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| **WHOLESALE DISTRIBUTOR INSPECTION REPORT** | | | | | | | | | | | | | | |
| [Great seal of Massachusetts - click to see all state seals](http://www.statesymbolsusa.org/Lists/state_seals.html) | **The Commonwealth of Massachusetts**  **Executive Office of Health and Human Services**  **Department of Public Health**  **Bureau of Health Professions Licensure** | | | | | | | | | | | | |
| **Board of Registration in Pharmacy**  **250 Washington Street, Boston, MA 02108-4619**  **(617) 973-0800**  **(617) 973-0988 TTY** | | | | | | | | | | | | | |
| DATE(S) OF INSPECTION: | |  | | | | INSPECTION #: | | |  | | | | |
| BUSINESS NAME (DBA): | |  | | | | | | | | | | | |
| STREET ADDRESS: | |  | | | | | | | | | | | |
| CITY / STATE / ZIP: | |  | | | | | | | | | | | |
| DESIGNATED REPRESENTATIVE (REP): | |  | | | | | | | | | | | |
| REP. YEARS AT BUSINESS: | |  | | | | | | | | | | | |
| REP. TELEPHONE: | |  | | | | | | | | | | | |
| REP. FAX: | |  | | | | | | | | | | | |
| REP EMAIL: | |  | | | | | | | | | | | |
| WHOLESALER PERMIT #: | |  | | | | | | | | | | | |
| PERMIT EXPIRATION: | |  | | | | | | | | | | | |
| DEA REG. NUMBER: | |  | | | | | | | | | | | |
| DEA REG. EXPIRATION: | |  | | | | | | | | | | | |
| OPERATING HOURS: | | MON |  | TUE |  | | WED |  | | THU |  | FRI |  |
| SAT |  | | | | SUN |  | | | | | |
| # OF YEARS AT CURRENT BUSINESS ADDRESS: | |  | | | | | | | | | | | |
| STATES SHIPPING INTO: | |  | | | | | | | | | | | |
| AVG. ORDERS SHIPPED DAILY: | |  | | | | | | | | | | | |
| GENERAL DESCRIPTION OF DISTRIBUTION ACTIVITIES: | |  | | | | | | | | | | | |
| BUSINESS MEMBERS PRESENT FOR INSPECTION AND ROLE: | |  | | | | | | | | | | | |

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| **Item #** | **Requirement** | **Y/N/N/A** | **Comment** |
| **A** | **Laws/Regulations** |  |  |
| 1 | Are systems in place for ongoing monitoring of state and federal laws/regulations for changes? |  |  |
| 2 | Are resources and related training in place for staff to apply the changes in laws/regulations into current practices? |  |  |
| 3 | Are the most stringent laws/regulations followed between the host state, the state being shipped into, and federal requirements, where applicable, and including DSCSA? |  |  |
| 4 | If the above functions are performed at a different location, who is the primary contact? |  |  |
| 5 | Does the applicant have any open or pending regulatory actions pertaining to the distribution of drugs or operation of the facility? |  |  |
| **B** | **Reporting and notifications** |  |  |
| 6 | Who is responsible at this facility for making suspect product determinations? (NA if Virtual) |  |  |
| 7 | Has the facility received any requests for verification of suspect product from FDA? |  |  |
| 8 | Has any suspect product been identified by the facility (defined by DSCSA as counterfeit, diverted, stolen, intentionally adulterated, part of a fraudulent transaction)? |  |  |
| 9 | Has suspect product been investigated? |  |  |
| 10 | Has any product been determined to be illegitimate? |  |  |
| 11 | Was the determination made in coordination with the manufacturer? |  |  |
| 12 | Was it reported to FDA and to anyone to whom the product was shipped (if applicable), within 24 hours? |  |  |
| 13 | * Has a termination notification taken place in consultation with FDA?   *NOTE: Mark NA if they have no illegitimate product.* |  |  |
| 14 | Have any illegitimate product notifications been **received** from FDA or from trading partners? |  |  |
| 15 | Was a corresponding suspect product investigation conducted? |  |  |
| 16 | Did the facility have any of the illegitimate product indicated in the notification in stock? |  |  |
| 17 | If so, was it moved to quarantine and a sample kept? |  |  |
| 18 | Was the FDA notified within 24 hours? |  |  |
| 19 | Did they receive, transfer or distribute any of the product indicated in the notice? |  |  |
| 20 | If so, did they notify applicable trading partners within 24 hours? |  |  |
| 21 | Has any other prescription drug or device (not defined as illegitimate product under the DSCSA such as APIs, blood components, IV products, etc.) been identified which is counterfeit, diverted, misbranded, adulterated or tampered with, part of a fraudulent transaction, or otherwise unlawful? |  |  |
| 22 | Was it reported outside the facility? To whom? *Review reports.* |  |  |

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| **Item #** | **Requirement** | **Y/N/N/A** | **Comment** |
| **B** | **Reporting and notifications** |  |  |
| 23 | Has any theft, pilferage, or unexplained excessive loss of any prescription drug been identified? |  |  |
