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| **DATE(S) OF INSPECTION:** | **ISP# -** | | |
| **PHARMACY DBA NAME:** |  | | |
| **STORE NUMBER:** |  | | |
| **STREET ADDRESS:** |  | | |
| **CITY / STATE / ZIP:** |  | | |
| **TELEPHONE:** |  | | |
| **FAX:** |  | | |
| **EMAIL:** |  | | |
|  |  | | |
| **PHARMACY LIC. NUMBERS:** |  | | |
| **PHARMACY LIC. EXPIRATION:** |  | | |
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| **MANAGER OF RECORD (MOR):** |  | | |
| **MOR LIC. NUMBER:** |  | | |
|  |  | | |
| **COMPOUNDING INVESTIGATIONAL MEDICATION(S):** | **YES** | **NO** | |
| **COMPOUNDING DIETARY / NUTRITIONAL**  **SUPPLEMENTS:** | **YES** | **NO** | |
| **HIGHEST COMPOUNDING RISK LEVEL:** | **SIMPLE** | **MODERATE** | **COMPLEX** |
| **DAILY PHARMACY VOLUME (NON-STERILE**  **COMPOUNDING):** |  | | |
|  |  | | |
| **HOURS OF OPERATION:** | **M – F:** | **SAT:** | **SUN:** |



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| **A. Regulatory Requirements** | | | | | |
| **Item#** | **Requirements** | **Yes** | **No** | **N/A** | **Additional Information** |
| **1** | Compounder is appropriately licensed. |  |  |  |  |
| **2** | If compounder prepares a significant number of  non-patient specific preparations (e.g. >5% of the compounder's volume), the compounder is  registered as a drug manufacturer with the FDA, if  required. |  |  |  |  |
| **3** | If compounder prepares non-patient specific  controlled substances preparations, the compounder is registered as a drug manufacturer with the DEA. |  |  |  |  |
| **4** | All pharmacists are licensed in the state in which  they are practicing. |  |  |  |  |
| **5** | All pharmacy technicians are licensed or registered  in the state in which they are practicing. |  |  |  |  |
| **6** | Compounder meets or exceeds state required  pharmacist-to-pharmacy technician ratios for the state in which the compounding center is located. |  |  |  |  |
| **7** | If an FDA-approved product is commercially  available (not on backorder), the compounder does not prepare the same drug formulation using non-  sterile powders or other components. |  |  |  |  |
| **8** | When no commercial source exists to prepare  compounded products, the compounder uses USP grade bulk ingredients obtained from a GMP  compliant supplier. If yes, the compounder  provides a certificate of analysis and potency testing of all bulk ingredients used. |  |  |  |  |
| **9** | Compounded preparations are dispensed pursuant to  a valid prescription/order of an authorized practitioner to a specific patient. |  |  |  |  |
| **10** | Compounder meets regulatory requirements for  handling of hazardous agents. |  |  |  |  |



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| **B. Quality Requirements** | | | | | |
| **Item#** | **Requirements** | **Yes** | **No** | **N/A** | **Additional Information** |
| **11** | Compounder can provide documentation that  confirms staff competency (garbing and hand hygiene, compounding technique and related  practices, and cleaning and disinfection procedures)  is evaluated prior to compounding of actual drug preparations. |  |  |  |  |
| **12** | Compounder can provide documentation that  confirms that pharmacists and pharmacy technicians are pre-qualified to perform their assigned duties. |  |  |  |  |
| **13** | United States Pharmacopeia (USP), National  Formulary (NF) or Food Chemicals Codex (FCC) Substance is utilized as the source ingredients for  compounding all preparations |  |  |  |  |
| **14** | Compounders shall attempt to use components  manufactured in an FDA-registered facility |  |  |  |  |
| **15** | Compounded preparations are prepared from  ingredients that meet requirements of the compendial monograph for those individual  ingredients for which monographs are provided. |  |  |  |  |
| **16** | Does compounding facility compound preparations  intended for use as a dietary or nutritional supplement? (either yes or N/A) |  |  |  |  |
| **17** | Does compounding facility utilize any components  obtained or derived from ruminant animals (e.g. bovine, caprine, ovine)? (either yes or N/A) |  |  |  |  |
| **18** | Does compounding facility have available the FDA  list of components that have been withdrawn or removed from the market for safety or efficacy reasons. (see [www.FDA.gov](http://www.fda.gov/)) |  |  |  |  |



