Appendix F Certification Reports

RC Kennedy Consulting
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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.

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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.

Client
Lauren Reveley, Drug Importation Program Manager
Kelly Swartzendruber, Pharm.D. – Drug Importation Pharmacist
State of Colorado Department of Health Care Policy & Financing
1570 Grant Street
Denver CO 80203

Performer, Document Author:
Tyler Foley
Principal Consultant

Project Scope:
Assist State of Colorado Dept. of HCPF in auditing Premier Pharmaceuticals for their drug reimportation program by conducting a site visit of the Premier Pharmaceuticals to verify facility meets compliance to appropriately warehouse and distribute pharmaceutical products.

Project number:
WO-1002663

Körber Pharma Inc. – a Körber group company
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Tyler.Foley@Koerber.com

Koerber-Pharma.com

Confidential
June 29th, 2022

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 Premier Pharmaceuticals' 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 Premier warehouse 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
- Recent internal audits
- Facility floor plans
- Environmental monitoring logs

The Premier warehouse 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 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 and 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 near 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 and humidity controlled and monitored. The storage area is separated from external environment factors by 3 secured doors that are procedurally not allowed to be open at the same time. All temperature and humidity recorded are well within USP specifications and show only an impressive insignificant variance of under one degree centigrade. The HVAC system and electric required for refrigerated storage are backed up with a natural gas 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 plan.

Premier has recently invested in the expansion and improvement of its existing facilities to better meet existing business and be able to support anticipated expansion more easily. Plans also exist to further expand existing warehousing into adjacent spaces already controlled by Premier.

Recommendations

Premier Pharmaceuticals has demonstrated sufficient capacity, knowledge and expertise to provide the warehousing and distribution services required in support of the Colorado HCPF drug re-importation project. The distributor is already a known and active member of the industry providing drug products and devices to pharmacies across the United States. Korber Pharma Inc. is confident that they can adequately provide the services necessary to make this program successful. We would endorse the Colorado Dept. of HCPF selection of this distributor.

Sincerely,

Tyler Foley

Principal Consultant

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Premier Pharmaceuticals Visit
6/30/22
Observations and Comments

General Assessment

The Premier site in Boise, ID was visited by a team representing the Colorado Importation program. The purpose of the visit was to conduct a follow-up review from a visit last year to review the Premier operations. In that first visit, a series of recommendations were made to Premier to advance them toward compliance with generally good practices for pharmaceutical operations.

As a general statement, Premier has made significant improvements in every area discussed, regarding facilities, procedures, and systems. Specifically, with respect to systems, Premier has deployed NetSuite as their ERP platform giving them an industry leading system that has functionality and controls to properly manage pharmaceuticals.

The following report details observations of the operation from the visit of 6/27/22.

System

Premier has implemented the NetSuite ERP system with the native WMS as a replacement for Fishbowl. The new system has been in use since mid-January of 2022. NetSuite is used for financial management, CRM, inventory management and document management. The system is also used for customer order management where Premier sales staff can directly create orders, or, customers can use the Premier portal and those orders will arrive in NetSuite through a Premier built interface.

NetSuite is a highly popular ERP system owned by Oracle that is exclusively cloud based. NetSuite is one of the leading ERP systems in the market. The company has a strong support organization, is highly innovative with a strong R&D capability. NetSuite is also supported by a large partner solution community that provide additional partner solutions and services to augment the NetSuite core software.

As a cloud-based system, NetSuite deploys their software in a true SaaS, or multi-tenant scheme. The company houses the software in NetSuite data centers that are structured for security and redundancy. Currently NetSuite has 12 data centers in locations around the globe. For more information on the NetSuite data centers use this link: https://www.netsuite.com/portal/assets/pdf/ds-netsuite-data-center.pdf.

Standard Operating Procedures (SOP's)

Premier has invested in an effort to create and document SOP's that detail how processes are conducted. The SOP's are available in hard copy and will also be electronically kept in NetSuite. Premier has built a full collection of SOPs to direct each specific task being conducted in the operation. Each SOP is version controlled and employs signature verification for changes.

Training program

Premier originally purchased training from NetSuite for the lead staff users. The intent is to use those users to transfer their training knowledge to additional staff as needed based on job roles. A core group of Premier staff have been trained in their specific use of the system.

Security

As mentioned above, NetSuite provides the facility to restrict access to the system based on user roles, and the assignment of individual users to those roles. In this manner, Premier has created a security hierarchy that restricts access to only those screens that are defined for a particular role. Further, access has been restricted by transaction by role so that certain user roles are restricted in what they can transact. For example, some fields can be updated, others can only be viewed.

