Appendix F Certification Reports

RC Kennedy Consulting
208 Holmard St
Gaithersburg, MD 20878
www.rckennedysc.com

AdiraMedica Visit
4/11/22
Observations and Comments

General

A team representing the Colorado Importation Program visited AdiraMedica and Bioscript Logistics on 4/11/22 for a review of their business and operations in consideration of their participation as an importer for the program. The visit included a visit to the Adira offices in Toronto and to Adira's 3PL partner, Bioscript.

Adira is a pharmaceutical sourcing firm touting a global reach for the sourcing of drugs. The firm is based in Clark, NJ, with offices in Toronto. Their primary business is sourcing active pharmaceutical ingredients, finished dosage forms, raw materials, intermediates and excipients. A core part of their business is in support of clinical trials.

As this review is primarily focused on the storage and distribution of drugs, the focus is on the visit to Bioscript. Bioscript Logistics is a Toronto based 3PL that specializes in the distribution of pharmaceuticals in Canada. We ensure products are imported, stored and delivered securely, on time and with quality assured. Bioscript touts their GMP-compliant facility with cold chain capabilities from ambient to refrigerated and frozen inventory, ensuring that the integrity of your product is maintained. Bioscript focuses their business on importation and distribution of pharmaceuticals and medical devices in Canada. They hold a Drug Establishment License (DEL) for wholesale and packaging.

System

The WMS and inventory management system used by Bioscript is proprietary. The system was built by a Bioscript partner specifically around the needs of their business model. The system is quite capable regarding the ability to manage a pharma distribution center with strict system controls on the movement of inventory and rules for storage. Mobile devices equipped with scanners are deployed both on the inbound and outbound process to verify the accuracy and timeliness of receiving and picking.

Though the system is supportive of good practices for lot-controlled items, it is maintained by a single individual who is a Bioscript contractor. There does not appear to be a back-up plan for support, nor does there appear to be sufficient documentation of code for knowledge transfer. This puts Bioscript at risk of a single point of failure. Steps should be taken with urgency to transfer knowledge and create documentation for the system.

Process

Bioscript management clearly understands the requirements of managing pharmaceuticals, particularly regarding the management of lots and expiration dates. As a 3PL, Bioscript has multiple pharma customers and so has been through rigorous past reviews and validation of their processes. The facility appeared to be quite full of inventory, and we were informed that there is an expansion planned to accommodate growth that is already expected aside from the Colorado process.

Training and SOP's

Though the visit did not provide time for a detailed review, management claimed that the users have been formally trained on their tasks and responsibilities. As a GMP compliant facility and as a 3PL with multiple pharma clients, it is likely true that both a training program and set of SOPs is in place.

Summary

Adira, partnered with Bioscript, present Colorado with a capable and experienced partner for sourcing and managing drugs for the Importation program. Related specifically to drug storage and distribution, as an existing third-party logistics provider in the pharmaceutical space, and with multiple other pharma companies as customers, Bioscript is a competent and experienced company capable for the Colorado Importation program.

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Gaithersburg, MD 20878
www.rckennedysc.com

AdiraMedica Visit
1/09/24
Observations and Comments

General

A team representing the Colorado Importation Program visited AdiraMedica and Bioscript Logistics on 1/09/24. This visit was a follow-up after the original visit in April 2022. The purpose was to conduct a review of their business and operations in consideration of their participation as a foreign seller for the program. The visit included a visit to the Adira offices in Mississauga and to Adira's 3PL partner, Bioscript Logistics.

Adira is a pharmaceutical sourcing firm touting a global reach for the sourcing of drugs. The firm is based in Clark, NJ, with offices in the Toronto area, Ireland, Australia, and India. Their primary business is sourcing active pharmaceutical ingredients, finished dosage forms, raw materials, intermediates, and excipients. A core part of their business is to conduct clinical trials.

As this review is primarily focused on the storage and distribution of drugs, this report covers the visit to Bioscript Logistics. Bioscript is an Adira partner for distribution. They are a Toronto-based 3PL that specializes in the distribution of pharmaceuticals in Canada. Bioscript touts their GMP-compliant facility with cold chain capabilities from ambient to refrigerated and frozen inventory, ensuring that the integrity of product is maintained. Bioscript focuses their business on importation and distribution of pharmaceuticals and medical devices in Canada. They hold a Drug Establishment License (DEL) for wholesale and packaging.

Recently, in the last quarter of 2023, Bioscript completed a move into a newer and larger facility. The new facility provides 20,000SF of space compared to the old one, which was only 3,000SF. Given that less than approximately 25% of the new space is being utilized by Bioscript's other customers (approximately 12), the new facility will more than accommodate the addition of the importation business for Colorado. The facility is clean, well-lit, and protected with security cameras placed inside the facility as well as on the outside perimeter. Access to the warehouse is restricted by keypad locks.

System

Bioscript uses a proprietary enterprise system for order management, financials, inventory management, and warehouse management. The system was originally built over 20 years ago by a Bioscript partner specifically around the needs of their business model. The warehouse management module is capable of managing a pharma distribution center with strict system controls on 1) the movement of inventory, 2) management of lots and expiration dating, and 3) rules for storage. The WMS module can digitally segregate inventory by company code so that Bioscript can manage the inventory of their multiple customers individually.

The system can manage movement and storage of inventory by assigning statuses to products or lots. A status can be designated as shippable or quarantined so that shipping is prevented. Bioscript has conducted system compliance/validation testing and published documentation so that it can claim compliance with FDA Part 11 and Health Canada GUI-0050 requirements.

Process

All receipts are verified and documented, as well as inspected as appropriate per Bioscript procedures. Receipts are committed into inventory by Bioscript personnel using mobile devices with scanners to confirm the items and

lots, and the reserve locations. Customer orders are assigned to personnel using mobile devices. Orders are picked complete by the assigned resource. Items, quantity, and lots are confirmed by the person picking the order via the mobile device. All picked containers are assigned a barcoded license plate to track in-process movement. Order components are 100% verified at the packing operation and then weighed and assigned shipping information using a Descartes rating and shipping system.

Cycle counts are performed where issues arise in the process. Cycle counts are system driven but can also be assigned as needed by Bioscript personnel.

The system includes security capabilities that permit/restrict transactions based on a resource profile. Access to security functions is restricted to just a few management personnel.

Documentation

Bioscript personnel informed us that they have a full, published set of standard operating procedures and training records for personnel, which is a core requirement of a system validation process that they informed us was conducted and completed. During the visit we were able to review their Validation Summary report covering an extensive list of the protocols tested and their results.

Personnel

Background checks are performed for each new hire. Bioscript claims a very strong retention rate for warehouse employees. Employees are trained and cross-trained on the system and process. Effectiveness tests are conducted and must be passed by each resource.

Summary

Adira, partnered with Bioscript, is an existing third-party logistics provider in the pharmaceutical space with specific experience in drug storage and distribution, and managing multiple other pharma companies as customers. I believe their operation presents Colorado with a capable and experienced partner for sourcing and managing drugs for the Importation program as a Foreign Seller.

LDT Health Solutions, Inc.
38 Cedar Place
Wayne, NJ 07470
862. 221.9575
www.LDTRx.com

5.5.22

Report to:

Colorado Dept. of Health Care Policy & Financing / Pharmacy Office **(the "Client")**
1570 Grant Street, [State Relay – 711]
Denver, CO 80203
Attn: Dr. Kelly Swartzendruber, Pharm.D. – Drug Importation Pharmacist

Re:

Q Laboratories
1930 Radcliff Drive
Cincinnati, OH 45204-1823
(513) 471-1300
www.qlaboratories.com

DUNS # 0807377501
FEIN # 1527260

Overview

LDT Health Solutions Inc. ("LDT") is a medication safety & quality management consulting firm specializing in compliance programs and independent review activities related to the production of compounded preparations, regulatory compliance, including FDA matters, and other specialty areas of pharmacy practice. Our principals have over 70 years of experience in multiple healthcare settings. Our current consulting work includes FDA approved manufacturers, 503B Outsourcing Facilities, and hospitals.

LDT Health Solutions, Inc. was engaged to provide consulting services to the Client to facilitate the Client's contract decision regarding the importation wholesaler / distributor model by verifying the activities related to that project by the contract laboratory named above. LDT inspected visit to this laboratory to assist in evaluating the quality, scope, and regulatory compliance, of the laboratory. As well as to assist in analyzing the contracted services required by any importation partner or contractor engaged in this drug importation program to access their operations and related compliance issues in connection with the State importation system.

Observations & Findings

The following characterizations of the operations and physical plant conditions currently at Q Laboratory LLC were made by direct observation, and document review provided by the lab's quality staff and were used as a basis for this report.

General Scope-

The following LDT intellectual properties, Federal regulations and other guidance documents were utilized by LDT to facilitate its final determination of regulatory compliance:

1. LDT's document (12-01A.01) **ISO/IEC 17025**[1] General Accreditation Requirements Compliance Crosswalk -
    a. Covering the following required areas-
        i. General
        ii. Confidentiality
        iii. Structural
        iv. Personnel
        v. Record retention
        vi. Facilities and Environmental Conditions
        vii. Equipment
            1. Metrological Traceability
            2. Traceability of Results
            3. Externally Provided products & services
        viii. Process (controlled)
            1. Requests, tenders, and contracts
            2. Selection, Verification, and validations of Methods
            3. Validation of Methods & record retention
            4. Sampling plans
            5. Handling of tests and calibration of items
        ix. Technical Records
        x. Reporting of results
            1. Conformity statements
            2. Amendments to reports
        xi. Complaints
        xii. Non-conforming work
        xiii. Data control and Information Management
        xiv. Control of Management System Documents
            1. Internal audits & findings
            2. Management reviews & reporting

2. Compliance to applicable federal statues, rules, and regulations governing analytical laboratories, as described by the Drug Quality & Security Act (DQSA)[2] and the applicable sections of the USP/NF and the Federal Food Drug & Cosmetic Act (FDCA).
    a. **Colorado Senate Bill 19-005**, passed in 2019, the Department of HealthCare Policy & Financing (Department) / Canadian Prescription Drug importation program.
    b. Compliance to relevant FDA Guidance documents for Reference Laboratory Establishments.

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[1] ISO 17025 - https://www.iso.org/ISO-IEC-17025-testing-and-calibration-laboratories.html
[2] https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa

c. Compliance to Local Department of Health Regulation in the jurisdiction the laboratory is registered (Ohio).
d. Review of policies and procedures relating to receiving, processing, storage, security, holding, and processing of drug inventory samples (as applicable).
e. Review of compliance with relevant recordkeeping requirements, including sampling of current operation files.

Findings & General Impressions of Current Q-Labs Operations –

Utilizing the provided documents listed below, in advance of the visit and additional documents which were requested by LDT on-site to complete the assessment of compliance required by the statement-of-work agreed to by LDT and the Colorado Dept. of Health Care Policy & Financing / Pharmacy Office.

These documents were, in part:

1. A copy of the complete table-of-contents of the policy manual for the lab.
2. A copy of a new employee orientation/training checklist (new hire)
3. A copy of an annual employee training checklist
4. A copy of the firm's table of organization.
5. A floor plan of the entire space including the processing area(s)
6. Two (2) lab technician training files
    a. The newest employee
    b. A tenured employee
7. Temperature, Humidity, & Pressure Logs for the last 30 days.
8. Cleaning Logs for the last 30 days.
9. A copy of any open correspondence with any state, federal or local licensing authority.

The laboratory was most cooperative, and all records requested were made available in short order and those documents were in good order and complete. LDT did request the following documents as representative of the scope, quality and completeness of the information provided:

1. A summary of Q Labs LLC quality operations, services, and a description of the organization, structure & scope of business. (Site Master File)[3]
2. A current table of Organization of Q-labs LLC[4]
3. A complete table of contents of standard operating procedures (Policy & Procedures)[5]
4. Current floor plans of Q-labs production building (levels I & II) for reference. [6]

The documents revealed an FDA registered establishment in good standing holding an ISO 17025 accreditation *(most recently conducted November 12-14, 2019).* They have no open or unresolved issues with FDA. Their applicable state registration (OH) is in good standing and current.

The site is of suitable size and construction to accommodate current operations and appears to have sufficient unutilized space to accommodate some increased production volume. Discussion with

[3] ATTACHMENT ONE - Q-Labs site master file
[4] ATTACHMENT TWO – Q-Labs TOO
[5] ATTACHMENT THREE – Q-Labs SOP TOC
[6] ATTACHMENT FOUR – Q-Labs Floor plans (level I & II) 1911 Radcliffe Drive, Cincinnati, OH 452204

ownership revealed a future expansion plan that includes development of adjoining real estate which is already owned and controlled by Q Labs LLC.

The lab maintains its major equipment in good repair and all requisite independent calibrations and certifications were evident. Evidence of regular cleaning, maintenance, and calibration of equipment in-use was apparent.

Q-labs only sub-contracts lab work outside its organization if a customer requests it, or if the lab is temporarily unable to perform the necessary work, and only after specific approval by the customer.

Critical documents, including policy & procedure, and master work instructions are properly maintained, and secure. Document control is all maintained electronically. Quality Management System shows a high level of control, sophistication, and is well developed for the operations. Security, documents control, version control and accountability are maintained electronically and under the scrutiny of both the Quality Unit and C-suite management.

It is apparent that the company invested in physical plant construction, continues to invest in the maintenance, upkeep, and expansion of the business. Along with that investment in capital equipment, Q-labs continues to invest and provide an orientation, training & development program for employees which is broad and on-going and appears to be sufficient to support current operations.