| 24 | If it involved a controlled substance, was it reported to DEA? |  |  |
| 25 | Was it reported to any other agency outside the facility? |  |  |
| 26 | If criminal activity involving inventory is suspected, does reporting to outside agencies happen within 3 days? |  |  |
| **C** | **Facility Licenses/Permits/registrations** |  |  |
| 27 | Is there any substantial change to the customer base and/or state licenses since the last information was provided to NABP? |  |  |
| 28 | Is the business licensed in all applicable jurisdictions where prescription products are distributed? (or received from, for reverse distributors). |  |  |
| 29 | Review at least three customer profiles and compare addresses to licenses? Is there a license for each state in which the customer resides? |  |  |
| 30 | Are domicile state licenses displayed, and other state licenses available for review? |  |  |
| 31 | Does the facility hold federal and state controlled substance licenses appropriate to their controlled substance activity? Observe the licenses to ensure they are valid. |  |  |
| 32 | If repackager, does facility hold appropriate Food and Drug Administration (FDA) registration? |  |  |
| 33 | Are adequate systems in place for maintaining current licenses? |  |  |
| 34 | Are sufficient systems in place to prevent prescription products from being shipped into states (or received from states for reverse distributors) where the applicant does not hold a license? |  |  |
| 35 | If any of the above is done at a different location, who is the primary contact? |  |  |
| **D** | **POLICIES & PROCEDURES AND Record Retention** |  |  |
| 36 | Are the policies and procedures site specific? *.* |  |  |
| 37 | each owned by an individual or department for updating and implementation? |  |  |
| 38 | reviewed routinely to ensure they stay current? |  |  |
| 39 | Is the most current P&P being followed? |  |  |
| 40 | Are adequate systems, processes, facilities, and employee training in place to facilitate the collection and archiving of all records associated with a wholesale distributor as required by law/regulation? |  |  |
| 41 | Does the system include adjustments to audits? |  |  |
| 42 | Does the system include records of destruction? |  |  |
| 43 | Does the system include DEA records (controlled substance product movement and inventories)? |  |  |

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| **Item #** | **Requirement** | **Y/N/N/A** | **Comment** |
| **D** | **POLICIES & PROCEDURES AND Record Retention** |  |  |
| 44 | Are suspect product investigations, illegitimate product determinations and product tracing information (Transaction Information, Transaction History, Transaction Statement) archived for at least 6 years? |  |  |
| 45 | Are pedigree records archived? |  |  |
| **E** | **Personnel** |  |  |
| 46 | Is the designated representative physically present at the applicant facility during normal business hours (except for customary leave times), and actively involved in the management of overall distribution operations? |  |  |
| 47 | Are job applicants required to complete adequate application/resumes? Do they include contact information, previous employment, references, education, etc? |  |  |
| 48 | Is application information confirmed with relevant parties, and the confirmations documented? |  |  |
| 49 | Are criminal background checks conducted on “key” employees with access to drugs/devices? |  |  |
| 50 | Do new employees receive adequate training related to: |  |  |
| 51 | the general operations/systems of the facility? |  |  |
| 52 | critical operations related to their assigned task? |  |  |
| 53 | operational safety? |  |  |
| 54 | Do employees receive continued training in critical operations? How often? |  |  |
| 55 | Is training documented? |  |  |
| 56 | Are job appraisals/performance reviews and disciplinary actions performed and documented? |  |  |
| **F** | **IT Security** |  |  |
| 57 | Are computers password protected? |  |  |
| 58 | Are passwords required to be changed at least every 90 days? |  |  |
| 59 | Are systematic processes in place to prevent employees from accessing data/systems unrelated to their job critical task? |  |  |
| 60 | Are purchases, sales, shipments, and inventory-adjustment data files audit controlled? |  |  |
| 61 | How often is data backed-up? |  |  |
| 62 | Is backup data stored off-site? |  |  |
| 63 | Do other entities (corporate, related divisions, or other companies) have access to computer data? |  |  |
| **G** | **authorized trading partner – sources/vendors** |  |  |
