distribution and the practice of pharmacy that submits a proposal to FDA that describes a program to facilitate the importation of prescription drugs from Canada under section 804 of the Federal Food, Drug, and Cosmetic Act and is responsible for oversight of the implementation of the program.

X. “Signal Detection” shall mean activities performed to identify possible events which need further review and consideration for possible Product label changes. These events are generally unexpected (i.e., unlabeled). These events may or may not be serious and may or may not be due to or caused by the Product.

Y. “Statistical Process Control” - the use of statistical techniques to control a process or production method. SPC tools and procedures can help monitor process behavior, discover issues in internal systems, and find solutions for production issues.

APPENDIX 2

CONTACTS:

Case Exchange Contacts

Exchange Partner	Contact Person	Contact Details
Denver Health & Hospital Authority, a political subdivision of the State of Colorado ("DHHA") Address: 777 Bannock Street, Mail Code 0180, Denver, Colorado 80204	Winnie Forward	RMPDS 1391 Speer Blvd, Suite 600, MC 0180 Denver, CO Redacted Email: **Redacted**

Exchange Partner	Contact Person	Contact Details
AdiraMedica, LLC 77 Brant Ave, Suite 325 Clark, NJ 07066, USA	Arvind Bhandari	77 Brant Ave, Suite 325 Clark, NJ 07066, USA Redacted Email: Redacted

Exchange Partner	Contact Person	Contact Details
Colorado Department of Health Care Policy & Financing 303 East 17th Avenue Denver, CO 80203	Kelly Swartzendruber	303 E. 17th Avenue, Denver, CO 80203 C: 720.483.4091 Kelly.swartzendruber@state.co.us