Disaster Recovery

There are several components of a master disaster recovery plan, such of which Premier have implemented, or are in the process of implementing:

1. System reliability. Because the business system is NetSuite, and is therefore hosted in NetSuite datacenters, the system is secure against extended downtime. Oracle data centers are architected for failover and redundancy, assuring 99% plus uptime. As long as Premier has internet access, they will have access to their system.
2. Premier has purchased a high-end backup generator that will enable continuous operations in the event of a power outage, ensuring continuous internet access.
3. Facility access. Premier has only the Boise facility to house the drugs that will be included in the Colorado import program. Plans for distribution of drugs to additional facilities are in process. Until then, in any event where the facility is put out of commission, either through natural events, fire or flooding, plans need to be developed for quick response recovery.
4. Communication. Premier is developing a formal, structured communication plan for quick response to a disaster which will define the communication chain and designate who is responsible and what is the order of communication.

Inventory Management

The NetSuite system is the primary record of inventory, including the physical management of inventory. NetSuite includes essential capabilities for the management of pharmaceuticals, including:

1. management of lots and expiration dates for each drug. Users can apply transactions to inventory that make it available or not for processing. Lots can be restricted to alternative storage based on availability status. Lots can be applied to orders automatically by NetSuite in the order creation process based on FEFO.
2. Inventory is managed by location, that is, each item is assigned to a specific location, visible in the system. One item only is assigned to a location. Multiple lots of that item can be stored in the same location. There is an overflow area where inventory can be temporarily assigned when space is not available in the primary location. That inventory can be transferred to the primary through a Bin Transfer transaction in the system.
3. Premier conducts full physical inventories twice annually. Discrepancies are handled through NetSuite using inventory adjustments, which update the inventory records and include the ability to attach a reason code. Access to inventory adjustments can be restricted, so that the persons handling inventory through normal operational processes are not also adjusting inventory.

Process Flow inbound

Purchase orders are created by Premier staff in NetSuite. As inventory arrives, product is checked in by physically opening cartons and inspecting/verifying accuracy by first comparing the actual receipt against the vendor

packing list. The product is then also verified against the PO using the appropriate NetSuite screens. Best practices suggest that the electronic status of inventory in the system should always reflect the physical status. In the short term, this can be somewhat addressed manually. In the longer term, Premier is investigate inserting a putaway transaction between receipt check in and storage. This transaction will be enhanced in accuracy with the future use of mobile terminals to scan products to confirm location putaway.

Premier does process a small amount of returns, using NetSuite to create a return authorization to accompany the shipment back to Premier. Returned items are then inspected and returned to inventory or disposed.

Process Flow Outbound

Once a customer order is added to NetSuite, it holds a status of Pending Fulfillment, and is visible to the user for completion. Lots can be assigned by the system, or in relevant cases, can be manually assigned. Typically, orders are processed in the sequence of when they were created, though Premier can choose to process any order in any sequence. Larger orders may be assigned and completed individually through a pass through the warehouse. Smaller orders may be "clustered" together and picked simultaneously. Several steps are involved in processing the completion of an order through NetSuite:

1. Assign and Fulfill

   When this transaction is completed, a packlist is printed and inventory is allocated to the order. The packlist is also used as a pick sheet. With the completion the system also decrements inventory of the item and the lot and the product is physically decremented from the shelf for packing.

2. Inspection and Packing

   As items are picked and then physically packed, the system is updated to reflect that. Premier uses a double inspection of picked/packed items to ensure accuracy.

3. Ship and Bill

   Once packed and inspected, the FEDEX label is printed, which accords the shipment a status of shipped. Then the order is moved to a status of billed so that the invoice can be printed and inserted into the carton. For future growth, Premier is investigating the possibility of inserting a status of "staged" for those orders that are completed and awaiting pickup.

Future Considerations

1. Mobile Terminals and Scanning

   Premier has plans to eventually introduce the use of mobile terminals into the process. These units will be equipped with scanners. The introduction of these units will be critical for future growth as they are a means of closing the receiving and picking gaps mentioned above by enabling more real time transactions, and, the scanning will introduce better accuracy into the putaway process and pick confirmation process.

2. Cycle Counting

   As the business grows, Premier should investigate the availability of cycle counting with the NetSuite system. A system managed cycle count capability will better ensure the verification counting of inventory locations and do so much more efficiently than manual physical inventory counts.

3. Cluster or Batch Picking

   As mentioned, Premier will sometimes group multiple smaller orders together to be picked simultaneously. For future consideration, Premier should investigate whether NetSuite carries the logic to manage this process. Most WMS software has a batch picking capability.