| 64 | Does applicant determine that each new vendor holds appropriate licenses/permits/registrations for the level of service it’s providing? |  |  |
| 65 | Does the applicant verify these directly with the appropriate state and federal agencies (including FDA) prior to engaging in purchasing? |  |  |
| **Item #** | **Requirement** | **Y/N/N/A** | **Comment** |
| **G** | **authorized trading partner – sources/vendors** |  |  |
| 66 | Does applicant re-verify vendors’ licenses/permits/registrations directly with the appropriate state and federal agencies at least annually (including FDA)? |  |  |
| 67 | Are there any vendors (non-manufacturer) from whom the facility has purchased prescription drugs and devices that are NOT on the most recent submitted vendor list? *.* |  |  |
| 68 | Has the facility purchased prescription drugs and devices from a non-manufacturer vendor who subsequently exhibited suspect activity (unusually low price, prescription labels on bottles, worn labeling, shortage drugs with questionable procurement history, etc.) or were unable/unwilling to supply complete transaction information, or provided questionable transaction history (pedigree if prior to 1/1/15), in the last 3 years? |  |  |
| 69 | Do you still purchase products from the vendors identified above? |  |  |
| 70 | Are prescription drugs and devices purchased from wholesalers or repackagers that did not purchase those items directly from the manufacturer? |  |  |
| 71 | * If yes, are any due diligence activities conducted with each trading partner? |  |  |
| 72 | Does the facility have processes in place to ensure trading partners provide prescription drugs that were legitimately obtained from each previous owner? |  |  |
| 73 | Does the facility ensure that prescription drugs and devices purchased from trading partners were not previously distributed to: (1) pharmacies; (2) healthcare entities; or, (3) in violation of contracts for “own use” or other restrictions limited by Group Purchasing Contracts or Federal Purchasing Programs, such as 340B. |  |  |
| 74 | Does the facility purchase (or sell/broker for Virtuals) API (bulk active pharmaceutical ingredients)? |  |  |
| 75 | Do they determine that the supplier of the API is legitimate? |  |  |
| 76 | Do they determine the legitimacy of the supplier’s **sources** of API? |  |  |
| 77 | Do they determine that the API is legitimate? |  |  |
| **H** | **authorized trading partner - customers** |  |  |
| 78 | Does applicant determine that each new customer holds appropriate licenses/permits/registrations for the level of service it’s providing? |  |  |
| 79 | Does applicant verify customers’ licenses directly with the appropriate state and federal agencies (including FDA)? |  |  |
| 80 | Does applicant have adequate processes in place for monitoring purchase activity of customers and identifying ordering patterns that suggest criminal activity related to controlled substances? |  |  |
| 81 | Was a suspicious order monitoring report available to observe? |  |  |
| **I** | **Quality Program** |  |  |
| 82 | Is a quality assurance/improvement program in place that addresses areas of critical operations? |  |  |
| 83 | Is information collected as part of the program used to track trends and improve processes? |  |  |
| **Item #** | **Requirement** | **Y/N/N/A** | **Comment** |
| **I** | **Quality Program** |  |  |
| 84 | Are **product** complaint files maintained locally (Complaints from customers about the product integrity, not delivery times, etc.)? |  |  |
| 85 | Do any of the product complaints investigation result in a determination that the product is a “suspect” or “illegitimate” product? |  |  |
| 86 | If so, what actions were taken as a result of the determination?*.* |  |  |
| **J** | **Recalls** |  |  |
| 87 | If a specific item is subject to a recall, is there a way to identify all the customers to whom the product has been distributed? |  |  |
| 88 | Are recall records maintained and reports made to FDA/manufacturer when required by the recall notice? |  |  |
| 89 | Do employees demonstrate adequate knowledge of processes and proper techniques for complying with all classes of recalls? |  |  |
| 90 | Are recalled products immediately removed from stock and placed in quarantine when required by the recall notice? (NA for Virtuals) |  |  |
| **K** | **Crisis Operations** |  |  |
| 91 | Are adequate processes in place to ensure security, product integrity, and maintenance of critical records during emergency conditions? |  |  |
| 92 | Does staff receive training related to crisis operations? |  |  |
| 93 | Are adequate processes in place, and is staff properly trained to conduct after-action assessment of prescription products to ensure products’ integrity was not compromised due to the crisis? (NA for Virtuals) |  |  |
