NCDQS QAS Accreditation Standards – Virtual Manufacturers

V1.0 5/16/2022

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, and paper and electronic data security and disposition.

Environment and Security

1. Neat, clean, and of adequate size for the volume of business.
2. An alarm system is present and operational. There is a procedure for responding to alarms or alerts from building security.
3. Doors are kept locked from the outside.
4. 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.
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.

6. Computer systems
    a. Unique ID and passwords. Passwords are biometric, or changed every 90 days, or every 180 days with long, complex password or passphrase plus 2-factor authentication.
    b. Access level is restricted and dependent on position.
    c. Screens and programs "time out" for inactivity to prevent access by others.
    d. Remote access is through a VPN or other secure, encrypted process.

Human Resources

1. Hiring process includes verification of education and work history, and criminal background checks. Drug screening performed at hire for employees that access DEA registrant facilities (such as sales force). Financial background checks recommended 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.
4. There is an employee performance and competency review process that includes how reviews are documented.
5. For-cause criminal 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 building and computer access.

Vendors

1. Contract Manufacturers (including testing laboratories, packagers and labelers, etc.)
    a. Initial verification and authentication of vendors including licensure verification directly with licensing agencies (state and federal), review of any disciplinary actions, and verification of accreditation (if accredited) directly with accrediting agency.
    b. Process when unable to authenticate and verify a vendor, including reporting.
    c. Process for authentication of vendor licensing and accreditation when licenses/accreditation expires.
    d. Process for authentication of vendor least annually (in addition to the time of license expiration).
    e. An on-site qualification audit was performed with each vendor prior to starting production.
    f. There is a quality or technical agreement in place for each vendor for the implementation of quality oversight and controls over the manufacture of drugs, including the safety of raw materials, materials used in drug manufacturing, and finished drug products.
    g. The vendor is responsible for complying with cGMP and communicating any out-of-specification results to the virtual manufacturer's quality unit for investigation.
    h. The virtual manufacturer's quality unit is responsible for approving or rejecting the vendor manufactured drug products.
    i. There is ongoing oversight of the vendor that includes regular site visits and ongoing quality performance assessments.

2. Third-Party Logistics (3PL)
    a. Initial verification and authentication of 3PL vendors, includes licensure verification directly with licensing agencies (state and federal), review of any disciplinary actions, and verification of 3PL reporting to FDA.
    b. Initial verification of accreditation directly with accrediting agency. Use of a non-accredited 3PLs shall require additional authentication and verification of 3PL operations.
    c. Process when unable to authenticate and verify a vendor, including reporting.
    d. Process for authentication of 3PL licensing and current accreditation when licenses/accreditation expires.
    e. Process for authentication of 3PL license and accreditation status at least annually (in addition to the time of license expiration).
    f. A qualification audit was performed prior to starting distribution activities.
    g. There is a quality or technical agreement in place for the implementation of quality oversight and controls over the receipt, storage, handling, quarantine, and distribution of the products.
    h. The 3PL is responsible for complying with regulations and accreditation standards, including communicating any out-of-specification incidents to the virtual manufacturer's quality unit for investigation.
    i. The virtual manufacturer's quality unit is responsible for deciding disposition of products where the integrity of the product may be in question.
    j. Product is regularly inventoried by the 3PL. Any discrepancies in the inventories are communicated to the quality unit and investigated. Inventories and discrepancies (including investigations) are appropriately documented and reported.
    k. There is a process for handling recalls and market withdrawals.
    l. There is ongoing oversight of the vendor that includes regular site visits and ongoing quality performance assessments.

Customers

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

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, authorized, and verified "ship to" address on file.
4. Packing and shipping of products includes the use of validated shippers to ensure the integrity of temperature sensitive products, protection from heat and protection from products being frozen.
    a. If using temperature indicators, provision of instructions to customers.
    b. Proper handling and packing of hazardous materials including an indication to the customer that a product is hazardous.
5. There is a process for authorizing and accepting product returns to the 3PL from customers. Returned products that will be returned to active stock are evaluated by the 3PL and authorized by the virtual manufacturer's quality unit.
6. There is a process for handling drug products sent to the virtual manufacturer office in error that includes how and where the product is secured from unauthorized access, documentation of receipt, and disposition of the product.

Quality Program

1. There is a process for handling complaints, including determination of whether the complaint is a quality issue or an adverse event (or combination), that includes investigation and reporting.
2. There is a process for handling suspicious or illegitimate product complaints or notifications from trading partners and regulatory agencies that includes documentation, investigation, and reporting.
3. There is a quality committee, meetings are held quarterly (or more often), and are documented.
4. There is a process to gather data, investigate, review, and analyze data, trend data over time, create improvements and evaluate effectiveness (CAPA) that includes (but is not limited to):
    a. Vendors: failed authentication or verification, manufacture, supply or quality 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 records, 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.

V1.0 4/2/2022 approved 5/16/2022
Developed from NCDQS QAS Accreditation to refine standards as applicable to Virtual Manufacturers.