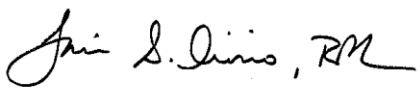
FINAL DETERMINATION OF COMPLAINCE & SUITABLITY OF SERVICES-

Q-Labs LLC appears to have sufficient capacity, knowledge, and expertise to provide the technical services required to support this drug importation project. The laboratory is currently providing these services to numerous other customers in the Pharma & healthcare sectors without incident. LDT is confident that they can deliver the services to make this program successful.

We would endorse the CO Dept. of Health Care Policy & Financing / Pharmacy Office's selection/approval of this service provider.

Thank you for the opportunity to serve you, your staff, and patients.

Very truly yours,



Louis S. Diorio, RPh, FAPhA

Principal

LDT Health Solutions, Inc.
38 Cedar Place
Wayne, NJ 07470
862. 221.9575
www.LDTRx.com

6.20.24

Report to:

Colorado Dept. of Health Care Policy & Financing / Pharmacy Office **(the "Client")**
1570 Grant Street, [State Relay – 711]
Denver, CO 80203
Attn: Dr. Kelly Swartzendruber, Pharm.D. – Drug Importation Pharmacist

Re:

Q Laboratories
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LDT Health Solutions, Inc. was engaged to provide consulting services to the Client to facilitate the Client's contract decision regarding the importation wholesaler / distributor model by verifying the continued activities related to that project by the contract laboratory named above to assist in this pre-implementation phase of the project.

LDT inspected visit to this laboratory to assist in evaluating the quality, scope, and regulatory compliance, of the laboratory. As well as to assist in analyzing the contracted services required by any importation partner or contractor engaged in this drug importation program to access their operations and related compliance issues in connection with the State importation system.

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[1] ISO 17025 - https://www.iso.org/ISO-IEC-17025-testing-and-calibration-laboratories.html
[2] https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa

b. Compliance with relevant FDA Guidance documents for Reference Laboratory Establishments.
c. Compliance to Local Department of Health Regulation in the jurisdiction the laboratory is registered (Ohio).
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Findings & General Impressions of Current Q-Labs Operations –

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These documents were, in part:

1. A copy of the complete table-of-contents of the policy manual for the lab.
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ownership revealed a future expansion plan that includes development of adjoining real estate which is already owned and controlled by Q Labs LLC.

The lab maintains its major equipment in good repair and all requisite independent calibrations and certifications were evident. Evidence of regular cleaning, maintenance, and calibration of equipment in-use was apparent. Furthermore, there is evidence of continued investment in new and expanded instruments and equipment.

Q-labs only sub-contracts lab work outside its organization if a customer requests it, or if the lab is temporarily unable to perform the necessary work, and only after specific approval by the customer.

Critical documents, including policy & procedure, and master work instructions are properly maintained, and secure. Document control is all maintained electronically. Quality Management System shows a high level of control, sophistication, and is well developed for the operations. Security, documents control, version control and accountability are maintained electronically and under the scrutiny of both the Quality Unit and C-suite management.

It is apparent that the company invested in physical plant construction continues to invest in the maintenance, upkeep, and expansion of the business. Along with that investment in capital equipment, Q-labs continues to invest and provide an orientation, training & development program for employees which is broad and on-going and appears to be sufficient to support current operations.

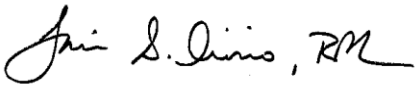
FINAL DETERMINATION OF COMPLIANCE & SUITABLITY OF SERVICES-

Q-Labs LLC appears to have sufficient capacity, knowledge, and expertise to provide the technical services required to support this drug importation project. The laboratory is currently providing these services to numerous other customers in the Pharma & healthcare sectors without incident. LDT is confident that they can deliver the services to make this program successful.

We continue to endorse the CO Dept. of Health Care Policy & Financing / Pharmacy Office's selection/approval of this service provider to move into the next phase of the implementation of the project.

Thank you for the opportunity to serve you, your staff, and patients.

Very truly yours,



Louis S. Diorio, RPh, FAPhA

Principal

Cc: File

Attachments

Site Master File

Table of Contents

1. Scope

This Site Master File (SMF) is a version-controlled document that describes the structure of Q Labs' organization, the site and facilities, the testing activities carried out, and the details of how the Quality Management System (QMS) functions to ensure data integrity.

2. Purpose

The purpose of this document is to provide an overview of the facilities and operations of Q Labs LLC located in Cincinnati, Ohio. This document describes the activities of the Company to demonstrate that it has a cGMP-compliant Quality System in place. The Quality Unit will review the Site Master File annually or any time the Company makes material changes to its operations.

3. Corporate Authorizations

Q Labs LLC is registered with the U.S. Food & Drug Administration (FDA) as a testing laboratory for pharmaceutical products, over-the-counter (OTC) drugs and cosmetic products. Since moving to electronic registration, FDA has begun utilizing Data Universal Numbering System (DUNS) numbers in combination with Facility Establishment Identifier (FEI) Numbers. DUNS Number for Q Labs is 080737501, and its FEI Number is 1527260. Q Labs LLC is current with its FDA registration as a drug establishment. The organization is currently ISO 17025 accredited through the A2LA accreditation body. The most recent FDA inspection was November 14-21, 2019. There are no unresolved regulatory issues. Registrations with applicable State and Federal regulatory agencies are current and in good standing.

4. Product Services

Q Labs LLC is a full-service contract testing laboratory for food, pharmaceutical, personal care products, cosmetic, medical device, animal health and dietary supplement industries. Testing services include microbiology, analytical chemistry, method development/validation and research & development support. Q Labs does not currently provide testing for Drug Enforcement Agency regulated products.

5. Facility Location Description

Q Labs facilities are located within the city limits of Cincinnati, Ohio. The testing laboratory site is bounded by residential neighborhoods, business sites and government property.

Q Labs currently operates at the following locations:

- **1911 Radcliff Drive, Cincinnati, Ohio, 45204** (30,000 ft_2), on two levels to include microbiology and analytical chemistry laboratories.
- **1930 Radcliff Drive, Cincinnati, Ohio 45204** (15,000 ft_2), this building includes microbiology R&D, stability chambers, quality department, sales/marketing department, sample distribution and IT**.**
- **1920 Radcliff Drive, Cincinnati, Ohio 45204** (10,000 ft_2), includes administrative support (executive offices, HR, finance, purchasing), facility engineering support, and receiving warehouse for supplies.

6. Company History

Q Laboratories was founded in 1966 by Herbert Quinn. The "Q" in the company name represents the founder. Mr. Quinn originally operated a small microbiology laboratory testing mostly water.
In 1985, Michael Knight, a former FDA investigator, bought the company from Mr. Quinn and moved it into a facility in the South Fairmount neighborhood of Cincinnati. Mr. Knight leveraged his FDA background to expand the services offered to include testing of food, pharmaceuticals, cosmetics and dietary supplements. He also opened the analytical chemistry department, implementing GMP quality standards throughout the operation.
With continued success, Q Laboratories eventually outgrew the South Fairmount facility and, in 1997, moved to 1400 Harrison Avenue. This lab building has a unique place in Cincinnati history. Built in 1911, it comprises over 14,000 square feet of space located in one of the city's oldest neighborhoods, just five minutes from downtown Cincinnati. The building originally housed the offices of the Herancourt Brewing Company, a now defunct brewery that operated in the early 20th century.
In 2000, the business was acquired by David Goins, who at that point served as the Laboratory Director. Growth continued and, in 2010, Q Laboratories opened a new 9,000 square foot addition which allowed for the expansion of laboratory space and a more efficient workflow.
Continued success has required another major facility expansion. In 2017, the company acquired investment capital and began construction of a new Q Laboratories campus – a 25,000 square foot administrative building along with a state-of-the-art, 30,000 square foot laboratory facility. The goal of this latest expansion: Enable Q Laboratories to continue to provide clients with cutting-edge scientific technologies capable of accommodating projects and sample volumes of virtually any size. The 1911 laboratory building was officially opened for business in May 2018.

7. Site Description

Each building is of suitable size, construction, and design to facilitate maintenance, cleaning, and operations. Space is adequate for orderly placement of equipment and testing of materials. Separate or defined areas are maintained to prevent contamination of products during receiving, and testing operations. Each building is maintained in a clean and sanitary condition. Commercial HVAC filtration systems are used to maintain the laboratory environments.

The buildings are adequately secured against entry of unauthorized personnel. Security controls include a 24-hour security system supported by security personnel. All employees are required to utilize badge access to enter the facility. A safety committee operates under the direction of the Chemical Hygiene Officer. The institutional biosafety committee operates under the direction of the Biological Safety Officer. Written policies for safety are established. First aid kits and fire extinguishers are suitably located throughout the buildings. Emergency evacuation maps are posted where necessary. Electronic copies of SDS are also maintained and may be accessed at each company computer through a desktop icon.

Openings to each building are protected against entry by rodents and other pests. Warehouse roll up doors are closed when not in use. HVAC filters in the laboratory area are inspected and changed every two months. There is adequate lighting in the laboratory areas to facilitate housekeeping, safety and operations.

Biological Safety Cabinets (BSC) with HEPA filtration are used for sample preparation in the GMP microbiology laboratory. The BSC are cleaned daily. There are 18 fume hoods and 4 acid hoods in the analytical chemistry area for sample preparation as applicable.

There are several separate laboratory areas for testing operations. The GMP microbiology laboratory has identified separate areas for sample preparation, antimicrobial effectiveness testing, and microbial identification to reduce the potential of contamination of samples. Food Microbiological testing is performed in a separate laboratory area from the GMP testing. The microbiology R&D laboratory is adequately separated from the routine laboratory testing areas. On the analytical chemistry floor, there are separate laboratory areas for food sample preparation, hazardous chemical storage, metals analysis, total organic carbon analysis, chromatography operations, mass spectroscopy operations and analytical R&D.

Staff amenities, including breakrooms and locker facilities, are separate from testing and quality control areas.

Restrooms are maintained and readily accessible in all buildings. They are properly lit and ventilated. Hand-washing facilities are provided and furnish soap, hand dryers, and running water at a suitable temperature. Laboratory personnel are required to remove and hang up their lab coats prior to entering the restroom.

Work instructions (masters) and standard operating procedures address processes for the maintenance of buildings and equipment. A documented environmental monitoring program is maintained. Pest control is addressed through an appropriate SOP. A pest control manual is maintained for each facility. Inspections are conducted by the facilities department. Exclusion measures are adequate for excluding pests from the buildings and for protecting against the contamination of samples. Insect light traps are installed at various locations in the facilities. Pest activity logs are in place. Exterior bait stations are in use.

Attachment 1 – Facility Layout

8. Organization Charts & Department Staffing

Q Labs employs approximately 134 full-time employees and 17 part-time employees. The organization operates 7 days a week regarding routine microbiological testing and 5 days a week for analytical testing. Additional testing hours will be provided on an as contracted basis for client support.

9. Management Responsibilities

Jayson Arling, President, is the most responsible person at Q Labs. Attachment 2 depicts the executive management organization.

There are an adequate number of supervisory and management employees with the necessary qualifications, training, or practical experience. There are organizational charts showing the key positions, as well as their areas of responsibility and lines of authority. Employees in responsible positions have written job descriptions describing their specific duties.

Key personnel include the persons nominated as responsible for Testing and Quality. Full-time personnel occupy key positions. Part-time employees are utilized for support functions within the laboratory and operational groups. Contracted labor is not employed at Q Labs. Personnel identified to perform Quality operations have the necessary independence and authority to ensure that Quality measures are employed in the testing all products. Laboratory personnel performing microbiological and analytical testing are suitably qualified.

Each laboratory have designated quality employees that facilitate data review, quality investigations, and procedural improvements. Q Labs has established the role of Metrologist with the focus on continuous improvement in maintenance, calibration, and qualification support of the laboratory equipment. The stability team lead is responsible for the stability chambers and the associated stability protocols. Document Control is supported by members of the Quality Assurance Unit responsible for controlling master testing forms, client procedures, SOPs and policies.

10. USP Purified Water System

Water used in the preparation of media for microbiological testing is purified to meet current USP requirements using deionization, UV sanitization, and filtration. The system was installed in 2018, has undergone qualification, and remains in a qualified state.

The water for the 1911 purified water system is supplied by the city of Cincinnati through the local municipal piping system. The city water passes through a softener, two carbon beds, two mixed resin beds, a 1-micron filter before it is treated by a UV lamp with bio filter. The purified water is transferred to the storage tank. The storage tank is fitted with a 0.2-micron vent filter. The water exits the storage

tank through a pump to another mixed resin bed which is followed by a 1-micron filter. The water is further treated by a UV lamp and bio filter before distribution to the points of use. The distribution loop circulates back to the storage tank. There are two continuously circulating water distribution lines, one line to the upper level for the chemistry area and one line to the lower level supplying the microbiology labs. Point-of-use (POU) drops are installed throughout each laboratory. The system is sampled monthly at beginning, middle, and end POU's. Chemical (TOC and Conductivity) and microbial alert and action levels are monitored and managed by Quality/Metrology.

The Milli Q purified water system located in the metals laboratory provides USP purified water for all testing performed in the chemistry laboratory area to include elemental analysis and chromatography. The system qualification was completed in September 2019.

11. Quality Management System

Q Labs has a documented Quality Management System (QMS), supported by management, that is well-established and maintained. Adequate resources are provided to achieve each aspect of the system.

- The Quality Management System ensures that managerial responsibilities are clearly defined, documented and exercised
- Testing operations are specified, and good manufacturing and good laboratory practices are followed
- Supplies meet required specifications
- Necessary controls on testing and data are carried out
- Final reports are not released before an authorized person has signed that each sample has been tested in accordance with documented procedures, meets required specifications, and meets all required Quality tests
- Appropriate storage conditions are maintained
- There is a procedure for conducting internal Quality System audits that appraise the effectiveness and application of the QMS.