| 94 | Is sufficient power back-up in place (such as a generator) for use during emergency conditions? (NA for Virtuals) |  |  |
| 95 | If components of crisis operation procedures are outsourced (such as security or climate controlled off-site storage facilities), are contracts/formal agreements in place guaranteeing the availability of the services at time of a crisis. (NA for Virtuals) |  |  |
| **L** | **Common Carrier** (NA for Virtuals) |  |  |
| 96 | Does the facility use its own fleet and drivers to deliver prescription products? |  |  |
| 97 | Does the facility use any couriers or common carriers to deliver prescription products? |  |  |
| 98 | For couriers/common carriers, are processes in place to  ensure security of products while the items are in their care? |  |  |
| 99 | Are adequate processes in place for monitoring trends related to all prescription product losses while in-transit? |  |  |
| 100 | reporting losses and trends to the carrier? |  |  |
| 101 | discontinuing business with a carrier if trending determines a pattern of unresolved losses? |  |  |
| 102 | investigating losses in coordination with the carrier? |  |  |
| 103 | reporting trends of in-transit losses to law enforcement agency(s)? |  |  |
| **Item #** | **Requirement** | **Y/N/N/A** | **Comment** |
| **M** | **Facility** |  |  |
| 104 | Is the facility of sufficient size, construction, and design to provide adequate lighting, separation of work areas, and storage/movement of product in an orderly and safe manner? (NA for Virtuals) |  |  |
| 105 | Is the applicant located in a personal dwelling? |  |  |
| 106 | Are restrictions enforced on food/drink and/or personal items (purses, backpacks, large coats) in the prescription processing and storage areas? (NA for Virtuals) |  |  |
| 107 | Are housekeeping functions sufficient to ensure the facility is kept in a clean and well maintained manner at all times? Review supporting documentation for cleaning and sanitation schedules. (NA for Virtuals) |  |  |
| 108 | Are there secure trash removal processes in place in order to deter or detect theft of prescription product, packaging and product labeling? (NA for Virtuals)*.* |  |  |
| 109 | Are pest control services sufficient to control against insects, birds, and vermin? (NA for Virtuals) |  |  |
| **N** | **Facility Security** (NA for Virtuals) |  |  |
| 110 | Is the perimeter of the facility adequately secured and well lighted? |  |  |
| 111 | Does the facility have a security system (contact alarms, motion detectors, glass break detectors, etc.) that adequately covers product storage areas including all entrances/exits or other openings (windows that open, skylights, roof access doors) during and after business hours? |  |  |
| 112 | Are emergency exits equipped with an audible alarm or other means to detect opening during normal business hours? |  |  |
| 113 | Are alarm codes and after-hours entry authorizations limited to only necessary management? |  |  |
| 114 | Can the facility identify who accesses the facility after hours? |  |  |
| 115 | Are visitors required to sign-in/sign-out? |  |  |
| 116 | If there are contract services (housekeeping, pest control), have employees had background checks and are bonded? |  |  |
| 117 | Are visitors escorted at all times they are in the facility? |  |  |
| 118 | Is any area of the facility shared with another business? |  |  |
| 119 | Identify and describe the other business. |  |  |
| 120 | Are there prescription drug transactions between the applicant and the co-located business? |  |  |
| 121 | Are adequate methods/systems/devices in place for separating out/securing all aspects of the applicant’s operations, both physical and financial? |  |  |
| 122 | Are systematic processes and equipment in place to limit entry into the prescription processing/storage area to only authorized task-critical employees? |  |  |
| 123 | Are adequate security devices in place for securing bay doors? |  |  |
| 124 | Are video surveillance methods in place? (Not required) |  |  |
| **Item #** | **Requirement** | **Y/N/N/A** | **Comment** |
| **N** | **Facility Security** (NA for Virtuals) |  |  |
| 125 | Is the monitoring station secured? |  |  |
| 126 | Who has access to the monitoring station and tapes/images? |  |  |
| 127 | Are tapes/images retained? |  |  |
| **O** | **in-bound product and Receiving** (NA for Virtuals) |  |  |
| 128 | **Do employees demonstrate proper knowledge and techniques related to:**  Examination of the physical package, case, or tote for signs it has been opened, broken seal, damaged, leaking, repaired, or altered |  |  |