4. Weights and Measures

   Premier is in the process of collecting dimension and weight data primarily for shipping use. That process may be able to be facilitated by the use of a Cubiscan device, or through an effort to collect the data from manufacturers. As the business grows, that data could become useful for other purposes such as picking containerization, putaway allocated and storage zoning.

Summary

Since the first visit to the Premier site, the company has made substantial improvements that address original comments regarding security, systems, and facility. This investment in their business indicates that the Importation program is an important strategic direction for Premier. These improvements, coupled with an experienced and capable management team, position Premier to be a capable partner for the Importation program

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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.

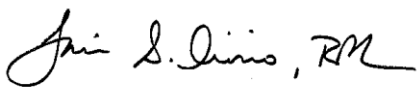
FINAL DETERMINATION OF COMPLAINCE & SUITABLITY OF SERVICES-

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

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Premier Site Visit
Boise, ID
10/30/24
Observations and Comments

General Assessment

On October 21st through the 22nd, a team representing the State of Colorado Drug Importation Program visited the Premier Pharmaceutical site in Boise, ID. Team members included:

Kelly Swartzendruber	Drug Importation Program Manager
Vincent Giglierano	Drug Importation Program Administrator
R Kennedy	Consultant, RC Kennedy Consulting, LLC

The visit was conducted as an annual review of the facility to ensure continued compliance as specified by FDA regulations including 21 CFR 210[1], 21 CFR CFR 211[2], and 21 CFR 251[3] . The Colorado team met with the Premier management team. The following report details observations of the operation from the visit.

Operation

Product enters and exits the facility through two controlled access doors, one for handling parcels and the other for full pallet loads. Premier has secondary level-controlled access into the warehouse. The physical warehouse is well-organized and clean, and locations are clearly marked. Processes are well-documented. All products are staged and stored within the warehouse for processing.

System

Premier has implemented the NetSuite ERP system with the native WMS for their business and has been using it since the last visit. NetSuite is the system of record for all transactions and inventory. NetSuite is used for financial management, CRM, inventory management and document management as well as customer order management. NetSuite includes essential capabilities for the management of pharmaceuticals, including management of lots and expiration dates (including FEFO management[4]) for each drug. Serial numbers can be recorded.

NetSuite is a highly popular ERP system owned by Oracle that is exclusively cloud based. NetSuite is one of the leading ERP systems in the market. The company has a strong support organization, is highly innovative with a strong R&D capability. As a cloud-based system, NetSuite deploys their software in a true SaaS, or multi-tenant scheme. The company houses the software in NetSuite data centers that are structured for security and redundancy.

[1] https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-210
[2] https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211
[3] https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-251
[4] FEFO = First Expired First Out

With respect to serialization (for DSCSA compliance and including imported products), Premier has selected Movilitas software. Movilitas will be integrated into the relabeling process for imported drugs as described in "SOP-804-006 Relabeling." Movilitas is a reputable track and trace software system that is widely used globally and that includes advanced abilities to integrate with other systems, including WMS and serial number repository systems, and print and apply systems.

Standard Operating Procedures (SOPs)

The Premier team has created a complete set of SOPs to guide the distribution operation, including SOPs for the Importation operation. The Importation SOPs were designed specifically for the Colorado program but were built using existing SOPs as a base. During this visit, the Colorado team did not review the current SOPs for the Boise facility as the team reviewed them at prior visits and verified there were little to no updates in the SOPs from the previous visits. Premier recently added an SOP to cover the process for relabeling drugs as compliant with requirements for Importation, including cold chain drugs which the Colorado team was actively involved with the drafting process. See SOP-804-006.

Security

Access to the facility is restricted by employee card readers. Dock doors remain closed and locked unless in active use, where those activities will be supervised by Premier personnel. Security cameras are deployed inside the facility by Premier and landlord cameras surround the exterior.

Access to the system is facilitated by NetSuite user profiles. Based on user roles, and the assignment of individual users to those roles, Premier has created a security hierarchy that restricts access to only those screens that are defined for a particular role. Further, access has been restricted by transaction by role so that certain user roles are restricted in what they can transact. For example, some fields can be updated, others can only be viewed.

Disaster Recovery

There are several components of a master disaster recovery plan, much of which Premier implemented, or are in the process of implementing:

1. System reliability. Because the business system is NetSuite, and is therefore hosted in NetSuite datacenters, the system is secure against extended downtime. Oracle data centers are architected for failover and redundancy, assuring 99% plus uptime.
2. Premier has purchased a high-end backup generator that will enable continuous operations in the event of a power outage, ensuring continuous internet access.
3. Communication. Premier has developed a formal, structured communication plan for quick response to a disaster which will define the communication chain and designate who is responsible and what is the order of communication.

