Business Information

1. The business is appropriately registered or incorporated and carries general and product liability insurance.
2. The business has a defined organizational structure and clear lines of authority (management and supervision).
3. The facility has and maintains appropriate current, valid federal licensure, permits and/or registrations
4. The facility has and maintains appropriate current, valid state licensure, permits and/or registrations in its home state and in any state into which products are distributed. This includes any state-issued controlled substance license/registration/permit.
5. There is a process for ensuring compliance and keeping up-to-date with state and federal laws, rules and regulations, including all states into which products are distributed.
6. There is a process for keeping informed and up-do-date with industry best practices and compliance with accreditation requirements and standards.
7. There is a process to complete appropriate reporting to federal and state agencies and accreditation organizations; and to complete and keep on file self-inspections or reports where required.
8. The business has a finance department or uses a CPA, develops an annual budget or plan and reviews periodic financial reports of performance to the budget.
9. Co-located businesses, if any, have appropriate physical and electronic segregation of products and operations.
10. The business has a designated representative for the facility who has appropriate education, training and experience and is actively involved in the day-to-day operations of a single facility.

Administration

1. There is a document control policy and procedure that describes how policies and procedures are developed, reviewed, revised, approved, and archived.
2. There is a document retention policy that includes where documents are stored, how documents are kept secure, how documents are accessed and by whom, and how documents are destroyed at the end of the required storage time.

Safety and Crisis Operations

1. A safety and crisis plan is developed and a hard copy of the safety and crisis plan is kept on the premises and with key personnel.
2. Contact lists are maintained for emergency services and for repair vendors (such as electric company, HVAC repair, etc.). A list of employee contact information is maintained.
3. Maps are posted indicating exits, location of fire extinguishers and first aid kits (at a minimum), and safe areas to congregate for weather emergencies (tornado, etc.) as appropriate.
4. Plans address people safety, business continuity, product security and disposition, and paper and electronic data security and disposition.

Environment

1. Neat, clean, free from pests and of adequate size for the volume of business.
2. Products are stored off the floor.

3. Appropriate storage areas for controlled substances, listed chemicals, and EPA hazardous products.
4. All areas where products are stored (including quarantine areas, refrigerators and freezers) are continuously monitored for temperature. Probes are placed based on temperature mapping when appropriate and replaced or calibrated annually.
5. Products are stored within conditions indicated on the packaging or labeling for the products. If there is no indication of storage conditions, product will be stored at USP defined controlled room temperature.
6. General product storage and quarantine areas are also monitored for humidity.
7. Temperature and humidity excursions are communicated to appropriate staff in real time and there is an action plan that includes the quarantine of product that has experienced an excursion.

Security

1. An alarm system is present, operational, and includes appropriate alarm contacts at entry points. Additional monitoring as appropriate, such as glass break, motion detectors, etc. There is a procedure for responding to alarms.
2. Doors are kept locked from the outside.
3. Authorized staff have unique alarm codes for alarm system arming and disarming. Reports are reviewed, or there are real-time alerts for after-hours access.
4. Access to drug storage areas is restricted.
5. Visitors (all non-employees) are required to provide current, valid ID and sign in and out of the facility on a log sheet, book, or electronically, and are accompanied when in drug storage and handling areas.
6. Cameras are in use with appropriate placement, there is a process to secure the recorded data from alteration or deletion, and recordings are kept for the length of time to be useful in investigating inventory discrepancies or other issues. There is a procedure for the appropriate use and review of recordings.
7. Controlled substance cages and vaults are locked, part of the alarm system and included in the camera monitoring system.
8. Access to the controlled substance cage/vault limited to authorized personnel with a list of authorized personnel posted, a log kept of non-authorized person's access, and a procedure to ensure non-authorized persons are accompanied when in the cage/vault.
9. Computer systems
    a. Unique ID and passwords. Passwords are biometric, or changed every 90 days, or changed every 180 days with long, complex password / passphrase plus 2-factor authentication.
    b. Access level is restricted and dependent on position.
    c. Remote access is through a VPN or other secure, encrypted process.

Human Resources

1. Hiring process includes verification of education and work history, criminal background checks and drug screening. Financial background checks for select personnel.
2. Training process developed that includes initial training, training on new or revised policies and procedures, and ongoing annual training. Training is tracked and documented.

3. Content of training includes orientation, review of job description, policies and procedures, crisis plans, safety training, and training specific to the position and any equipment to be used.
4. There is an employee performance and competency review process that includes how reviews are documented.
5. Routine, random and for-cause criminal and financial background checks and drug screening process for all employees is in place and documented including the process for handling results.
6. Stepped disciplinary process including a procedure for reporting, if appropriate.
7. Process to deal with termination or resignation of employees that includes immediate deactivation of alarm codes and computer access.

Vendors

1. Vendors for prescription products procure products directly from manufacturers or repackagers, or from other wholesale distributors that purchase directly from manufacturers or repackagers. If the product has additional transactions, transactions are only between manufacturers, repackagers, and wholesale distributors. There are no transactions showing the product was purchased by or from a pharmacy, dispenser, or other healthcare provider or healthcare facility.
2. Vendors for OTC products procure products directly from manufacturers or repackagers, or from other wholesale distributors that purchase directly from manufacturers or repackagers. Products shall not have been previously purchased by or from a person, pharmacy, dispenser, or other healthcare provider or healthcare facility.
3. Initial verification and authentication of vendors, including licensure verification directly with licensing agencies (state and federal), any disciplinary actions, verification of wholesaler and 3PL reporting to FDA, and verification of vendors sources of products (including OTC vendors).
4. Process when unable to authenticate and verify a vendor, including reporting.
5. Process for authentication of vendor licensing when license expires.
6. Process for authentication of vendors at least annually (in addition to the time of license expiration).