| 129 | Examination of label on the package, case, or tote examined for shipping address, postmarks, shipping address cut out, other indications that the product came from an unexpected foreign entity or source |  |  |
| 130 | Examination of the product for short dating, damage, leaking, broken seals, prescription labels or tape residue, missing package inserts or package inserts for different product |  |  |
| 131 | Foreign labeling, altered information on product, smudged or difficult to read print, missing lot number/NDC or strength, worn labels, misspelled words, bubbling on surface of the label, color or format of label does not seem usual |  |  |
| 132 | Doesn’t match purchase order, packing slip discrepancies, order changed since it was last received for an unexplained reason (e.g., a notification about the change from the manufacturer has not been received). |  |  |
| 133 | If any of the above are detected, process for refusing the package, or moving to quarantine? |  |  |
| 134 | Are the issues detected reported to management? |  |  |
| 135 | Identifying temperature-sensitive items, and the method of ensuring that temperatures are maintained within label requirements upon receipt? |  |  |
| 136 | Identifying controlled substances products and securing them upon receipt? |  |  |
| 137 | Is the receipt of transaction data verified prior to receiving product into active stock (for those products for which it is required)? |  |  |
| 138 | Returns – returns of prescription products are identified at receiving and moved to quarantine in a timely manner? |  |  |
| 139 | Are received products entered into a computer database for tracking throughout the period applicable to inventory record requirements? |  |  |
| **P** | **Product tracing** |  |  |
| 140 | Does the facility identify “products” (as defined under section 581(13) of the FD&C Act) requiring “Transaction” data? |  |  |
| 141 | Does the facility purchase/receive (sell/broker if Virtual) prescription drugs that are NOT defined as “products” (so do NOT require transaction data)? |  |  |
| 142 | Is transaction data received for all products for which transaction data is required*.* |  |  |
| 143 | Is transaction data transmitted for all products for which transaction data is required. |  |  |

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| **Item #** | **Requirement** | **Y/N/N/A** | **Comment** |
| **P** | **Product tracing** |  |  |
| 144 | Select a product from each of the vendors indicated in the surveyor notes above and examine transaction data (Transaction Information, Transaction History, Transaction Statement). List vendors in comments. |  |  |
| 145 | Is the transaction data received and complete? |  |  |
| 146 | Does the data trace back to the manufacturer (may include direct purchase statements)? |  |  |
| 147 | Is data transmitted to all customers (surveyor view/verify all subsequent transactions)? |  |  |
| 148 | Select a product from each vendor that the facility purchases from that is NOT on the list of vendors supplied to NABP (if applicable) and examine transaction data. |  |  |
| **Q** | **Temperature** (NA for Virtuals) |  |  |
| 149 | Does the facility have both heating and cooling (HVAC) for all product storage areas? |  |  |
| 150 | Are processes and sufficient equipment in place for monitoring and recording temperature: |  |  |
| 151 | at all times **(24/7/365)?** |  |  |
| 152 | in the general prescription product receipt, storage, and shipping areas? |  |  |
| 153 | in cold storage areas (refrigerators/freezers/cold rooms)? |  |  |
| 154 | Are monitors/probes located sufficiently and in ample numbers to adequately cover all prescription products in processing/storage areas? |  |  |
| 155 | Is monitoring equipment calibrated no less than annually or otherwise in compliance with its manufacturer’s recommendations? |  |  |
| 156 | Are records of temperature storage conditions maintained? |  |  |
| 157 | Is the temperature in the main storage area within range set? |  |  |
| 158 | Is the temperature in the refrigerated area(s) within range set? |  |  |
| 159 | Is the temperature in the freezer(s) area within range set? |  |  |
| 160 | Do employees demonstrate adequate knowledge and proper techniques related to: |  |  |
| 161 | identifying temperature requirements for all products? |  |  |
| 162 | following up when a temperature excursion occurs 24/7/365? |  |  |
| **R** | **Humidity** (NA for Virtuals) |  |  |
| 163 | Does the facility handle products with specific humidity requirements or APIs? |  |  |
| 164 | If so, are processes and sufficient equipment in place for monitoring humidity: |  |  |