A system of Quality Control is established to ensure that product testing complies with their required standards. Quality personnel approve all written procedures, tests, and examinations affecting GMP product quality reports.

Q Labs has established a quality manual, a set of Standard Operating Procedures (SOPs) and Masters (forms) to support the Quality Management System. The responsibilities and procedures applicable to the Quality Unit are described in SOP's and the quality manual.

Internal audits are conducted by representatives of the Quality Unit, with each department audited at a minimum of once each calendar year.

12. Resource Training

Employee training requirements are addressed in SOPs that detail job specific training, GMPs, and safety training for personnel. Department managers are responsible for training their employees. Internal training records are maintained by Quality to include the date and type of training, and person(s) trained. Personnel responsibilities related to confidentiality and undue pressure are reviewed annually with the employee.

13. Quality Control & Assurance

Testing supplies/materials are purchased from approved vendors that are periodically reviewed. Supplies are assigned an expiration date to ensure adequate control. Q Labs has established, written procedures for the receipt, identification, testing, and reporting of testing data. Each sample received is issued a Q Labs number (QL#) for traceability. The sample will be assigned to a trained analyst. The analyst will record the testing data on the appropriate master form. The data will be submitted to operations for typing the report. The typed report and raw data will be reviewed by Quality prior to obtaining the Laboratory Supervisors signature on the final report. Test samples are retained for 30 days prior to destruction. All data and associated paperwork are retained for 7 years.

The R&D Labs are responsible for method validations/verifications and GLP studies.

The GMP microbiology laboratory performs various microbial testing procedures on raw materials, bulk, and finished products from clients. Tests are performed against established specifications following validated customer-specified or USP Test Methods. Identification of bacteria, yeasts and mold are performed using the Bruker identification system. The majority of the media is prepared on site by the Media Lab and tested according to written instructions with documentation on the appropriate master. QC tests are conducted on prepared media. Purchased media plates are QC tested prior to use. Microbial testing of the purified water system is performed using membrane filtration and pour plate methods. Microbial alert and action levels are established. Test results are documented. Routine microbial test results for product release are recorded on both the sample master sheet as well as on the laboratory report that is sent to the client. Additional environmental testing is performed to monitor air and lab surface quality in the microbiological labs. Representative sites are sampled for air quality weekly while lab surfaces are sampled weekly to cover all sites within the month.

The analytical laboratory performs various physical and analytical testing procedures on raw materials, bulk, and finished products for clients. Tests are performed against established specifications and the results recorded. All testing is performed according to written Test Methods. Test data is recorded on a laboratory report that is sent to the client. The raw data is maintained for 7 years.

Laboratory management will notify the client and Q Labs Quality Unit of any out of specification (OOS) results in a timely manner of the discovery of the OOS result. Quality will perform an investigation to determine if laboratory error was the root cause. An investigation report will be issued to the client for further investigation and product disposition.

14. Stability

Q Labs provides ICH (International Conference on Harmonisation Regulations) compliant stability services and shelf-life studies. The stability chambers are monitored utilizing continuous monitoring probes. Each chamber is mapped and certified annually. Studies may include weight loss, freeze/thaw, or thermal cycling depending on the product and container closure system. The testing and storage conditions will be outlined in the protocol prepared by the Stability Team Lead.

15. Third-Party Contracts

Q Labs only subcontracts its testing operations when the customer requests it or if the lab is temporarily unable to perform the test. The client must agree to have the test subcontracted. Q Labs will review and submit the final report to the client.

Q Labs utilizes a professional security service to provide the security services described above.

16. Document Control Procedures

Processes and associated activities in the testing of drug and personal care products are documented, and critical documents are subject to a system of document control. Employees are assigned to facilitate Document Control as part of the Quality Unit organization.

Documents are approved, signed and dated by appropriate and authorized persons. Master SOPs are maintained electronically in an electronic Quality Management System, Veeva Quality One Vault. Responsibilities of Quality related to document control include establishing and maintaining Quality policies/procedures, as well as retiring and archiving obsolete procedure. Master documents used to document test data are controlled forms managed by Quality. SOPs are reviewed, at a minimum, every 3 years. The results of the review are recorded.

17. **Data Integrity Program**

The Data Integrity Program is intended to ensure the integrity of data, across the data lifecycle from creation through long-term archival, used to make safety, efficacy, quality and regulatory compliance decisions at this site. The Data Integrity Plan for Q Labs LLC is intended to align with current US FDA, Health Canada, MHRA, and World Health Organization guidelines for a risk-based approach and a data lifecycle concept as they pertain to data integrity and computerized systems validation.

REVISION HISTORY:

Rev	Date	Section	Changes
7	10/25/23	7	Clarified BSC cleaning process
7	10/25/23	8	Updated full-time employees to 134 and part-time employees to 17.
7	10/25/23	9	Replaced Jeff Rowe with Jayson Arling as most responsible person at Q Labs.
7	10/25/23	16	Noted that SOPs are now stored within an electronic Quality Management System, Veeva's Vault Quality One
7	10/10/23	Entire Document	Removed signature fields.

Document Approvals

Approved Date: 12/12/2023

Task: Approval Task Verdict: Approve	August Smithmeyer, (asmithmeyer@qlaboratories.com) Management Approval 04-Dec-2023 21:24:40 GMT+0000

Task: Approval Task Verdict: Approve	Jayson Arling, (jarling@qlaboratories.com) Management Approval 12-Dec-2023 14:26:14 GMT+0000

Task: QA Approval Verdict: Approve	Jeff Knowles, (jknowles@qlaboratories.com) Quality Assurance Approval 12-Dec-2023 18:18:03 GMT+0000

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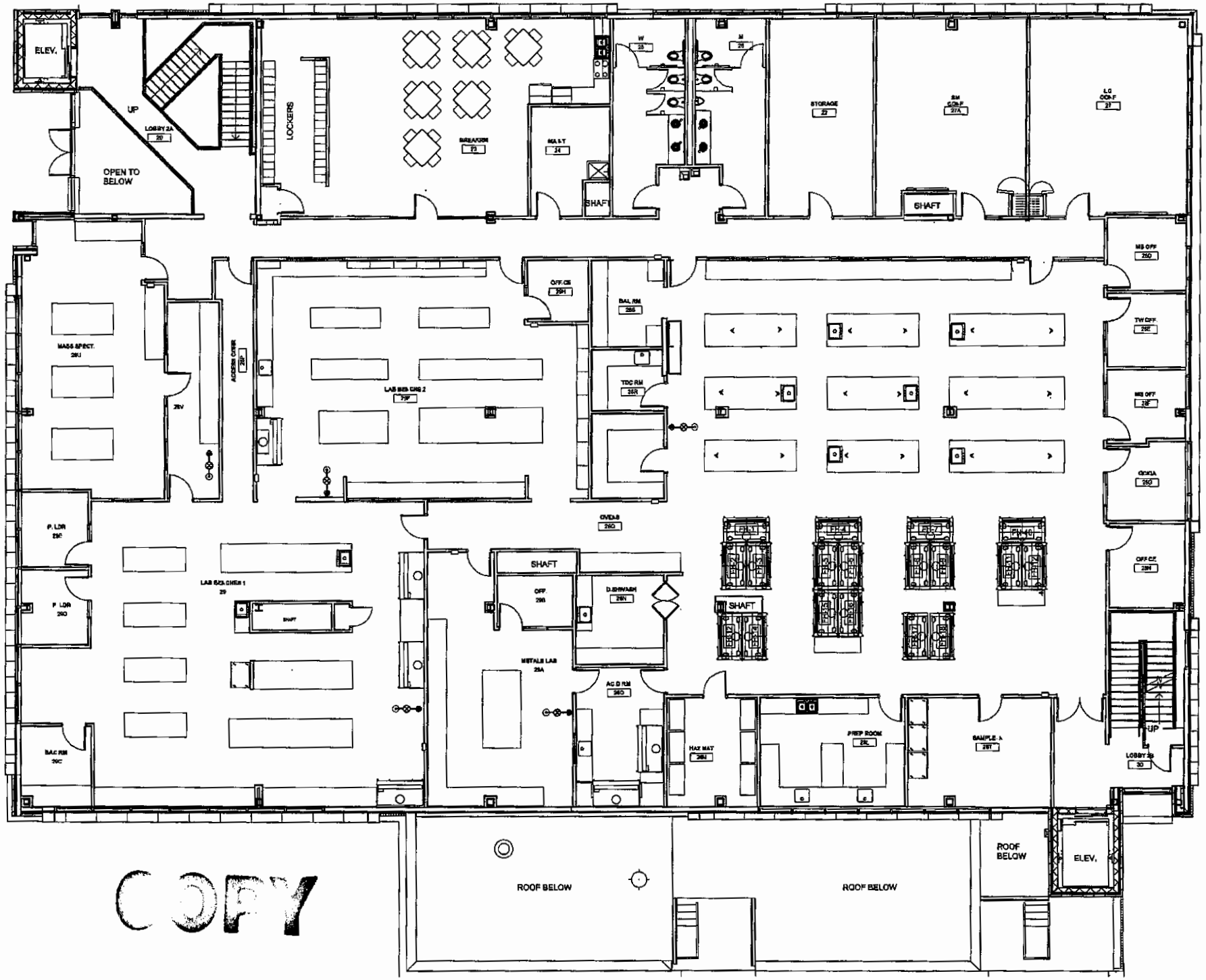
Q LABS SOP TOC

20-ADMN-POLI-004	Q Labs LLC Data Integrity Plan
20-ADMN-POLI-005	Site Master File
20-ADMN-ISO-001	Creation, Review, Approval & Distribution of SOPs and Forms
20-ADMN-ISO-002	Protection of Client's Confidentiality
20-ADMN-ISO-003	Subcontracting of Tests
20-ADMN-ISO-004	Ethical Conduct & Freedom from Undue Pressure & Conflicts of Interest
20-ADMN-ISO-005	Procurement
20-ADMN-ISO-006	Management Reviews
20-ADMN-ISO-007	Requirements of Equipment
20-ADMN-ISO-008	Control of Records
20-ADMN-ISO-009	Good Documentation Practices
20-ADMN-ISO-010	Investigation of Nonconforming Work
20-ADMN-ISO-011	Change Control
20-ADMN-ISO-012	Q Laboratories Quality System
20-ADMN-ISO-013	Training
20-ADMN-ISO-014	Corrective and Preventative Actions
20-ADMN-ISO-016	Quality Assurance Unit
20-ADMN-ISO-018	Inspection of Testing Facility/Visitor Policy
20-ADMN-ISO-019	Storage Requirements of Reagents and Chemicals
20-ADMN-ISO-020	Review of Requests and Contracts
20-ADMN-ISO-021	Reporting & Reviewing Test Results
20-ADMN-ISO-022	Traceability of Materials and Standards
20-ADMN-ISO-023	Method Development and Validation
20-ADMN-ISO-024	Deviations from Standard Test Methods & Q Laboratories Procedures
20-ADMN-ISO-025	Software Development, Modification and Validation
20-ADMN-ISO-028	Proficiency Testing Program
20-ADMN-ISO-029	Customer Feedback
20-ADMN-ISO-030	Control Charting and the Measuring of Uncertainty of Data for Microbiology
20-ADMN-ISO-035	Significant Figures and Rounding
20-ADMN-ISO-036	Pest Control Program
20-ADMN-ISO-037	Onboarding New Employees
20-ADMN-ISO-038	Blue Mountain Calibration Manager
20-ADMN-ISO-040	Control Charting and the Measuring Uncertainty of Data for Chemistry
20-ADMN-ISO-041	Quality Control Program
20-ADMN-ISO-042	Data Integrity
20-ADMN-ISO-043	Transfer of Samples
20-ADMN-ISO-045	Q Laboratories Deionized Water System, 1911 Radcliff
20-ADMN-ISO-046	Risk and Opportunity Management Using SWOT Analysis
20-ADMN-ISO-047	Maintenance and Calibration of Equipment
20-ADMN-CGMP-001	Conduct of CGMP Studies
20-ADMN-CGMP-002	Validation/Verification of GMP Methods
20-ADMN-CGMP-005	Stability Chambers and Stability Testing

ATTACHMENT TWO

20-ADMN-CGMP-006	Qualification of Laboratory Instruments
20-ADMN-CGMP-009	Inspection of Testing Facility by Regulatory Agencies
20-ADMN-CGMP-010	Guidelines for Analytical Method Transfer
20-ADMN-CGMP-011	Compliance of Laboratory Computer Systems to 21 CFR 11
20-ADMN-CGMP-012	Guidelines for Microbiology Method Transfer
20-ADMN-CGMP-013	Control of Master Data Sheets
20-ADMN-CGMP-014	OOS Investigations