Relabeling

Premier is designated as the importation entity for the Colorado program. In order to meet FDA requirements for importation, Premier must comply with certain rules regarding the labeling of imported drugs. Following best practices for quality inspection and relabeling, Premier plans to create a separate area, with limited and controlled access to the distribution center, for the purposes of relabeling. Premier has also built detailed operating procedures for the relabeling operation.

The plan to cordon off an area and restrict access, where the relabeling operation will be self-contained as a separate operation will ensure that Premier meets quality and good practices compliant rules of the FDA for relabeling.

Summary

In general, the site is well-managed, with experienced personnel responsible for the operation. The operation has been active for multiple years and as such has long standing practices for compliance and drug safety. Processes are well defined and documented.

Including newly implemented processes and systems, Premier has positioned themselves to be a compliant partner for the Colorado Drug Importation program.

We recommend, consistent with Colorado Department of Health Care Policy & Financing requirements, that the site be reviewed again after production has commenced for distribution and relabeling, focusing especially on the relabeling operation.

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.

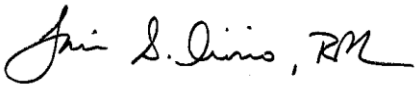
FINAL DETERMINATION OF COMPLIANCE & SUITABLITY OF SERVICES-

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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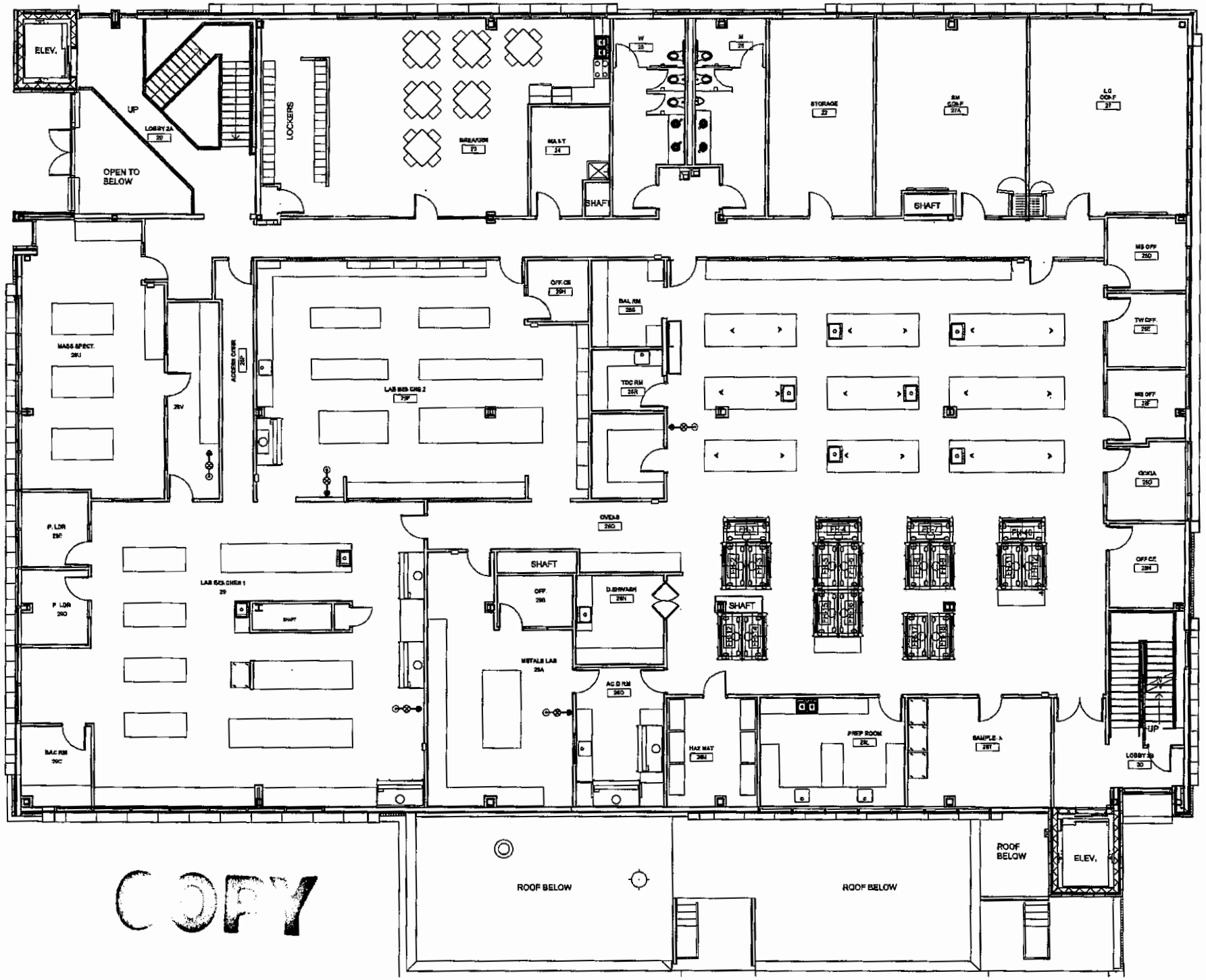
Q LABS SOP TOC

