Appendix F Certification Reports

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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.

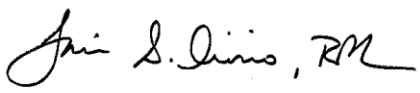
FINAL DETERMINATION OF COMPLAINCE & SUITABLITY OF SERVICES-

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
Perrysville, OH
10/05/23
Observations and Comments

General Assessment

Premier Pharma has opened a new facility in Perrysville, OH. The new facility will be operated by their affiliated Premier Mid-America (PMA) entity. The facility has been designated by Premier to manage the importation of drugs for the Colorado Importation program. The decision to use the new facility is a change from the original direction to use the existing facility in Boise, Idaho because of the new facility's proximity to the point of importation, making it compliant with FDA requirements for location. At the time of this report, the facility was completed but had not yet begun operations.

The purpose of the visit was to conduct a review of the Perrysville facility toward ensuring it meets the requirements for the Importation program, similar to the review from June of 2022 to the Boise site for the same purpose. Special attention was given to the potential positioning of a relabeling operation in the facility, co-existing with the distribution center.

The following report details observations of the operation from the visit of 10/5/2023.

Relabeling

Premier Mid-America (PMA) is designated as the importation entity for the Colorado program. In order to meet FDA requirements for importation, PMA must comply with certain rules regarding the labeling of imported drugs. Following best practices for quality inspection and relabeling, PMA plans to create a separate area, with limited and controlled access to the distribution center, for the purposes of relabeling. PMA 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 assure that PMA meets quality and good practices compliant rules of the FDA for relabeling.

System

Premier Pharma has implemented the NetSuite ERP system with the native WMS for their business and will be using the system at PMA. NetSuite is used for financial management, CRM, inventory management and document management as well as customer order management.

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.
Premier has also acquired LS Pedia for DSCSA compliance and will use that system at the PMA facility for track and trace and reporting of serial numbers applied by PMA. LS Pedia is a leading track and trace system with many customers using the system for DSCSA compliance.

As reported during the Boise visit, NetSuite system is the primary record of inventory, including the physical management of inventory. NetSuite includes essential capabilities for the management of pharmaceuticals, including management of lots and expiration dates for each drug. Serial numbers can be recorded.

Standard Operating Procedures (SOPs)

PMA has invested in an effort to create and document SOPs that detail how processes are conducted. The SOPs are available in hard copy and will also be electronically kept in NetSuite. PMA has built a full collection of SOPs to direct each specific task being conducted in both the distribution and relabeling operations. Each SOP is version controlled and employs signature verification for changes. As part of the Colorado program, all pertinent SOP's have been reviewed and validated. The set of SOPs include those required to manage the relabeling operation.

Personnel

PMA conducts background checks on all new hires. At the time of this report, three full-time staff members had been hired. PMA has committed to training their Perrysville staff using the program they developed for the Idaho facility, in the use of their systems and in the use of their SOPs to conduct business.

Security

Access to the facility is restricted by keypad. Dock doors remain closed and locked unless in active use, where those activities will be supervised by PMA personnel. Security cameras are deployed inside the facility and 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, PMA 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
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. PMA 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.

Summary

The PMA facility in Perrysville is new. Therefore, we were not able to view actual production operations, though we can confidently conclude after discussions with Premier management that the same level of good practices

will be deployed in this facility as has been developed for the Idaho facility. Most importantly, this facility will house the PMA relabeling operation, which will not be in production until after SIP approval. Again, after discussions with PMA management, and review of plans and SOP's, we are confident that PMA plans will result in a compliant operation.

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.