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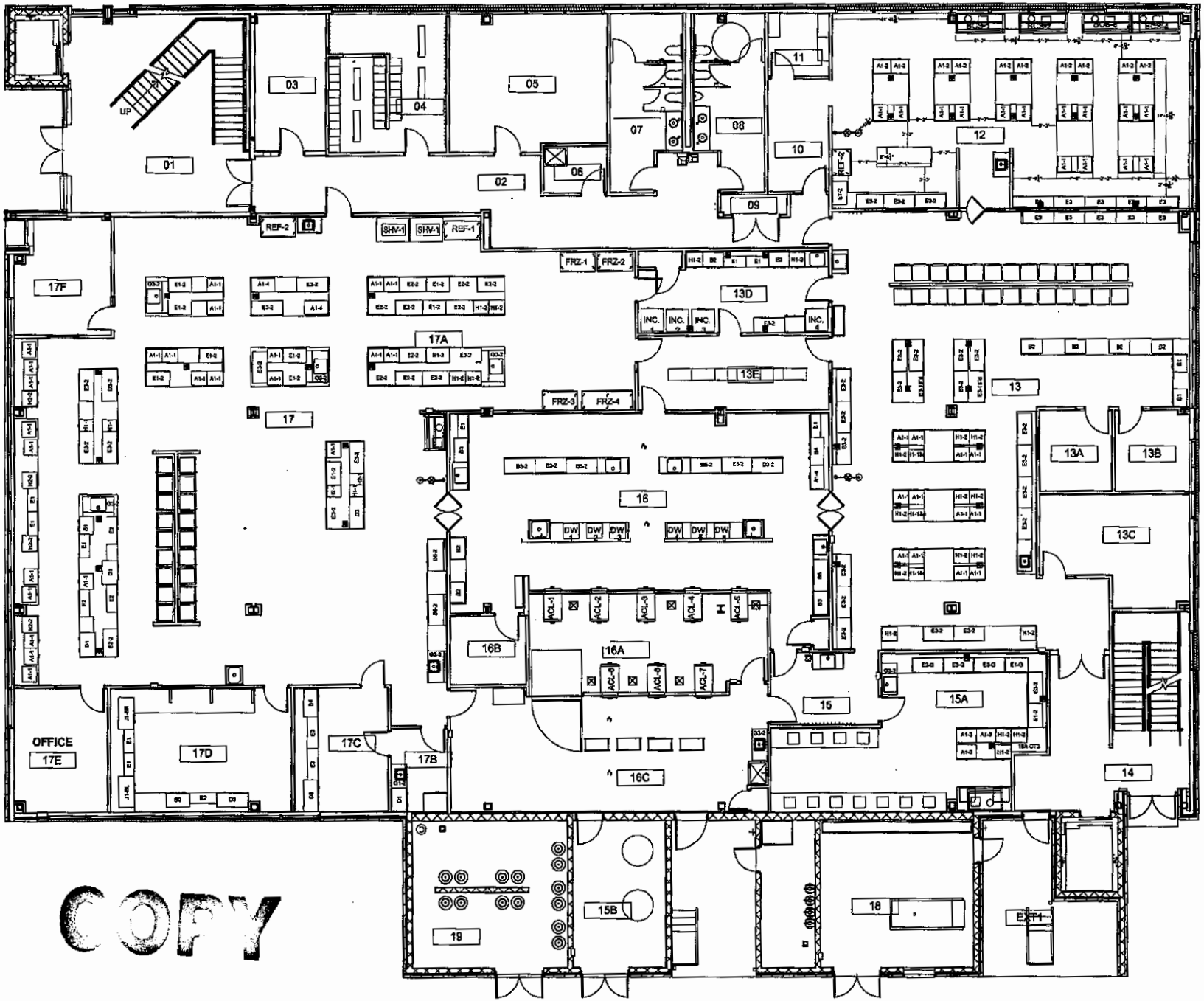
ATTACHMENT THREE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Client
Kelly Swartzendruber, Drug Importation Program Manager
State of Colorado Department of Health Care Policy & Financing
303 E. 17th Avenue, Suite 1100
Denver CO 80203

Performer, Document Author:
Tyler Foley – Principal Consultant
Robert Nagy – Senior Consultant

Project Scope:
Assist State of Colorado Dept. of HCPF in auditing AdiraMedica for their drug reimportation program by conducting a site visit of the AdiraMedica to verify facility meets compliance to appropriately warehouse, re-label, and distribute pharmaceutical products per the section 804 drug reimportation requirements.

Project number:
WO-1004585

Date:
05 Aug 2025

Delivering the difference

Körber Pharma Inc. – a Körber group company
2243 Energy Drive Apex, NC 27502, USA
Tyler.Foley@Koerber.com

Koerber-Pharma.com

Introduction

Korber Pharma Inc. (KPI) specializes in pharmaceutical product inspection, secondary packaging, and storage of finished drug products. Our consultants are industry experts with decades of training and actual pharmaceutical industry experience doing the respective work. Korber Pharma Inc has been engaged to provide consulting services to the State of Colorado Dept. HCPF to assist in the evaluation of AdiraMedica's ability to adhere to cGMP principles and compliance with appropriate regulations and industry best practices.

Trip Report

The below regulations and industry guidance documentation were utilized by KPI to facilitate its final determination of regulatory compliance:

- 21 CFR 211 part C
- 21 CFR 1301.71-7
- 21 CFR 205.50
- USP 1079
- USP 659
- Canada GUI-0069

The characterizations and conditions of the AdiraMedica facility were made by direct observation during facility walkthrough and observations of personnel performing their actual assigned work tasks, along with review of the following documentation provided by the facility's management:

- The complete set of company SOPs
- Employee training forms
- Maintenance, Cleaning, and Pest Control logs
- Facility floor plans
- Environmental monitoring logs
- Template batch records

The AdiraMedica facility is of suitable size, construction, and location to facilitate cleaning, maintenance, and proper operations. Work processes are segregated into specifically designated areas with physical and procedural control systems in place to prevent product mix-ups during the course of normal operations. Lighting is adequately provided in all areas both inside and outside the building for required work processes and illumination of spaces for security observations. Appropriate facilities and utilities exist for the cleaning and sanitation required for the areas used to store drug products. Building maintenance, pest control, and cleaning is performed and logged on a routine schedule.

All documentation including SOPs, work instructions and logs are properly maintained and secure. Documentation control is currently maintained via a paper-based system with plans to convert to an electronic-based document management system in the future. Employees are trained to the appropriate SOPs for their job functions. The Quality Management System shows an appropriate level of control for the operations. Security, document control, version control and accountability are under the scrutiny of both the quality unit and the C-suite management.

All areas designated to store drug products are temperature controlled and humidity monitored. All temperature and humidity recorded are well within USP specifications. The HVAC and electric systems required for refrigerated storage are backed up with a 5 day (minimum) supplied diesel generator.

Temperature, humidity, and security footage are available in real time and accessible via the internet at any location. Monitoring systems are set to alarm and notify management and select users through email, text, and phone call outs. The alarms are set at levels still within specification so that corrections can be made before going out of specification. The local environmental conditions and potential natural disasters have been considered in risk analysis and disaster recovery planning.

AdiraMedica has acknowledged that the existing designated facility will need to be expanded to meet the projected year 3 needs of the program and is already in planning to meet those needs. Additional software solutions are also being investigated to help streamline operations as volume scales. These include a Warehouse Management System and the expansion of the already used Serialization System to support in-house relabeling activities.

Recommendations

AdiraMedica has demonstrated sufficient capacity, knowledge and expertise to provide the warehousing, re-labeling, and distribution services required to fulfill the role of an Importer in support of the Colorado HCPF drug re-importation project under Colorado's Section 804 Importation Program. The company is already a known and active member of the industry providing services across the United States. Additionally, sister AdiraMedica companies are set up globally to provide additional support as needed. Korber Pharma Inc. is confident that they can adequately provide the services necessary to successfully execute Colorado's Importation Program. We would endorse the Colorado Dept. of HCPF selection of this vendor.

Sincerely,

Tyler Foley

Principal Consultant

RC Kennedy Consulting
208 Holmard St
Gaithersburg, MD 20878
www.rckennedysc.com

AdiraMedica Visit
08/04-05/2025

Background

RCK Consulting specializes in inventory and warehouse management systems with particular expertise and experience in the distribution of pharmaceuticals. Bob Kennedy of RCK Consulting has participated in systems implementations for many of the world's largest pharmaceutical manufacturers, wholesalers, distributors and 3PL's. RCK has been participating in a consulting role in support of the Colorado Importation program.

General

A team representing the Colorado Importation Program visited AdiraMedica in Aston, PA on August 4th and 5th, 2025. The purpose of the meetings was to conduct a review of their business and operations in consideration of Adira's participation as an importer/distributor for the Colorado Importation program. RC Kennedy participated in the meetings for a general assessment of the operations and facility and particularly to assess Adira's readiness regarding warehouse best operational practices, processes and systems.

Participants included:

Adira

Sharon Johnson	Ops Manager
Jackie Fox	Consultant
Alex Santos	VP Clinical Trial Services
Doris Correa	Quality Assurance
Arvind Bhandari	President and CEO

Colorado

Kelly Swartzendruber	Program Manager
Bob Kennedy	Consultant
Tyler Foley	Consultant Koerber
Robert Nagy	Consultant Koerber
Theresa Chua	Consultant Rocky Mountain Poison & Drug Safety (RMPDS)

Adira is a pharmaceutical sourcing firm touting a global reach for the sourcing of drugs. The firm is based in Clark, NJ, with offices in the Philadelphia area, Toronto, Canada, area, Ireland, Australia, India among other locations. Their primary business is sourcing active pharmaceutical ingredients, finished dosage forms, raw materials, intermediates, and excipients. A core part of their business is to support clinical trials. Currently, the Aston facility is dedicated to clinical trials, specifically, to sourcing comparable drugs. For the Colorado program, Adira is prepared to extend the use of the facility for the storage and distribution of imported drugs.

Aston Facility

There is a more detailed summary of the facility is included in a separate report from Koerber. The Aston facility will more than accommodate the addition of the importation business for Colorado at least for the short term. The facility is clean, well-lit, and protected with security cameras placed inside the facility as well as on the outside perimeter. Access to the warehouse is restricted by keypad locks. The main warehouse consists of approximately 10,000 SF of space, with pallet racking (four levels) and shelving. There is a separate caged storage area and significant refrigeration space. The facility is temperature controlled. There are also separate rooms under security control for labeling and relabeling of products.

Given the nature of the clinical business, inventory comes through the building in waves to support the timing of the clinical trial. Very little inventory stays in storage for any extended period of time. In general, the facility was well-lit, clean, and organized.

Under normal operations, there are 12 workers in the warehouse. When there are increases in volume due to the size of the particular trial, the workforce will be augmented with 4-5 additional temporary employees.

System

Due to the nature of the Aston site as a clinical trial operation, management of operations and of inventory is mostly done manually using a well-structured and documented process. This process has been reviewed and audited by the US DEA and the Pennsylvania Department of Health Board of Pharmacy and can remain in place, adapted for the commercial operation, for the short term and expected low volume. Further, Adira has been audited by several of their customers.

Adira is planning the purchase and use of a WMS system to extend their capabilities to provide the operation with additional best practice features and functions common to pharmaceutical distribution and support the Colorado program needs. These upgraded functions will provide:

- extended abilities to attach an electronic status records to product
- electronic records of order shipment history
- electronic records of receipt history
- extended capabilities to manage recalls and returns
- Improve accuracy of products in receipt and order fulfillment
- Support existing QA policies and procedures

Adira is rolling out the TrackTraceRX system for DSCSA compliance for serialization. Currently the staff is under training and expects to begin utilizing the system in the near future. TrackTraceRX is a commercially available product designed specifically for DSCSA compliance and has wide adoption in the market. The system has serial number capture capabilities using mobile computers and acts as a VRS. According to their web-site, the company 100,000 trading partners.

Documentation

Adira has a comprehensive and complete set of printed and electronic Standard Operating Procedures (SOPs) that are well-maintained and organized. As Adira extends their business into commercial storage and distribution, they recognize that there will be an effort to be undertaken to add and update the set of SOPs. That process has commenced.

Summary

Adira is a highly capable drug distribution company as discovered in prior meetings with them. The Aston facility will meet the compliance and volume demands of the Colorado program in the early years of the program. The staff is highly experienced and long-tenured. Adira's plans for WMS implementation and SOP expansion will support the Colorado program well. RCK will continue to support AdiraMedica with the WMS implementation.

Summary Report of Rocky Mountain Poison and Drug Safety Pharmacovigilance Audit

24 JUNE 2025

Authored By	Reviewed By
Izi Bruker PhD, MPH Fellow, Clinical and Regulatory Affairs Kymanox 430 Davis Dr. #300 Morrisville, NC 27560 Main: 919 246 4896 Mobile: 781 856 5833 Izi.bruker@kymanox.com	Lauren Winstead Manager of Compliance Kymanox 430 Davis Dr. #300 Morrisville, NC 27560 Main: 919 246 4896 Mobile: 252 532 4746 Lauren.Winstead@kymanox.com
(Signature / Date)	(Signature / Date)
Signed by Izi Bruker Izi Bruker I am the author of this document 14-Jul-2025 | 10:49 AM EDT 949C534E5CB341C09B892E158A3342DC	Signed by Lauren Winstead Lauren Winstead I approve this document 14-Jul-2025 | 11:05 AM EDT 44092B475B5643FAA8C446930B45CD0D

1 Executive Summary

Kymanox, on behalf of Koerber Pharma Inc. performed an audit of Rocky Mountain Poison and Drug Safety (RMPDS) located at 1391 Speer Blvd UNIT 600, Denver, CO 80204 on June 24, 2025. The audit was conducted in person. The audit was a scheduled audit with an emphasis on Pharmacovigilance (PV) for purposes of importation of drugs from Canada as per 21 CFR part 251 –Section 804 and Colorado's description and requirements of the program as per https://hcpf.colorado.gov/drug-importation.

During the audit, compliance of the PV process and SOPs to the relevant FDA regulations and guidance documents, as well as the procedures (Quality Assurance, Personnel, Training, Business continuity, Data Integrity and access) supporting the PV program were reviewed.

All items in the agenda (see attachment) were covered through in person interviews, review of presented and/or uploaded documentation, and SOP reviews.

Ideagen is the eQMS utilized. The QMS is ISO 9001:2015 certified. The audit of the QMS system which included PV has been completed in May of 2015. There were no observations, and the certificate is in progress.

Kymanox review of the Internal Audit SOP and documentation did not identify any issues.

Kymanox review of the Training SOP and records did not identify any issues.

Kymanox review of the MedDRA Training to the latest version did not identify any issues.

Kymanox review of CLINEVO PV database audit by RMPDS did not identify any issues.