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| **Item#** | **Requirements** | **Yes** | **No** | **N/A** | **Additional Information** |
| **19** | Does compounding facility compound preparations  for food-producing animals? (either yes or N/A) |  |  |  |  |
| **20** | Are components used in the compounding of  preparations stored as directed by the manufacturer, or per USP, NF. FCC monograph requirements? |  |  |  |  |
| **21** | Compounder provides customers with substantial  evidence that supports beyond-use-dating (BUD) for compounded preparations as identified in USP  <1191>. BUD is appropriately identified on preparation container or label. |  |  |  |  |
| **22** | Compounder performs studies to determine  extended BUDs, using evidence-based and validated stability testing procedures for which no extended  BUD evidence exists. |  |  |  |  |
| **23** | Compounder has a policy that requires validation of  new or changed facilities, equipment, processes, container types, for sterility, and repeatability. (i.e.,  Change Control) |  |  |  |  |
| **24** | There is a mechanism to promptly address  equipment problems. |  |  |  |  |
| **25** | A quality assurance program for compounding  includes at least the following separate, but integrated components: (1) training; (2) standard  operating procedures; (3) documentation; (4)  verification; (5) testing; (6) cleaning and disinfecting; (7) containers, packaging, repackaging,  and storage. |  |  |  |  |



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| **Item#** | **Requirements** | **Yes** | **No** | **N/A** | **Additional Information** |
|  | **Ongoing Monitoring** |  |  |  |  |
|  | *All personnel involved in the compounding, evaluation, packaging and dispensing of compounded preparations are properly trained and*  *evaluated to include:* | | | | |
| **26** | **Non-sterile Compounding - simple preparations**  [A preparation that has a USP monograph or appears in a peer-reviewed journal article that  contains specific quantities of all components, compounding procedure and equipment, and BUD; or manipulating commercial product that may  require the addition of one or more ingredients.] |  |  |  |  |
| **27** | **Non-sterile Compounding - medium preparations** [A preparation that requires special  calculations or procedures to determine quantities of  components per preparation or per individualized dosage units; or making a preparation for which stability data for that specific formulation are not available.] |  |  |  |  |
| **28** | **Non-sterile Compounding - complex preparations** [A preparation that requires special  training, environment, facilities, equipment, and  procedures to ensure appropriate therapeutic outcomes.] |  |  |  |  |
| **29** | Compounder develops and implements methods for  improving quality based on analyzed data. |  |  |  |  |
| **30** | Compounder evaluates and continuously monitors  the methods used for the packaging, handling, and transport of compounded medication? |  |  |  |  |
| **31** | Compounder evaluates and continuously monitors  the storage of compounding components to ensure compliance with appropriate storage conditions. |  |  |  |  |



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| **Item#** | **Requirements** | **Yes** | **No** | **N/A** | **Additional Information** |
| **32** | Drug storage refrigerators, freezers and medication  storage areas have daily monitoring and documentation of temperatures. |  |  |  |  |
| **33** | Personnel inspect all drug storage areas routinely to  ensure drugs are stored separately from food. |  |  |  |  |
| **34** | Solutions, medications, equipment, and supplies (in  all areas) are stored per the manufacturer or USP requirements and are inspected routinely (per P&P)  for proper conditions of light, temperature, moisture, and ventilation. |  |  |  |  |
| **35** | Personnel determine whether a compounded  medication not administered as originally intended can be used for an alternate patient or under  alternate conditions |  |  |  |  |
| **36** | Didactic training, visual process validation and  written assessment of personnel is documented. |  |  |  |  |
| **37** | Are personnel who compound hazardous drugs fully  trained in the storage, handling, and disposal of these drugs? |  |  |  |  |
| **38** | Do personnel receive training prior to preparing  and handling hazardous drugs and verified by testing specific hazardous drug preparation techniques? Is training repeated annually? |  |  |  |  |
| **39** | Does the annual training and assessment for  hazardous drugs include didactic overview including mutagenic, teratogenic, and carcinogenic properties? |  |  |  |  |
| **40** | Is there a process for ongoing training for each new  hazardous drug that enters the marketplace? |  |  |  |  |



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| **Item#** | **Requirements** | **Yes** | **No** | **N/A** | **Additional Information** |
| **41** | Do compounding personnel of reproductive  capability confirm in writing that they understand the risks of handling hazardous drugs as part of the orientation process and repeat acknowledgment annually? |  |  |  |  |
| **42** | Does the compounder maintain results of quality  control procedures (e.g. weight range of filled capsules, pH of aqueous liquids, etc)? |  |  |  |  |
| **43** | Does the compounding record contain  documentation of any quality control issues and any adverse reactions or preparation problems reported  by the patient or caregiver? |  |  |  |  |
| **44** | Does the compounder observe the finished  preparation to ensure that it appears as expected to ensure accuracy and completeness? |  |  |  |  |
| **45** | The compounding facility investigates all  discrepancies and takes appropriate corrective action prior to dispensing to patients? |  |  |  |  |
| **46** | Documentation is available for any quality control  issues and any adverse reactions reported by the patient or caregiver? |  |  |  |  |