Product Receipt

1. Process for receiving products from vendors including verification against the purchase order, review/verification of transaction data, and physical inspection of outer containers or boxes and inner packs and units.
2. Process for quarantine of products that are damaged or exposed to temperature excursions during transit that may affect product integrity.
3. Process for quarantine of products when a discrepancy is detected (does not match purchase order, transaction data, etc.).
4. Process for quarantine of product that may be suspicious or illegitimate.
5. Process for the handling of controlled substances and refrigerated/frozen products upon receipt.
6. Process for quarantine of product returns received from customers.

Product Storage

1. Process to detect and prevent diversion, theft, and loss of product within the facility.

2. Process for defacing, shredding or destruction of labels, containers, product boxes and cases to prevent their use in counterfeiting.
3. Inventories
    a. Full physical inventory of all products process.
    b. Cycle count processes including frequency of controlled substance and listed chemical inventories.
    c. Inventory discrepancy procedure for documentation, investigation, and reporting.
    d. Process for short-dated and expired products, and for products that have been damaged or whose integrity is questionable (temperature excursions, etc.).
    e. Process for investigation, documentation and reporting of suspected theft or significant loss.
    f. Process for handling products that are recalled or withdrawn from the market.
    g. Procedure for handling requests for information or notifications regarding suspicious or illegitimate product from trading partners, state agencies, DEA, and FDA.
    h. Process to segregate product (physically or electronically) that is 340B, samples, limited distribution, or specific contract product to prevent distribution to unauthorized customers.

Quarantine

1. Separate, distinct, and secure areas for quarantined product (general storage, refrigerated, frozen, controlled substances).
2. Separation and labeling of products or areas for different types of products in quarantine.
3. Quarantined product is part of the physical inventory processes.
4. Process to handle recalls and withdrawals disposition and documentation.
5. Process to evaluate customer-returned product and documentation.
6. Process to evaluate products that have experienced a temperature excursion or other condition that may affect product integrity and documentation.
7. Process to investigate product quarantined due to other discrepancies including appropriate notifications and reporting to FDA, DEA, state regulatory agencies and trading partners as appropriate, such as:
    a. Orders received damaged.
    b. Issues matching product received to purchase orders.
    c. Transaction data missing, incomplete, or other discrepancies.
    d. Suspicious product procedure.
    e. Illegitimate product procedure.
8. Process to handle and document disposition of quarantined product including:
    a. Product returns to manufacturer or distributor.
    b. Sending products to a reverse distributor for credit or destruction including receiving confirmation of destruction.
    c. In-house destruction of products.

Customers

1. Prior to distribution of products, initial verification and authentication of customers that includes the process to review ARCOS data (for controlled substances, if appropriate), licensure information verified directly with the state or federal licensing agency (including any disciplinary actions noted), confirming “ship to” address is legitimate.

2. Process to follow if unable to authenticate and verify a customer including reporting.
3. Process for authentication of customer licensing when license expires.
4. Process for authentication of customers at least annually (in addition to the time of license expiration).

Customer Orders

1. Process for suspicious order detection, investigation, and reporting of controlled substance and non-controlled substance orders.
2. Process to prevent distribution to customers whose license has expired, or when there is an issue, discrepancy, or active investigation of a suspicious order.
3. Process to prevent distribution to a different address than the licensed or authorized and verified ship-to address on file.
4. Process to ensure accuracy in picking products.
5. Packing orders process that includes:
    a. Visual inspection of products for damage and accuracy of picked order verified prior to packing.
    b. Confirming appropriate materials are used in packing orders to ensure the integrity of temperature sensitive products, protection from heat and protection from products being frozen.
    c. If using temperature indicators, provision of instructions to customers.
    d. Proper handling and packing of hazardous product including an indication to the customer that a product is hazardous.
6. Shipping orders
    a. Process to provide transaction data to customers at or before the time the customer receives products.
    b. Process to ensure security and storage conditions of packed shipments as appropriate prior to carrier pick up.
    c. Verification and authentication of common carriers used, that includes verification of driver security training, background checks and drug testing of drivers.
    d. Process to track orders.

Quality Program

1. There is a quality committee, meetings are held at least quarterly and are documented.
2. There is a process to gather data, investigate, review, and analyze data, trend data over time, create improvements and evaluate effectiveness (CAPA).
3. The process includes (but is not limited to) a review of:
    a. Vendors: failed authentication or verification, supply issues.
    b. Customers: comments and complaints, failed authentication or verification, suspicious orders.
    c. Carriers: delivery/damage issues, theft/loss.
    d. Inventory: failed product receipt, inventory adjustment records, theft/loss, temperature and humidity records, suspicious or illegitimate product investigations and requests/notifications from trading partners or regulatory agencies.
    e. HR: performance, disciplinary actions, background checks and drug testing results.
    f. Internal audits, external audits, inspections or survey results.

Update History:
V1.1 10/1/19 approved 10/10/19
Vendors. Added additional clarification to items (1.) and (2.) to indicate products may have multiple transactions in the history, and that no transactions are allowed where the product was obtained from a dispenser, pharmacy, or other healthcare provider.
V1.2 4/2/2022 approved 5/16/2022
Minor grammatical changes throughout. Security 3. added real-time alerts; 5. added electronic visitor sign-in; 9. added 180-day password change that includes 2-part authentication; Vendors 2. added “person”; Product Storage 3.h. added samples; Customer orders 1. added inclusion of both controlled and non-controlled substances.