Kymanox review of Change Control, CAPA and Risk Management Methodology identified potential process improvements regarding assessment of risk and rationale for opening a CAPA by providing additional guidance to authors and reviewers to ensure longitudinal consistency throughout the process between departments and employee turnover.

The PV Workflow elements that are contracted by the State of Colorado to be performed by RMPDS were reviewed. The review included the following elements:

- Case Intake
- Adverse Events
- Product Complaints
- MedDRA coding
- Aggregate Reporting
- Reconciliation
- Outbound Communication

There were no compliance issues identified.

The Medical Reviewers could not be interviewed as they had not yet started their assignment.

It is recommended that the effectiveness of determination of “causality” and “severity” and expectedness prior to Medical Review be assessed as a Key Performance Indicator (KPI).

The functionality of the PV database provided by CLINEVO was reviewed by inspecting test cases of the User Acceptance Testing (UAT) verification acceptance criteria and test results. There were no issues identified with the verification testing which covered all the necessary tasks assigned to RMPDS.

Data Integrity audit agenda of the PV system during October 16-17 2024 was provided for review. The process for access to software and data as per job descriptions and roles were reviewed. No issues were identified.

Project Plan for PV implementation that started on 01NOV2023 has been completed 100% in 2025.

In general, there was uncertainty as to the assignment and responsibility of the tasks listed in the SOPs. It is recommended that the RMPDS SOPs be reviewed and assignment of responsibilities to departments, or job functions be clarified**.**

The audit resulted in the following findings:

- 0 Critical findings.
- 0 Major findings.
- 0 Minor findings
- 4 Recommendations

As a result of the audit, Kymanox, on behalf of Koerber, considers RMPDS to be acceptable as a potential supplier of Pharmacovigilance Services.

2 Audit Location

1391 Speer Blvd UNIT 600, Denver, CO 80204.

The audit was conducted in person by Izi Bruker. Marina Pranda participated virtually

3 Type of Audit

☒ Scheduled ☐ Non-Scheduled

☐ Due Diligence ☒ Qualification ☐ Routine ☐ For-Cause

☐ Other (Explain): _____

4 Participants

4.1 Auditees (RMPDS)

Name	Title/Function
Linda Henderson	Quality Assurance Manager
Lindsey Ayers	Pharmacist Training Supervisor
Theresa Chua	Associate Director, Medical Information
Katharine Colbert	Senior Director of Safety and Pharmacovigilance
Brandon Ensign	Interim Associate Chief Operating Officer
Chandra King	Pharmacist Supervisor of Systems Analysis
Kevin Nork	Associate Director, Pharmacovigilance
Colin Odle	Application Analyst Supervisor
Justin Reid	Project Administrator
Mike Stafford	Application Analyst-I
Nikki Wheeler	Sr. Operations Support Specialist QA
Brandon Arnold	Manager, IT Business Operations

4.2 Auditors (Kymanox)

Name	Title/Function
Izi Bruker PhD, MPH	Fellow, Clinical and Regulatory Affairs/Lead Auditor
Marina Pranda PhD	Clinical Services Specialist/Scribe

4.3 Translators

Translator Name	Title/Function
N/A	N/A

5 Objective

Kymanox, on behalf of Koerber Pharma Inc. performed an audit of Rocky Mountain Poison and Drug Safety (RMPDS) located at 1391 Speer Blvd UNIT 600, Denver, CO 80204 on June 24, 2025. The audit was conducted in person. The audit was a scheduled audit with an emphasis on Pharmacovigilance (PV) for purposes of importation of drugs from Canada as per 21 CFR part 251 –Section 804 and Colorado's description and requirements of the program as per https://hcpf.colorado.gov/drug-importation.

6 Audit Scope

The audit assessed compliance with the following:

- 21 CFR 310.305
- 21 CFR 314.80
- 21 CFR 314.98
- 21 CFR Part 4 Sub part B
- 21 CFR 803
- 21 CFR 806
- 21 CFR Part 11

and,

Relevant FDA Guidance Documents:

- Post-marketing Safety Reporting for Human Drug and Biological Products Including Vaccines (2001)
- Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment (2005)
- Post-marketing Safety Reporting for Combination Products (2019)
- E2B(R3) Electronic Transmission of ICSR Implementation Guide (2022)

7 Acknowledgements

Kymanox would like to thank all participants in the audit for their cooperation, time, and effort during the visit. At no time during the audit did any personnel appear to intentionally misrepresent themselves or the company. Additionally, all personnel acted and behaved in a manner consistent with attempting to perform due diligence in meeting all applicable compliance statutes.

8 Company Overview

Established in 1956, Rocky Mountain Poison and Drug Safety (RMPDS) has evolved into a globally recognized provider of medical information and pharmacovigilance services. Since expanding into the pharmaceutical industry in 1995, RMPDS has become a trusted partner for medical and drug safety services worldwide.

RMPDS is headquartered in Denver, CO and operates a 21,661 square foot facility that houses both its administrative offices and call centers. The organization employs 112 professionals and has had no turnover in the last twelve (12) months.

RMPDS is structured around three strategic pillars:

- Medical Information
    - Contact Center – Product Complaint and Adverse Event Intake
    - SciMax MI Database
- Pharmacovigilance and Post-Market Surveillance (PMS)
    - Global Safety Database
    - Periodic Reporting
    - ICSR FDA Submission
    - Web Monitoring Services
    - Clinevo Safety (cloudbased, AI enabled drug safety system)
- Support Teams (including IT, Quality Assurance, and Finance)
    - Ideagen Software – eQMS
    - Workday Learning – Training on Controlled Documents and RMPDS programs

The company delivers services across 62 countries on all seven continents, providing local language translation capabilities to support global operations. There have been 30 client audits over the past two years with no critical findings.

9 Audit Summary

9.1 Certificates and Prior Audit History:

RMPDS is ISO 9001: 2015 Certified for Medical Information Contact Center

RMPDS PV was added to the certification scope for 2025, and the audit was completed 29MAY2025. Certificate is pending.

FDA audit history (2003-2015) was reviewed. FDA issued 483 to RMPDS in 2015. There were two observations, one for CAPA system lack of evaluation the impact of activities with other clients and the second one regarding lack of a complaint procedure to identify and handle business process complaints from clients. Both were addressed and resolved (FDA Audit History and Outcomes Summary- 20023-2025 and FDA 483 Response 03165 Final). There has not been an audit of RMPDS by the FDA since 2015.

No issues were noted during the review of the Certificates and Past Audit History.

9.2 Internal Audits

The SOP RMPDS Internal Audit Procedure 2627.7, effective date 09JUN2025 was reviewed.

The redacted Internal Audit schedule effective date 11JUN2025 was reviewed (2025 Audit Schedule as of 06.11.2025_COI_Redacted.pdf). Agendas for the QMS full system audit that took place on May 6-7, 2025 and May 13-15, 2025 (IA2505039_2025 and IA 2505040_2025 respectively) were reviewed. The audit schedules had the initials or first names of the Quality Department Personnel responsible for the review and reviewees were noted. The SOPs that were subject of the audit were also noted on the agenda.

The full audit plans were written on RM FORM 2696.6 Effective Date 28APR2024 for both audits. Audit purpose, auditor names, auditee names, place, timing, and detailed agenda were included. Internal Audit Observation and Non-Conformance Action Tracking Report Log RM Form 3931.3 Effective Date 24 May 2023 was reviewed. Description of findings, Root Cause, Risk level, Action Plan and Closure were included. All Finding were closed.

No issues were noted during the review of the audit program.

9.3 Training

RMPDS Training Requirements by Job Function PV FORM 4414.4 Effective Date 07FEB2025 for Director of Pharmacovigilance, Associate Director, PV Specialist, Pharmacist Supervisor of Systems Analysis, Pharmacist Supervisor of Training, and Clinical Nurse Educator were reviewed. Training records for Kevin Nork – Director of Pharmacovigilance, Dr. Andrew Monte – Medical Director, Angel Coffey – PV Associate, Jennifer Lindroos – RN Trainer, and Katherine Holbert – Sr. Manager of Safety and PV were checked against requirements.

Training records for Justin Reid, Project Administrator, QA who recently joined RMPDS were reviewed for 30-day training compliance as per SOP 2624.8 Training, effective date 24MAY2024. Assigned training on SOP 2612.5 Record Digitization, SOP 2625.3 Client Audit Program, SOP 5563.2 Electronic Signature Request were verified to be completed.

GCP training is performed through the CITIPROGRAM and is performed every three years, the same program used by the U. of Colorado.

Medical reviewers will be trained on the SOP for PV Training 5113.3 on 24JUL2025. The medical reviewers are appointed in June of 2025 and start in July 2025.

No issues noted during the review of training.

9.4 Quality Oversight and Audit of Vendors

RMPDS Quality Oversight SOP 5112.3 Effective Date 13DEC2024, was reviewed. Section 3.1.2. identification of appropriate metrics to measure and monitor RM PV performance was discussed. According to RMPDS the requirements for reporting by RMPDS is in the contract with The State of Colorado (effective 25APR2025 -not shown) as per SOP 5121.2 PV Safety Data Exchange Agreements, Effective Date 16DEC2024. Expedited ICSR submission to the FDA within 15 calendar days is set to 100% conformance.

RMPDS Corrective and Preventive Action Procedure SOP 2629.8 Effective Date 09JUN2025 was reviewed. The CAPA process is described in section 6.0 and the responsibilities are described in section 4.0. The rationale for opening a CAPA, described in section 4.0 as a QA responsibility is described as a determination of CAPA "worthiness" and parameters either qualitative or quantitative are not outlined.

Recommendation 1: The parameters for CAPA "worthiness" could be described in the SOP or examples can be given as guidance for opening a CAPA.

RMPDS Risk Management Methodology SOP 2633.4 Effective Date 04JUN2025 was reviewed. The Risk management Heat Map which is a matrix of Probability (likelihood and/or frequency of occurrence) and Impact (Consequences, severity) was reviewed. The Heat Map categorizes the risks in the matrix as acceptable, action required, under review, closed, and N/A. The SOP did not have information as to how qualitatively or quantitatively to judge probabilities as well as Impact.

Recommendation 2: The ranges for probabilities of occurrence and description of impact (severities) be included in the SOP or in a work instruction to achieve consistency between teams and personnel performing risk analysis.

9.5 Workflow

9.5.1 Case Intake

RMPDS SOP Pharmacovigilance Intake 5107.4 Effective Date 16JUN2025 was reviewed. The processes for data entry, coding, causality and determination of seriousness were reviewed. The differences between the responsibilities of the PV Associate, PV Specialist, Director of PV and Medical Director were discussed. The process for follow-up in case of missing or unclear information is described in section 6.3. For cases requiring follow up, three (3) attempts are required. The responsibilities of RMPDS for reporting to the State of Colorado, and Premier Pharmaceuticals was discussed. Combination product (drug-device) case intake and reporting requirements were discussed in section 6.11.

The initial assignment of causality and expectedness is assigned to the PV specialist and later reviewed and confirmed by the Director of PV and the medical director. There is no client review of the classification.

Recommendation 3: Establish changes to the expectedness and causality determination of the PV specialist by the Medical Director as a Key Performance Indicator to provide feedback and training opportunity.

ICSRs will not be routed to the State, however, the State would be receiving quarterly de-identified line reports from RMPDS. Since the program for drug importation had not commenced, the Case Intake process in operation could not be assessed.

9.5.2 MedDRA Coding of Adverse Events

RMPDS SOP Pharmacovigilance MedDRA Coding Conventions and Dictionary Management 5111.4 Effective Date 16JUN2025 was reviewed.

The latest MedDRA revision v 28.0 has been validated in the PV database for RMPDS as of April 2025. The Pharmacy Training Supervisor (Lindsay Ayers) has been trained on the latest MedDRA version. RFI-11 RMPDS (UC) PV What's New with MedDRA v28.0-V1.pdf shows the completion of Lindsay Ayers' training on the newest MedDRA version. The Medical Reviewers will be trained on the latest MedDRA version in July of 2025.

RMPDS SOP PV Downtime Handling of Adverse Events 5110.3 Effective Date 16JUN2025 was reviewed. In section 3.0 of the SOP Responsibilities are listed, however, it is not clear as to which RMPDS staff or department is responsible for the tasks. This uncertainty has been observed on other SOPs.

Recommendation 4: Review RMPDS SOPs and clarify assignment of responsibilities to departments, or job functions.

9.5.3 Product Complaints

RMPDS SOP PV Product Quality Complaints 5123.3 Effective Date 25FEB2025 was reviewed. In general, RMPDS clients have their own quality program. In the case of the drug importation program retrieval of product is not assigned to RMPDS.

No issues were noted.

9.5.4 Aggregate Reporting

RMPDS SOP PV Aggregate Reporting 5109.4 Effective Date 16JUN2025 and RMPDS SOP PV Safety Data Exchange Agreements 5121.3 Effective Date 16JUN2025 were reviewed. As per the SDEA between the State of Colorado and RMPDS, Colorado does not receive individual ICSR forms but a quarterly line listing of AEs. The SOP reporting process is in line with FDA reporting requirements. There are no requirements for reporting to Health Canada. Reporting requirements are also described in SOP 5107.4 and are consistent.

No issues were noted.

9.5.5 Signal Detection, Escalation, Literature Search

These services will not be provided to the for the drug importation program as per the contract. No review was performed.

9.6 Validations, Data Protection and Business Continuity

9.6.1 Validations

9.6.1.1 User Acceptance Testing Performance Qualification Document Clinevo® Safety System:

Performance Qualification Report RDS_VAL_PV_PQ_005 for User Specification Document RDS_VAL_PV_URS_001.