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| **C. Compounding Environment** | | | | | |
| **Item#** | **Requirements** | **Yes** | **No** | **N/A** | **Additional Information** |
| **47** | Space is sufficient for the type and amount of  compounding done. |  |  |  |  |
| **48** | The space provides for orderly placement of  equipment and materials to prevent mix-ups between ingredients, containers, labels, in-process  materials, finished preparations. |  |  |  |  |
| **49** | Procedures are implemented to prevent cross-  contamination. |  |  |  |  |
| **50** | Areas used for **sterile** preparation are separate and  distinct from areas used for **non-sterile** preparation. |  |  |  |  |
| **51** | The compounding area is well-lighted. |  |  |  |  |
| **52** | Heating, ventilation and air conditioning systems  are controlled. A constant temperature is maintained 24 hours per day, 7 days per week. |  |  |  |  |
| **53** | The bulk storage area is adequately arranged, proper  temperature and humidity maintained and suitably controlled. |  |  |  |  |
| **54** | The compounding areas are maintained in a clean  and sanitary condition. |  |  |  |  |
| **55** | Hot and cold potable water is supplied for hand and  equipment washing in the compounding area. Soap or detergent and single-use towels or driers are  readily available. |  |  |  |  |
| **56** | Is the plumbing system free of defects that could  contribute to contamination of any compounded product? |  |  |  |  |



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| **Item#** | **Requirements** | **Yes** | **No** | **N/A** | **Additional Information** |
| **57** | Does the heating, ventilation, and air conditioning  system control the compounding environment to avoid the decomposition or result in the contamination of compounding materials or compounded products? |  |  |  |  |
| **58** | Does the compounding environment meet the  manufactures requirements for the storage and preparation of drug products? |  |  |  |  |
| **59** | If no specific directions or limitations are provided  in the individual USP drug or product monograph or labeling (that is recognized by USP) does the  environmental conditions for storage and  distribution, regardless of quantity, include protections from moisture, freezing, excessive heat, and from light, where necessary? |  |  |  |  |
| **60** | Are components, equipment, and all containers  stored off the floor? |  |  |  |  |
| **61** | Does the pharmacy provide space sufficient to  prevent contamination and permit inspection and cleaning of the compounding and storage areas? |  |  |  |  |
| **62** | Does the pharmacy ensure that hazardous  compounds and drugs are stored, prepared, and handled by appropriately trained personnel under conditions that protect the healthcare workers and other persons? |  |  |  |  |
| **63** | Does the disposal of hazardous drugs and waste  comply with all applicable federal and state regulations? |  |  |  |  |



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| **Item#** | **Requirements** | **Yes** | **No** | **N/A** | **Additional Information** |
| **64** | Are the compounding equipment, utensils, and  containers used for packaging composed of suitable materials that are neither reactive, additive, nor sorptive and will not affect or alter the purity of the compounded preparations? |  |  |  |  |
| **65** | Does the storage of compounding equipment,  utensils and packaging containers protect them from contamination and are they located in a manner to facilitate the use, maintenance, and cleaning? |  |  |  |  |
| **66** | Are automated, mechanical, electronic, and other  types of equipment checked/inspected immediately prior to use and routinely as part of a preventative maintenance program to ensure suitability for use and proper performance? |  |  |  |  |
| **67** | Is all equipment appropriately cleaned after use?  (evidence of soiled equipment and tools indicates inappropriate cleaning) |  |  |  |  |
| **68** | Are there processes that ensure extra care for  cleaning of equipment and tools used for hazardous compounding? |  |  |  |  |
| **69** | Is all equipment for hazardous compounding  dedicated for such use? |  |  |  |  |
| **70** | Does the compounding facility utilize disposable  equipment when compounding hazardous drugs to reduce the chances of bioburden and cross- contamination? (Yes or N/A) |  |  |  |  |
| **71** | The compounding record is signed and dated  affirming that all procedures were carried out properly to ensure uniformity, identity, strength,  quantity and purity. |  |  |  |  |