| 165 | at all times **(24/7/365)?** |  |  |
| 166 | in the general prescription product receipt, storage, and shipping areas? |  |  |
| 167 | are monitors/probes located sufficiently and in ample numbers to adequately cover all prescription products in processing/storage areas? |  |  |
| 168 | Is monitoring equipment calibrated no less than annually or otherwise in compliance with its manufacturer’s recommendations? |  |  |
| 169 | Are records of humidity storage conditions maintained? |  |  |
| 170 | Is the humidity in the drug storage areas within the range set? |  |  |
| 171 | Do employees demonstrate adequate knowledge and proper techniques related to: |  |  |
| **Item #** | **Requirement** | **Y/N/N/A** | **Comment** |
| **R** | **Humidity** (NA for Virtuals) |  |  |
| 172 | identifying humidity requirements for all products? |  |  |
| 173 | following up when a humidity excursion occurs? |  |  |
| **S** | **Controlled Substances** (NA for Virtuals) |  |  |
| 174 | Are controlled substances stored in a Drug Enforcement Administration (DEA) approved cage/vault? |  |  |
| 175 | Is the controlled substance cage/vault equipped to ensure entry is limited to only authorized personnel? |  |  |
| 176 | How is access to the cage/vault monitored such as a log book, electronic record, etc.? |  |  |
| 177 | Is there a visitor log maintained to document access by others (maintenance, inspections, etc.)? |  |  |
| 178 | Are non-controlled substances stored within the DEA cage/vault? |  |  |
| 179 | Are adequate processes in place for handling List I chemicals? |  |  |
| 180 | Are periodic inventories performed and reconciled for **Schedule II** controlled substances? |  |  |
| 181 | Are periodic inventories performed and reconciled for **Schedule III-Schedule V** controlled substances? |  |  |
| 182 | Does the facility conduct a complete inventory of all controlled substances at least biennially? |  |  |
| 183 | Are DEA 106 forms on file? Observe three to five reports. |  |  |
| 184 | If so, does the number of reports, or the quantity of product reported as lost, indicate possible inadequate controls? |  |  |
| 185 | Was appropriate internal follow-up conducted regarding the losses? |  |  |
| 186 | Are patterns of losses evident in the reports? |  |  |
| 187 | Is the facility operating under a DEA directive, either formal or informal, regarding the reporting of controlled substance purchases that are more restrictive than CFR requirements*?* |  |  |
| **T** | **Quarantine** (NA for Virtuals) |  |  |
| 188 | Are processes in place for segregating prescription drugs or devices: |  |  |
| 189 | that have been returned? |  |  |
| 190 | whose immediate container has been opened? |  |  |
| 191 | that are out of date? |  |  |
| 192 | that have been recalled? |  |  |
| 193 | are determined to be suspect or illegitimate product |  |  |
| 194 | any other prescription drug or device that may be damaged, counterfeit, contraband, adulterated, or misbranded, diverted, tampered with, or whose labeling is suspect? |  |  |
| 195 | Are quarantined products segregated from other stock? |  |  |
| 196 | If electronic, are processes adequate to ensure against quarantined products being commingled with saleable stock? |  |  |
| **Item #** | **Requirement** | **Y/N/N/A** | **Comment** |
| **T** | **Quarantine** (NA for Virtuals) |  |  |
| 197 | If manual, are sufficient physical barriers and signage present to prevent commingling? |  |  |
| 198 | Are adequate processes present to ensure security of quarantined controlled substances? |  |  |
| 199 | Is there a segregated quarantine area in the refrigerator and freezer (if applicable)? |  |  |
| 200 | Do employees performing quality checks on quarantined product being considered for placement into saleable stock (such as returns) demonstrate knowledge of processes and proper techniques? |  |  |
| 201 | Record decisive factors used for vetting of product before returning to stock. |  |  |
| 202 | Is there a record, evidence, or signed statement from the customer returning the item that indicates the products were stored under conditions to preserve product integrity (that includes transportation conditions for temperature sensitive items) |  |  |
| 203 | Are adequate records maintained for documenting the quality checks of quarantined product that is returned to stock? |  |  |
| 204 | Are returned products checked against list of recalled products? |  |  |
| 205 | Is a perpetual inventory maintained for all prescription products in quarantine? |  |  |
| 206 | **Are processes for destroying out-of-date or damaged products sufficient?** |  |  |
| 207 | If in-house, are disposals/destructions witnessed by an appropriately authorized person? |  |  |