Test cases reviewed during the audit: Case Registration and Data Entry, Case processing Quality Review, Case Processing Medical Review, Electronic Submission, Archival, Follow-up, Case Nullification, Case Import, ICH PSUR, Aggregate Report NDA/ANDA, Line Listing, Audit History, Case Delete, Cases in various Stages, Case Processing-Manual Submission. All cases passed and there were no deviations. Approved on 29SEP2024 by Linda Ayers, Kevin Nork, Theresa Chua and Pam Wagner.

9.6.1.2 Clinevo MedDRA Upgrade 2025 Change Control

Document ID VAL 10229 FORM 5448.2; Purpose: Clinevo® System, MedDRA upgraded to version 28.0; Signed 30APR2025

Document ID VAL 10230 FORM 5449.2; Purpose: Results from execution of the Clinevo® MedDRA upgrade v28.0; Signed 14MAY2025

No issues noted.

9.6.1.3 Clinevo Audit Agenda Screen Shot:

RFI-12 Clinevo -Proof Data Protection Audit October 16-17, 2024: IT Processes (Privacy, Business Continuity and IT Security), 21 CFR Part 11 Compliance, GDPR Compliance.

9.6.1.4 Project Plan for PV Implementation:

RFI-13 Project Plan for PV Implementation screen shot shows:

Project start on 18OCT2022

Project name DC/PV RFP and Implementation 2024

Project Status as green

Completion 100%

Year closed 2025.

9.6.2 System Access

System access to the PV database is granted by the IT administrator. Department head sends a service request to the IT team. New users are added with specific access depending on job function. The access rights are managed through HR with Workday® cloud-based enterprise management software.

No issues were noted during the review of system access.

9.6.3 Business Continuity

RMPDS SOP PV Business Continuity Plan 5630.1 Effective Date 13DEC2024 was reviewed. Appendix A describes the tasks according to severity of downtime while appendix B defined the severity of the downtime. The Medical Director and Sr. Manager of Safety and PV training on SOP PV Downtime Handling of Adverse Events 5110.4 Effective Date 16JUN2025 was confirmed through their training records.

The redundancy has been built for systems that are used to handle incoming medical information, as well as database utilization. There are multiple power surge and backup systems, two different network providers, and quarterly disaster recovery exercises. Additionally, as described in the Company Overview there are 2 (two) state-of-the-art Data Centers 16 miles apart to provide 99.999% availability for the PV database and system with temperature and humidity control.

No issues were noted.

10 Classification of Audit Observations

Findings are presented in this report in the following manner:

10.1 Critical Findings

Critical findings are observations where there are clear, evident, and serious violations that directly compromise the quality of the product, the safety of the patient, the authenticity of the data, and/or do not respect the fundamental regulatory body requirements. Critical findings require immediate intervention.

10.2 Major Findings

Major findings are observations which could indirectly or over time negatively influence the quality of the product or the data, therefore negatively influencing the safety of the patient. Major findings may be indicators of a deficiency in the quality management system and require prioritized interventions.

10.3 Minor Findings

Minor findings are observations that do not directly influence the quality of the data, product, or the safety of the patient yet could bear an influence over time if not corrected. Minor findings require only low priority interventions.

10.4 Recommendations

Recommendations are not a category of nonconformity; however, they are suggestions regarding aspects of the quality management system that could be improved.

11 Audit Observations

11.1 Findings

There were no critical, major or minor findings.

11.2 Recommendations

Recommendations ID #	Recommendation Description
1	It is recommended that the parameters for CAPA “worthiness” could be described in the SOP or examples can be given as guidance for opening a CAPA.
2	It is recommended that the ranges for probabilities of occurrence and description of impact (severities) be included in the SOP or in a work instruction to achieve consistency between teams and personnel performing risk analysis.
3	It is recommended that changes to the expectedness and causality determination of the PV specialist by the Medical Director established as a Key Performance Indicator to provide feedback and training opportunity.
4	It is recommended that RMPDS SOPs be reviewed to clarify assignment of responsibilities to departments, or job functions.

12 Conclusion

The audit resulted in 0 Critical findings, 0 Major findings, 0 Minor findings, and 4 Recommendations. As a result of the audit, Kymanox, on behalf of Koerber, considers the Rocky Mountain Poison and Drug Safety located at 1391 Speer Blvd UNIT 600, Denver, CO 80204 to be acceptable as a potential supplier of Pharmacovigilance Services for the drug importation program of the State of Colorado.

13 Attachments

Attachment 1: Agenda: Audit of RMPDS by Kymanox on Behalf of Koerber, 24JUN2025

14 Appendices:

14.1 List of Documents Reviewed

Document ID/Number	Document Title	Version Number/Date
SOP 2627.7	RMPDS Internal Audit Procedure	09JUN2025
SOP 5112.3	RMPDS Quality Oversight	13DEC2024
SOP 5121.2	PV Safety Data Exchange Agreements	16DEC2024
SOP 2629.8	RMPDS Corrective and Preventive Action Procedure	09JUN2025
SOP 2633.4	RMPDS Risk Management Methodology	04JUN2025
SOP 5107.4	Pharmacovigilance Case Intake	16JUN2025
SOP 5111.4	Pharmacovigilance MedDRA Coding Conventions and Dictionary Management	16JUN2025
SOP 5110.3	Pharmacovigilance Downtime Handling of Adverse Events	16JUN2025
SOP 5123.3	Pharmacovigilance Product Quality Complaints	25FEB2025
SOP 5109.4	Pharmacovigilance Aggregate Reporting	16JUN2025
SOP 5121.3	Pharmacovigilance Safety Data Exchange Agreements	16JUN2025
SOP 5630.1	Pharmacovigilance Business Continuity Plan	13DEC2024

14.2 List of Records Reviewed

Record Description	Record Identifier
HCPF Audit Presentation Jun2025_v4_Final.	RFI 07 24JUN2025
FDA Audit History and Outcomes Summary (2003-2015)	22JUN2025
FDA 483 Response 031615 Final-Redacted	22JUN2025
2025 Audit Schedule as of 06.11.2025_COI_Redacted.pdf	11JUN2025
Agenda Audit QMS Full System May 6-7, 2025	IA2505039_2025
Agenda Audit QMS Full System May 13-15	IA2505040_2025
Audit Plan Form 2696.6	28APR2024
Internal Audit Observation and Non-Conformance Action Tracking Report Log RM Form 3931.3	24MAY2023
RMPDS Training requirements by Job Function PV Form 4414.4	07FEB2025
Training records Kevin Nork, Dr.Andrew Monte, Angel Coffey, Jennifer Lindroos, Katherine Holbert	RFI-9 Training Records Requested 24JUN2025
Training records for Justin Reid, Project Administrator, QA	SOP 2612.5, SOP 2625.3, SOP 5563.2
Lindsay Ayers Training Record: RMPDS(UC) PV What's new with MedDRA v28.0-V1.pdf	RFI-11 24JUN2025
RDS_VAL_PV_PQ_005 Performance Qualification Report for User Specification Document Clinevo Safety Database	29SEP2024
RDS_VAL_PV_URS_001 User Specification Document Clinevo Safety Database	Not Captured
VAL 10229 FORM 5448.2 Clinevo System, MedDRA upgrade to v28.0, 30 APR2025	RFI-10 24JUN2025
VAL 10230 FORM 5449.2 Results from execution of the Clinevo MedDRA upgrade v 28.0, 14MAY2025	RFI-10 24JUN2025
Clinevo audit Agenda Screen Shot IT processes (Privacy, Business Continuity, and IT Security) and 21 CFR Part 11 Compliance, GDPR Compliance, October 16-17, 2024	RFI-12 24JUN2025
Project Plan for PV Implementation Screen Shot	RFI-13 24JUN2025

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LDT Health Solutions, Inc.
38 Cedar Place
Wayne, NJ 07470
862. 221.9575
www.LDTRx.com

6.20.24

Report to:

Colorado Dept. of Health Care Policy & Financing / Pharmacy Office **(the "Client")**
1570 Grant Street, [State Relay – 711]
Denver, CO 80203
Attn: Dr. Kelly Swartzendruber, Pharm.D. – Drug Importation Pharmacist

Re:

Q Laboratories
1930 Radcliff Drive
Cincinnati, OH 45204-1823
(513) 471-1300
www.qlaboratories.com

DUNS # 0807377501
FEIN # 1527260

Overview

LDT Health Solutions Inc. ("LDT") is a medication safety & quality management consulting firm specializing in compliance programs and independent review activities related to the production of compounded preparations, regulatory compliance, including FDA matters, and other specialty areas of pharmacy practice. Our principals have over 70 years of experience in multiple healthcare settings. Our current consulting work includes FDA approved manufacturers, 503B Outsourcing Facilities, and hospitals.

LDT Health Solutions, Inc. was engaged to provide consulting services to the Client to facilitate the Client's contract decision regarding the importation wholesaler / distributor model by verifying the continued activities related to that project by the contract laboratory named above to assist in this pre-implementation phase of the project.

LDT inspected visit to this laboratory to assist in evaluating the quality, scope, and regulatory compliance, of the laboratory. As well as to assist in analyzing the contracted services required by any importation partner or contractor engaged in this drug importation program to access their operations and related compliance issues in connection with the State importation system.

Observations & Findings

The following characterizations of the operations and physical plant conditions currently at Q Laboratory LLC were made by direct observation, and document review provided by the lab's quality staff and were used as a basis for this report.

General Scope-

The following LDT intellectual properties, Federal regulations and other guidance documents were utilized by LDT to facilitate its determination of continued regulatory compliance:

1. LDT's document (12-01A.01) **ISO/IEC 17025**[1] General Accreditation Requirements Compliance Crosswalk -
    a. Covering the following required areas-
        i. General
        ii. Confidentiality
        iii. Structural
        iv. Personnel
        v. Record retention
        vi. Facilities and Environmental Conditions
        vii. Equipment
            1. Metrological Traceability
            2. Traceability of Results
            3. Externally Provided products & services
        viii. Process (controlled)
            1. Requests, tenders, and contracts
            2. Selection, Verification, and validations of Methods
            3. Validation of Methods & record retention
            4. Sampling plans
            5. Handling of tests and calibration of items
        ix. Technical Records
        x. Reporting of results
            1. Conformity statements
            2. Amendments to reports
        xi. Complaints
        xii. Non-conforming work
        xiii. Data control and Information Management
        xiv. Control of Management System Documents
            1. Internal audits & findings
            2. Management reviews & reporting

2. Compliance to applicable federal statues, rules, and regulations governing analytical laboratories, as described by the Drug Quality & Security Act (DQSA)[2] and the applicable sections of the USP/NF and the Federal Food Drug & Cosmetic Act (FDCA).
    a. **Colorado Senate Bill 19-005**, passed in 2019, the Department of HealthCare Policy & Financing (Department) / Canadian Prescription Drug importation program.

[1] ISO 17025 - https://www.iso.org/ISO-IEC-17025-testing-and-calibration-laboratories.html
[2] https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa

b. Compliance with relevant FDA Guidance documents for Reference Laboratory Establishments.
c. Compliance to Local Department of Health Regulation in the jurisdiction the laboratory is registered (Ohio).
d. Review of policies and procedures relating to receiving, processing, storage, security, holding, and processing of drug inventory samples (as applicable).
e. Review of compliance with relevant recordkeeping requirements, including sampling of current operation files.

Findings & General Impressions of Current Q-Labs Operations –

Utilizing the provided documents listed below, in advance of the visit and additional documents which were requested by LDT on-site to complete the assessment of compliance required by the statement-of-work agreed to by LDT and the Colorado Dept. of Health Care Policy & Financing / Pharmacy Office.

These documents were, in part:

1. A copy of the complete table-of-contents of the policy manual for the lab.
2. A copy of a new employee orientation/training checklist (new hire)
3. A copy of an annual employee training checklist
4. A copy of the firm's table of organization.
5. A floor plan of the entire space including the processing area(s)
6. Two (2) lab technician training files
    a. The newest employee
    b. A tenured employee
7. Temperature, Humidity, & Pressure Logs for the last 30 days.
8. Cleaning Logs for the last 30 days.
9. A copy of any open correspondence with any state, federal or local licensing authority.

The laboratory was most cooperative, and all records requested were made available in short order and those documents were in good order and complete. LDT did request the following documents as representative of the scope, quality and completeness of the information provided:

1. A summary of Q Labs LLC quality operations, services, and a description of the organization, structure & scope of business. (Site Master File)[3]
2. A complete table of contents of standard operating procedures (Policy & Procedures)[4]
3. Current floor plans of Q-labs production building (levels I & II) for reference. [5]

The documents revealed an FDA registered establishment in good standing holding an ISO 17025 accreditation *(most recently conducted 2023).* They have no open or unresolved issues with FDA. Their applicable state registration (OH) is in good standing and current.

The site is of suitable size and construction to accommodate current operations and appears to have sufficient unutilized space to accommodate some increased production volume. Discussion with

[3] ATTACHMENT ONE - Q-Labs site master file
[4] ATTACHMENT TWO – Q-Labs SOP TOC
[5] ATTACHMENT THREE – Q-Labs Floor plans (level I & II) 1911 Radcliffe Drive, Cincinnati, OH 452204

ownership revealed a future expansion plan that includes development of adjoining real estate which is already owned and controlled by Q Labs LLC.

The lab maintains its major equipment in good repair and all requisite independent calibrations and certifications were evident. Evidence of regular cleaning, maintenance, and calibration of equipment in-use was apparent. Furthermore, there is evidence of continued investment in new and expanded instruments and equipment.

Q-labs only sub-contracts lab work outside its organization if a customer requests it, or if the lab is temporarily unable to perform the necessary work, and only after specific approval by the customer.

Critical documents, including policy & procedure, and master work instructions are properly maintained, and secure. Document control is all maintained electronically. Quality Management System shows a high level of control, sophistication, and is well developed for the operations. Security, documents control, version control and accountability are maintained electronically and under the scrutiny of both the Quality Unit and C-suite management.