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| **Item#** | **Requirements** | **Yes** | **No** | **N/A** | **Additional Information** |
| **72** | All substances have a complete label, batch control  number and future BUD on the container. |  |  |  |  |
| **73** | When manufactured products are used for  compounding, the labels contain a batch control number and a future BUD. |  |  |  |  |
| **74** | Capsules, powders, lozenges and tablets are  prepared per the standard practices and precautions for these dosage forms. |  |  |  |  |
| **75** | Emulsions, solutions and suspensions are prepared  per the standard practices and precautions for these dosage forms. |  |  |  |  |
| **76** | Suppositories are prepared per the standard practices  and precautions for these dosage forms. |  |  |  |  |
| **77** | Creams, topical gels, ointments and pastes are  prepared per the standard practices and precautions for these dosage forms. |  |  |  |  |
| **78** | The equipment generally is of appropriate design  and size for the compounding that is performed. |  |  |  |  |
| **79** | All equipment is thoroughly cleaned immediately  after use to avoid cross-contamination. |  |  |  |  |
| **80** | Equipment used for allergenic ingredients is  appropriately handled, cleaned and stored immediately after use. |  |  |  |  |
| **81** | All work surfaces are cleaned of loose materials and  residue from spills before compounding. |  |  |  |  |
| **82** | Product labels are appropriate and complete for safe  storage use |  |  |  |  |
| **83** | Trash is disposed of in a safe, sanitary and timely  manner (at least daily). |  |  |  |  |



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| **D. Compounding Procedures** | | | | | |
| **Item#** | **Requirements** | **Yes** | **No** | **N/A** | **Additional Information** |
| **84** | There is no smoking, food, drink, or chewing gum  allowed in the compounding area at any time. |  |  |  |  |
| **85** | At all steps in the compounding, dispensing, and  storage process, the compounder shall observe the compounded drug preparation for signs of  instability. |  |  |  |  |
| **86** | Primary Engineering Controls (PEC): e.g., airflow  workbench (powder hood) and negative pressure safety storage cabinets (Hazardous Drug Storage)  provide negative airflow with a minimum of 12 air  exchanges under dynamic conditions. |  |  |  |  |
| **87** | Do packaging and storage containers used in the  packaging of compounded preparations meet USP requirements (USP<660>; USP<661>; USP<671>;  USP<681>; USP<1136>; USP<1146>)? |  |  |  |  |
| **88** | All significant procedures performed in the  compounding area have standard operating procedures (SOP's). |  |  |  |  |
| **89** | All policies and procedures or SOP's are developed  for the facilities, equipment, personnel, preparation, packaging, and storage of compounded preparation to ensure accountability, accuracy, quality, safety, and uniformity in compounding. |  |  |  |  |
| **90** | Before putting on gloves, the nails should be  cleaned, and the hands, and wrists, should be washed thoroughly for at least 30 seconds with warm water and antimicrobial skin cleanser. |  |  |  |  |
| **91** | All components utilized in compounding are rotated  so that the oldest stock is utilized first? |  |  |  |  |



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| **Item#** | **Requirements** | **Yes** | **No** | **N/A** | **Additional Information** |
| **92** | All components are properly labeled and stored  appropriately including opened and partially used containers? |  |  |  |  |
| **93** | Compounding personnel check the quality, purity,  amount, and identity of all ingredients |  |  |  |  |
| **94** | Correct compounding procedures are used |  |  |  |  |
| **95** | During compounding, periodically disinfect gloves  with 70% isopropyl alcohol and allow them to dry thoroughly before continuing. |  |  |  |  |
| **96** | Product labels are appropriate and complete for safe  use |  |  |  |  |
| **97** | Deficiencies in compounding procedures can be  rapidly identified and corrected. |  |  |  |  |
| **98** | Completed compounded products are maintained in  a separate area away from the active compounding area. |  |  |  |  |
| **99** | Prescription containers are labeled to contain: name  of preparation; internal identification number; beyond-use date; initials of compounder who  prepared the label; storage requirements; other statements as required by law. |  |  |  |  |
| **100** | The compounding log is annotated and formulation  documented. |  |  |  |  |
| **101** | **Non-aqueous Formulations -** The BUD is not later  than the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier. |  |  |  |  |
| **102** | **For Water-Containing Oral Formulations -** The  BUD is not later than 14 days when stored at controlled cold temperatures. |  |  |  |  |
| **103** | **For Water-Containing Topical/Dermal and Mucosal Liquid and Semisolid Formulations -** The BUD is not later than 30 days. |  |  |  |  |