| 208 | If an outside vendor is used for destroying prescription products, what is the company name? |  |  |
| 209 | Does the applicant require proof of destruction records to be returned from the destruction agency? |  |  |
| 210 | Are records verifying destruction or product returned to the vendor maintained? |  |  |
| 211 | Do employees demonstrate adequate knowledge of processes and proper techniques for disposing of containers, labels, and packaging containing critical prescription product information to ensure that the items cannot be reused? |  |  |
| 212 | For repackagers or relabelers, are records of disposal/destruction of containers, labels, and packaging maintained? |  |  |
| 213 | **Suspect Product** is kept in quarantine until dispositioned (destroyed, returned, held for analysis) or cleared for distribution? |  |  |
| 214 | **Illegitimate product** is kept in quarantine until dispositioned |  |  |
| 215 | Sample is retained for analysis, if appropriate or requested by manufacturer or FDA? |  |  |
| 216 | *Review an illegitimate product notification sent to the FDA by the facility (if applicable), and audit on-hand quantity and disposition records against quantity indicated in the notification.*  Did the records and on-hand quantity match the quantity in the illegitimate product notification to FDA? |  |  |

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| **Item #** | **Requirement** | **Y/N/N/A** | **Comment** |
| **U** | **Inventory** (NA for Virtuals) |  |  |
| 217 | Do employees demonstrate adequate knowledge of processes and proper techniques related to:  monitoring prescription products for first-in, first-out/expiration dates? |  |  |
| 218 | identifying and moving to quarantine, products that while in stock at the facility: |  |  |
| 219 | have become out-of-date? |  |  |
| 220 | have had their packaging opened? |  |  |
| 221 | have possibly been subjected to temperature/humidity excursions? |  |  |
| 222 | have become suspected of being adulterated/misbranded/or the integrity of which might otherwise have been compromised? |  |  |
| 223 | Are cycle counts used to identify product shortages/losses? |  |  |
| 224 | How often are cycle counts performed? |  |  |
| 225 | Who has authority to adjust inventories related to inventory discrepancies? |  |  |
| 226 | Does that person sign off on all adjustment records? |  |  |
| 227 | Are inventory adjustment records archived for three years? |  |  |
| **V** | **Order Fulfillment and Shipping** (NA for Virtuals) |  |  |
| 228 | Do employees demonstrate adequate knowledge of processes and proper techniques for filling customers’ orders with accuracy and without jeopardizing the integrity of products? |  |  |
| 229 | Do employees demonstrate adequate knowledge of processes and proper techniques for  verifying and preparing orders for shipment? |  |  |
| 230 | ensuring the integrity of products (including maintaining temperature/humidity requirements) is not jeopardized while being staged/held in the shipping department? |  |  |
| 231 | prevent theft of prescription products while in the shipping area and during shipment? |  |  |
| 232 | ensuring that the integrity of products requiring refrigeration/freezing is maintained during shipment? |  |  |
| 233 | Are the shipping containers validated for maintaining appropriate temperature for the duration of shipment or other means to verify temperature? |  |  |
| 234 | Does the facility have testing data from the manufacturer or supplier of the packaging that indicates appropriate performance under the temperature extremes of the destinations to which products are shipped? |  |  |
| 235 | Does the facility perform its own testing during both hot and cold temperature extremes of the destinations to which products are shipped? |  |  |
| 236 | Does the facility utilize temperature indicators or devices? |  |  |
| 237 | Does the facility monitor weather/temperatures at the destinations and use to alter deliveries, if necessary? |  |  |

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| **Observations** |
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| **Plan of Correction:** |
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| **Inspection Completion** |
| **Exit Interview** |
| Plan of Correction (POC) Issued:  Yes  No  Plan of correction for all findings due within 15 business days. POC Due: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **Investigator Signatures** | |
| **Investigator:** |  |
| **Date:** |  |
| **Investigator:** |  |
| **Date:** |  |
| **Investigator:** |  |
| **Date:** |  |
| **Investigator:** |  |
| **Date:** |  |