It is apparent that the company invested in physical plant construction continues to invest in the maintenance, upkeep, and expansion of the business. Along with that investment in capital equipment, Q-labs continues to invest and provide an orientation, training & development program for employees which is broad and on-going and appears to be sufficient to support current operations.

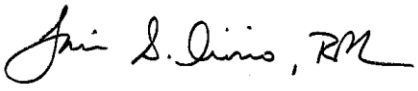
FINAL DETERMINATION OF COMPLIANCE & SUITABLITY OF SERVICES-

Q-Labs LLC appears to have sufficient capacity, knowledge, and expertise to provide the technical services required to support this drug importation project. The laboratory is currently providing these services to numerous other customers in the Pharma & healthcare sectors without incident. LDT is confident that they can deliver the services to make this program successful.

We continue to endorse the CO Dept. of Health Care Policy & Financing / Pharmacy Office's selection/approval of this service provider to move into the next phase of the implementation of the project.

Thank you for the opportunity to serve you, your staff, and patients.

Very truly yours,



Louis S. Diorio, RPh, FAPhA

Principal

Cc: File

Attachments

Site Master File

Table of Contents

1. Scope

This Site Master File (SMF) is a version-controlled document that describes the structure of Q Labs' organization, the site and facilities, the testing activities carried out, and the details of how the Quality Management System (QMS) functions to ensure data integrity.

2. Purpose

The purpose of this document is to provide an overview of the facilities and operations of Q Labs LLC located in Cincinnati, Ohio. This document describes the activities of the Company to demonstrate that it has a cGMP-compliant Quality System in place. The Quality Unit will review the Site Master File annually or any time the Company makes material changes to its operations.

3. Corporate Authorizations

Q Labs LLC is registered with the U.S. Food & Drug Administration (FDA) as a testing laboratory for pharmaceutical products, over-the-counter (OTC) drugs and cosmetic products. Since moving to electronic registration, FDA has begun utilizing Data Universal Numbering System (DUNS) numbers in combination with Facility Establishment Identifier (FEI) Numbers. DUNS Number for Q Labs is 080737501, and its FEI Number is 1527260. Q Labs LLC is current with its FDA registration as a drug establishment. The organization is currently ISO 17025 accredited through the A2LA accreditation body. The most recent FDA inspection was November 14-21, 2019. There are no unresolved regulatory issues. Registrations with applicable State and Federal regulatory agencies are current and in good standing.

4. Product Services

Q Labs LLC is a full-service contract testing laboratory for food, pharmaceutical, personal care products, cosmetic, medical device, animal health and dietary supplement industries. Testing services include microbiology, analytical chemistry, method development/validation and research & development support. Q Labs does not currently provide testing for Drug Enforcement Agency regulated products.

5. Facility Location Description

Q Labs facilities are located within the city limits of Cincinnati, Ohio. The testing laboratory site is bounded by residential neighborhoods, business sites and government property.

Q Labs currently operates at the following locations:

- **1911 Radcliff Drive, Cincinnati, Ohio, 45204** (30,000 ft_2), on two levels to include microbiology and analytical chemistry laboratories.
- **1930 Radcliff Drive, Cincinnati, Ohio 45204** (15,000 ft_2), this building includes microbiology R&D, stability chambers, quality department, sales/marketing department, sample distribution and IT**.**
- **1920 Radcliff Drive, Cincinnati, Ohio 45204** (10,000 ft_2), includes administrative support (executive offices, HR, finance, purchasing), facility engineering support, and receiving warehouse for supplies.

6. Company History

Q Laboratories was founded in 1966 by Herbert Quinn. The "Q" in the company name represents the founder. Mr. Quinn originally operated a small microbiology laboratory testing mostly water.
In 1985, Michael Knight, a former FDA investigator, bought the company from Mr. Quinn and moved it into a facility in the South Fairmount neighborhood of Cincinnati. Mr. Knight leveraged his FDA background to expand the services offered to include testing of food, pharmaceuticals, cosmetics and dietary supplements. He also opened the analytical chemistry department, implementing GMP quality standards throughout the operation.
With continued success, Q Laboratories eventually outgrew the South Fairmount facility and, in 1997, moved to 1400 Harrison Avenue. This lab building has a unique place in Cincinnati history. Built in 1911, it comprises over 14,000 square feet of space located in one of the city's oldest neighborhoods, just five minutes from downtown Cincinnati. The building originally housed the offices of the Herancourt Brewing Company, a now defunct brewery that operated in the early 20th century.
In 2000, the business was acquired by David Goins, who at that point served as the Laboratory Director. Growth continued and, in 2010, Q Laboratories opened a new 9,000 square foot addition which allowed for the expansion of laboratory space and a more efficient workflow.
Continued success has required another major facility expansion. In 2017, the company acquired investment capital and began construction of a new Q Laboratories campus – a 25,000 square foot administrative building along with a state-of-the-art, 30,000 square foot laboratory facility. The goal of this latest expansion: Enable Q Laboratories to continue to provide clients with cutting-edge scientific technologies capable of accommodating projects and sample volumes of virtually any size. The 1911 laboratory building was officially opened for business in May 2018.

7. Site Description

Each building is of suitable size, construction, and design to facilitate maintenance, cleaning, and operations. Space is adequate for orderly placement of equipment and testing of materials. Separate or defined areas are maintained to prevent contamination of products during receiving, and testing operations. Each building is maintained in a clean and sanitary condition. Commercial HVAC filtration systems are used to maintain the laboratory environments.

The buildings are adequately secured against entry of unauthorized personnel. Security controls include a 24-hour security system supported by security personnel. All employees are required to utilize badge access to enter the facility. A safety committee operates under the direction of the Chemical Hygiene Officer. The institutional biosafety committee operates under the direction of the Biological Safety Officer. Written policies for safety are established. First aid kits and fire extinguishers are suitably located throughout the buildings. Emergency evacuation maps are posted where necessary. Electronic copies of SDS are also maintained and may be accessed at each company computer through a desktop icon.

Openings to each building are protected against entry by rodents and other pests. Warehouse roll up doors are closed when not in use. HVAC filters in the laboratory area are inspected and changed every two months. There is adequate lighting in the laboratory areas to facilitate housekeeping, safety and operations.

Biological Safety Cabinets (BSC) with HEPA filtration are used for sample preparation in the GMP microbiology laboratory. The BSC are cleaned daily. There are 18 fume hoods and 4 acid hoods in the analytical chemistry area for sample preparation as applicable.

There are several separate laboratory areas for testing operations. The GMP microbiology laboratory has identified separate areas for sample preparation, antimicrobial effectiveness testing, and microbial identification to reduce the potential of contamination of samples. Food Microbiological testing is performed in a separate laboratory area from the GMP testing. The microbiology R&D laboratory is adequately separated from the routine laboratory testing areas. On the analytical chemistry floor, there are separate laboratory areas for food sample preparation, hazardous chemical storage, metals analysis, total organic carbon analysis, chromatography operations, mass spectroscopy operations and analytical R&D.

Staff amenities, including breakrooms and locker facilities, are separate from testing and quality control areas.

Restrooms are maintained and readily accessible in all buildings. They are properly lit and ventilated. Hand-washing facilities are provided and furnish soap, hand dryers, and running water at a suitable temperature. Laboratory personnel are required to remove and hang up their lab coats prior to entering the restroom.

Work instructions (masters) and standard operating procedures address processes for the maintenance of buildings and equipment. A documented environmental monitoring program is maintained. Pest control is addressed through an appropriate SOP. A pest control manual is maintained for each facility. Inspections are conducted by the facilities department. Exclusion measures are adequate for excluding pests from the buildings and for protecting against the contamination of samples. Insect light traps are installed at various locations in the facilities. Pest activity logs are in place. Exterior bait stations are in use.

Attachment 1 – Facility Layout

8. Organization Charts & Department Staffing

Q Labs employs approximately 134 full-time employees and 17 part-time employees. The organization operates 7 days a week regarding routine microbiological testing and 5 days a week for analytical testing. Additional testing hours will be provided on an as contracted basis for client support.

9. Management Responsibilities

Jayson Arling, President, is the most responsible person at Q Labs. Attachment 2 depicts the executive management organization.

There are an adequate number of supervisory and management employees with the necessary qualifications, training, or practical experience. There are organizational charts showing the key positions, as well as their areas of responsibility and lines of authority. Employees in responsible positions have written job descriptions describing their specific duties.

Key personnel include the persons nominated as responsible for Testing and Quality. Full-time personnel occupy key positions. Part-time employees are utilized for support functions within the laboratory and operational groups. Contracted labor is not employed at Q Labs. Personnel identified to perform Quality operations have the necessary independence and authority to ensure that Quality measures are employed in the testing all products. Laboratory personnel performing microbiological and analytical testing are suitably qualified.

Each laboratory have designated quality employees that facilitate data review, quality investigations, and procedural improvements. Q Labs has established the role of Metrologist with the focus on continuous improvement in maintenance, calibration, and qualification support of the laboratory equipment. The stability team lead is responsible for the stability chambers and the associated stability protocols. Document Control is supported by members of the Quality Assurance Unit responsible for controlling master testing forms, client procedures, SOPs and policies.

10. USP Purified Water System

Water used in the preparation of media for microbiological testing is purified to meet current USP requirements using deionization, UV sanitization, and filtration. The system was installed in 2018, has undergone qualification, and remains in a qualified state.

The water for the 1911 purified water system is supplied by the city of Cincinnati through the local municipal piping system. The city water passes through a softener, two carbon beds, two mixed resin beds, a 1-micron filter before it is treated by a UV lamp with bio filter. The purified water is transferred to the storage tank. The storage tank is fitted with a 0.2-micron vent filter. The water exits the storage

tank through a pump to another mixed resin bed which is followed by a 1-micron filter. The water is further treated by a UV lamp and bio filter before distribution to the points of use. The distribution loop circulates back to the storage tank. There are two continuously circulating water distribution lines, one line to the upper level for the chemistry area and one line to the lower level supplying the microbiology labs. Point-of-use (POU) drops are installed throughout each laboratory. The system is sampled monthly at beginning, middle, and end POU's. Chemical (TOC and Conductivity) and microbial alert and action levels are monitored and managed by Quality/Metrology.

The Milli Q purified water system located in the metals laboratory provides USP purified water for all testing performed in the chemistry laboratory area to include elemental analysis and chromatography. The system qualification was completed in September 2019.

11. Quality Management System

Q Labs has a documented Quality Management System (QMS), supported by management, that is well-established and maintained. Adequate resources are provided to achieve each aspect of the system.

- The Quality Management System ensures that managerial responsibilities are clearly defined, documented and exercised
- Testing operations are specified, and good manufacturing and good laboratory practices are followed
- Supplies meet required specifications
- Necessary controls on testing and data are carried out
- Final reports are not released before an authorized person has signed that each sample has been tested in accordance with documented procedures, meets required specifications, and meets all required Quality tests
- Appropriate storage conditions are maintained
- There is a procedure for conducting internal Quality System audits that appraise the effectiveness and application of the QMS.

A system of Quality Control is established to ensure that product testing complies with their required standards. Quality personnel approve all written procedures, tests, and examinations affecting GMP product quality reports.

Q Labs has established a quality manual, a set of Standard Operating Procedures (SOPs) and Masters (forms) to support the Quality Management System. The responsibilities and procedures applicable to the Quality Unit are described in SOP's and the quality manual.

Internal audits are conducted by representatives of the Quality Unit, with each department audited at a minimum of once each calendar year.

12. Resource Training

Employee training requirements are addressed in SOPs that detail job specific training, GMPs, and safety training for personnel. Department managers are responsible for training their employees. Internal training records are maintained by Quality to include the date and type of training, and person(s) trained. Personnel responsibilities related to confidentiality and undue pressure are reviewed annually with the employee.

13. Quality Control & Assurance

Testing supplies/materials are purchased from approved vendors that are periodically reviewed. Supplies are assigned an expiration date to ensure adequate control. Q Labs has established, written procedures for the receipt, identification, testing, and reporting of testing data. Each sample received is issued a Q Labs number (QL#) for traceability. The sample will be assigned to a trained analyst. The analyst will record the testing data on the appropriate master form. The data will be submitted to operations for typing the report. The typed report and raw data will be reviewed by Quality prior to obtaining the Laboratory Supervisors signature on the final report. Test samples are retained for 30 days prior to destruction. All data and associated paperwork are retained for 7 years.

The R&D Labs are responsible for method validations/verifications and GLP studies.

The GMP microbiology laboratory performs various microbial testing procedures on raw materials, bulk, and finished products from clients. Tests are performed against established specifications following validated customer-specified or USP Test Methods. Identification of bacteria, yeasts and mold are performed using the Bruker identification system. The majority of the media is prepared on site by the Media Lab and tested according to written instructions with documentation on the appropriate master. QC tests are conducted on prepared media. Purchased media plates are QC tested prior to use. Microbial testing of the purified water system is performed using membrane filtration and pour plate methods. Microbial alert and action levels are established. Test results are documented. Routine microbial test results for product release are recorded on both the sample master sheet as well as on the laboratory report that is sent to the client. Additional environmental testing is performed to monitor air and lab surface quality in the microbiological labs. Representative sites are sampled for air quality weekly while lab surfaces are sampled weekly to cover all sites within the month.

The analytical laboratory performs various physical and analytical testing procedures on raw materials, bulk, and finished products for clients. Tests are performed against established specifications and the results recorded. All testing is performed according to written Test Methods. Test data is recorded on a laboratory report that is sent to the client. The raw data is maintained for 7 years.

Laboratory management will notify the client and Q Labs Quality Unit of any out of specification (OOS) results in a timely manner of the discovery of the OOS result. Quality will perform an investigation to determine if laboratory error was the root cause. An investigation report will be issued to the client for further investigation and product disposition.