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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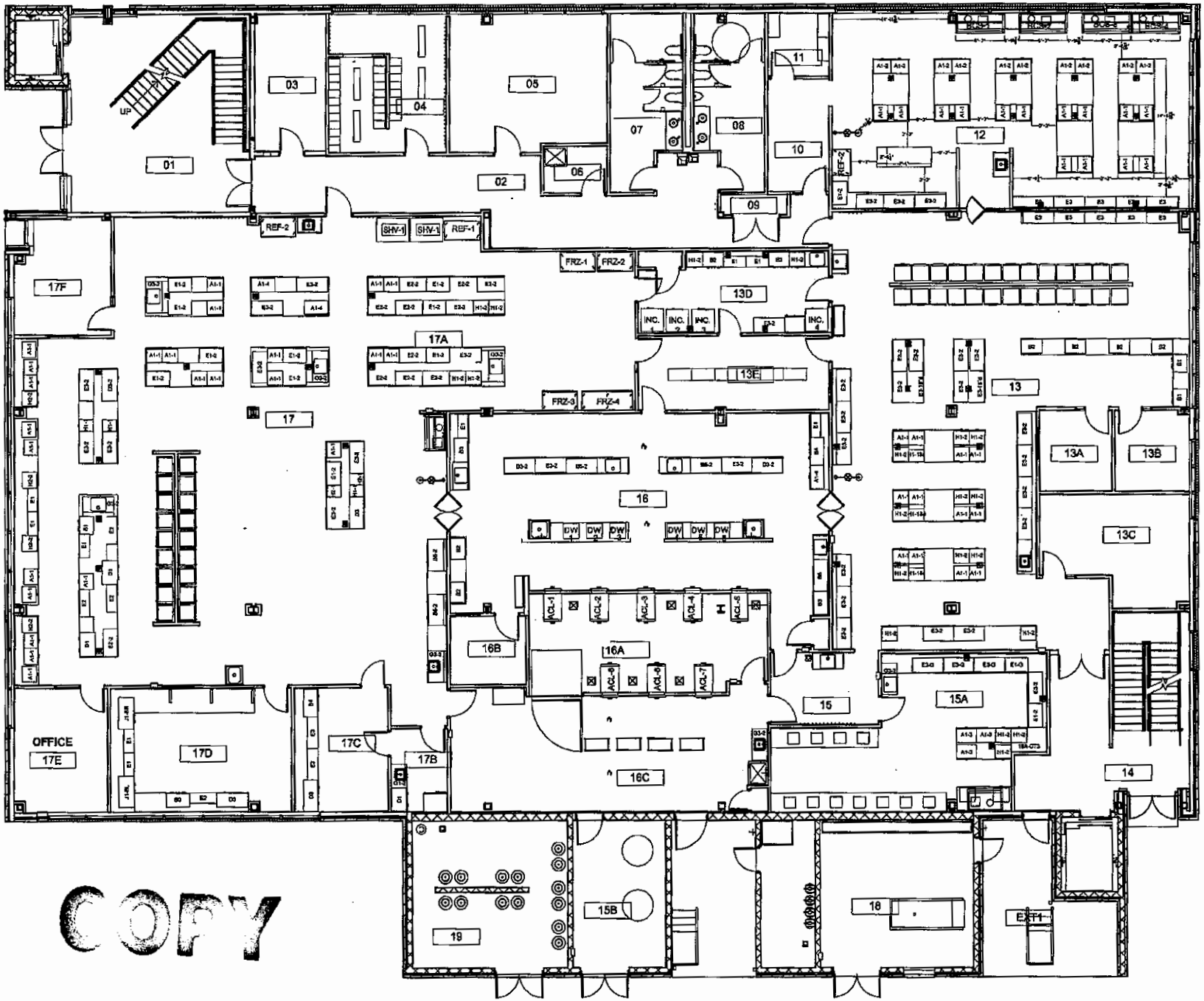
ATTACHMENT THREE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