14. Stability

Q Labs provides ICH (International Conference on Harmonisation Regulations) compliant stability services and shelf-life studies. The stability chambers are monitored utilizing continuous monitoring probes. Each chamber is mapped and certified annually. Studies may include weight loss, freeze/thaw, or thermal cycling depending on the product and container closure system. The testing and storage conditions will be outlined in the protocol prepared by the Stability Team Lead.

15. Third-Party Contracts

Q Labs only subcontracts its testing operations when the customer requests it or if the lab is temporarily unable to perform the test. The client must agree to have the test subcontracted. Q Labs will review and submit the final report to the client.

Q Labs utilizes a professional security service to provide the security services described above.

16. Document Control Procedures

Processes and associated activities in the testing of drug and personal care products are documented, and critical documents are subject to a system of document control. Employees are assigned to facilitate Document Control as part of the Quality Unit organization.

Documents are approved, signed and dated by appropriate and authorized persons. Master SOPs are maintained electronically in an electronic Quality Management System, Veeva Quality One Vault. Responsibilities of Quality related to document control include establishing and maintaining Quality policies/procedures, as well as retiring and archiving obsolete procedure. Master documents used to document test data are controlled forms managed by Quality. SOPs are reviewed, at a minimum, every 3 years. The results of the review are recorded.

17. **Data Integrity Program**

The Data Integrity Program is intended to ensure the integrity of data, across the data lifecycle from creation through long-term archival, used to make safety, efficacy, quality and regulatory compliance decisions at this site. The Data Integrity Plan for Q Labs LLC is intended to align with current US FDA, Health Canada, MHRA, and World Health Organization guidelines for a risk-based approach and a data lifecycle concept as they pertain to data integrity and computerized systems validation.

REVISION HISTORY:

Rev	Date	Section	Changes
7	10/25/23	7	Clarified BSC cleaning process
7	10/25/23	8	Updated full-time employees to 134 and part-time employees to 17.
7	10/25/23	9	Replaced Jeff Rowe with Jayson Arling as most responsible person at Q Labs.
7	10/25/23	16	Noted that SOPs are now stored within an electronic Quality Management System, Veeva's Vault Quality One
7	10/10/23	Entire Document	Removed signature fields.

Document Approvals

Approved Date: 12/12/2023

Task: Approval Task Verdict: Approve	August Smithmeyer, (asmithmeyer@qlaboratories.com) Management Approval 04-Dec-2023 21:24:40 GMT+0000

Task: Approval Task Verdict: Approve	Jayson Arling, (jarling@qlaboratories.com) Management Approval 12-Dec-2023 14:26:14 GMT+0000

Task: QA Approval Verdict: Approve	Jeff Knowles, (jknowles@qlaboratories.com) Quality Assurance Approval 12-Dec-2023 18:18:03 GMT+0000

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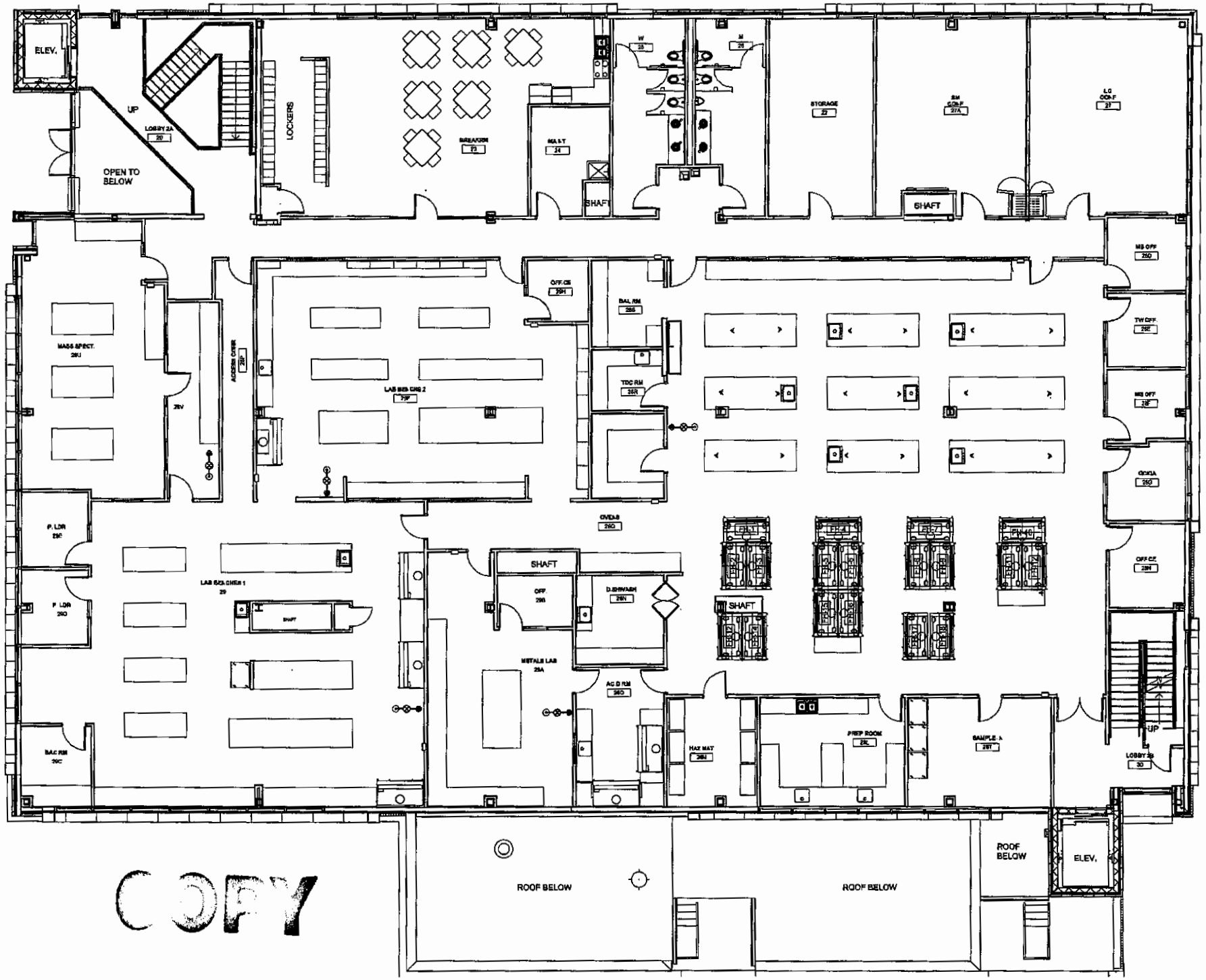
Q LABS SOP TOC

20-ADMN-POLI-004	Q Labs LLC Data Integrity Plan
20-ADMN-POLI-005	Site Master File
20-ADMN-ISO-001	Creation, Review, Approval & Distribution of SOPs and Forms
20-ADMN-ISO-002	Protection of Client's Confidentiality
20-ADMN-ISO-003	Subcontracting of Tests
20-ADMN-ISO-004	Ethical Conduct & Freedom from Undue Pressure & Conflicts of Interest
20-ADMN-ISO-005	Procurement
20-ADMN-ISO-006	Management Reviews
20-ADMN-ISO-007	Requirements of Equipment
20-ADMN-ISO-008	Control of Records
20-ADMN-ISO-009	Good Documentation Practices
20-ADMN-ISO-010	Investigation of Nonconforming Work
20-ADMN-ISO-011	Change Control
20-ADMN-ISO-012	Q Laboratories Quality System
20-ADMN-ISO-013	Training
20-ADMN-ISO-014	Corrective and Preventative Actions
20-ADMN-ISO-016	Quality Assurance Unit
20-ADMN-ISO-018	Inspection of Testing Facility/Visitor Policy
20-ADMN-ISO-019	Storage Requirements of Reagents and Chemicals
20-ADMN-ISO-020	Review of Requests and Contracts
20-ADMN-ISO-021	Reporting & Reviewing Test Results
20-ADMN-ISO-022	Traceability of Materials and Standards
20-ADMN-ISO-023	Method Development and Validation
20-ADMN-ISO-024	Deviations from Standard Test Methods & Q Laboratories Procedures
20-ADMN-ISO-025	Software Development, Modification and Validation
20-ADMN-ISO-028	Proficiency Testing Program
20-ADMN-ISO-029	Customer Feedback
20-ADMN-ISO-030	Control Charting and the Measuring of Uncertainty of Data for Microbiology
20-ADMN-ISO-035	Significant Figures and Rounding
20-ADMN-ISO-036	Pest Control Program
20-ADMN-ISO-037	Onboarding New Employees
20-ADMN-ISO-038	Blue Mountain Calibration Manager
20-ADMN-ISO-040	Control Charting and the Measuring Uncertainty of Data for Chemistry
20-ADMN-ISO-041	Quality Control Program
20-ADMN-ISO-042	Data Integrity
20-ADMN-ISO-043	Transfer of Samples
20-ADMN-ISO-045	Q Laboratories Deionized Water System, 1911 Radcliff
20-ADMN-ISO-046	Risk and Opportunity Management Using SWOT Analysis
20-ADMN-ISO-047	Maintenance and Calibration of Equipment
20-ADMN-CGMP-001	Conduct of CGMP Studies
20-ADMN-CGMP-002	Validation/Verification of GMP Methods
20-ADMN-CGMP-005	Stability Chambers and Stability Testing

ATTACHMENT TWO

20-ADMN-CGMP-006	Qualification of Laboratory Instruments
20-ADMN-CGMP-009	Inspection of Testing Facility by Regulatory Agencies
20-ADMN-CGMP-010	Guidelines for Analytical Method Transfer
20-ADMN-CGMP-011	Compliance of Laboratory Computer Systems to 21 CFR 11
20-ADMN-CGMP-012	Guidelines for Microbiology Method Transfer
20-ADMN-CGMP-013	Control of Master Data Sheets
20-ADMN-CGMP-014	OOS Investigations



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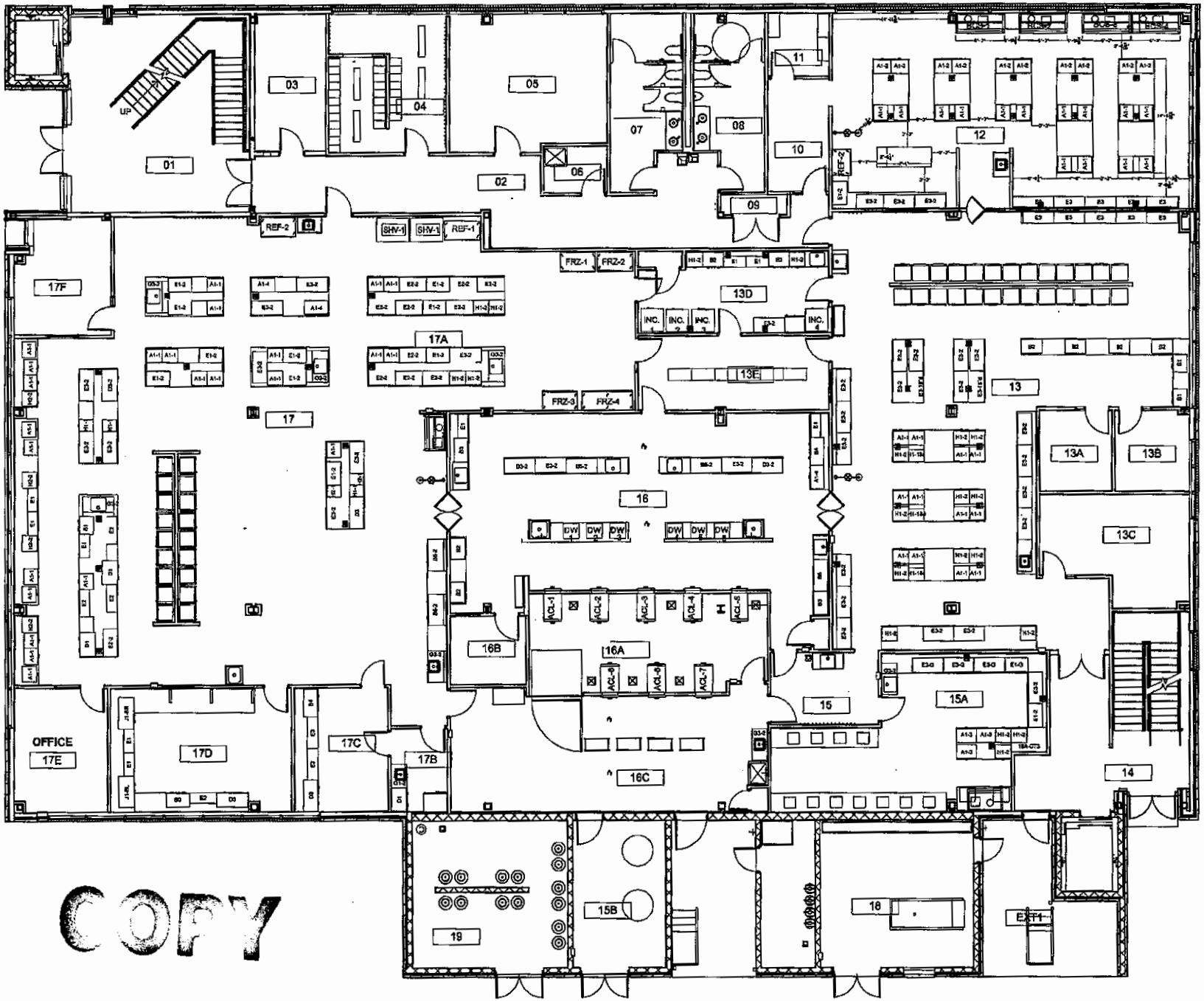
ATTACHMENT THREE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