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| **E. Records Management** | | | | | |
| **Item#** | **Requirements** | **Yes** | **No** | **N/A** | **Additional Information** |
| **104** | The record keeping requirements of the state are  followed. |  |  |  |  |
| **105** | The pharmacy is licensed to handle controlled  substances. |  |  |  |  |
| **106** | Compounding records and documents are  maintained for the time required by the state. |  |  |  |  |
| **107** | Does compounder provide written standard  operating procedures (SOP's) for pharmaceutical compounding for the facility to include equipment use, personnel, preparation, packaging, and the storage of compounded preparations to ensure accountability, accuracy, quality, safety, and uniformity in compounding? |  |  |  |  |
| **108** | Do written standard operating procedures (SOP's)  establish procedural consistency and provide a reference for orientation and training of personnel? |  |  |  |  |
| **109** | Material Safety Data Sheets or Safety Data Sheets  (MSDS or SDS) are readily accessible to all employees working with drug substances or bulk  chemicals located within the facility. Employees  know how to access MSDS file. |  |  |  |  |
| **110** | A procedure is defined for recalls. The recall file  should be maintained with information concerning any applicable recalled products affecting the  pharmacy. |  |  |  |  |
| **111** | Compounder provides minimum guaranteed shelf  life upon delivery. |  |  |  |  |



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| **Item#** | **Requirements** | **Yes** | **No** | **N/A** | **Additional Information** |
| **112** | A detailed formulation record is maintained for each  non-sterile compounded preparation and includes: name of preparation, strength and dosage form; all ingredients and their quantities; equipment used for the preparation; mixing instructions to include order of mixing, temperatures, duration of mixing and other pertinent factors; BUD; container used; storage requirements; quality control procedures. |  |  |  |  |
| **113** | A detailed compounding record is maintained for  each compounded non-sterile preparation and includes:   * Name, strength and dosage of the preparation; * Formulation record reference; * Names and quantities of all components; * Manufacturer or supplier and lot numbers of components; * Total number of dosage units compounded; * Name of person compounding the preparation; * Date of compounding; * Assigned internal identification number of the prescription number; * Assigned beyond-use date; * Results of quality control procedures (e.g., weight range of filled capsules, pH of aqueous liquids, etc.); * Name of person completing the quality control procedures; * Name of person who approved the preparations; * Duplicate label as described in the master formulation record; * Description of the final preparation. |  |  |  |  |



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| **Item#** | **Requirements** | **Yes** | **No** | **N/A** | **Additional Information** |
| **114** | Compounder provides quality control history and  quality assurance trend reports on a regular basis and upon request. |  |  |  |  |
| **115** | Compounder provides pedigree information that  documents that they do not purchase products outside of traditional drug distribution networks or  through secondary wholesalers. |  |  |  |  |
| **116** | Compounder has documented processes and  procedures (including shipping validation studies) to ensure that preparations leaving the site retain their integrity and stability through the shipping cycle. |  |  |  |  |
| **117** | Documentation is available that cleaning methods  and agents are effective in preventing contamination and cross-contamination of non-sterile materials and drugs within the compounding preparations areas. |  |  |  |  |



I have participated in a non-sterile compounding audit and have reviewed the audit report with the inspectors.

Plan of Correction Issued: Yes No

If yes, I will provide a plan of correction for all findings within 15 business days.

### Print Name: Signature:

**Title: License Number:**

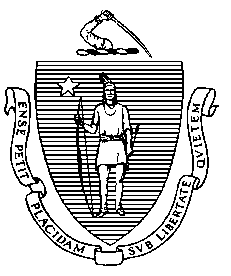
**Inspector: Date:**

**Inspector: Date:**

**Inspector: Date:**

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| **Comments:** |
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The Commonwealth of Massachusetts Executive Office of Health and Human Services Department of Public Health



## Bureau of Health Professions Licensure

239 Causeway Street, Suite 500, Boston, MA 02114

CHARLES D. BAKER

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KARYN E. POLITO

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[www.mass.gov/dph/boards](http://www.mass.gov/dph/boards)

MARYLOU SUDDERS

Secretary

MONICA BHAREL, MD, MPH

Commissioner

**Massachusetts Board of Registration in Pharmacy Non-Sterile Compounding Documents for Inspection**

# Licenses:

* Massachusetts Drug Store Pharmacy License
* Massachusetts Controlled Substance Registration
* DEA Controlled Substance Registration Certificate
* Non-Resident Drug Store Pharmacy Licenses for all States Doing Business In Massachusetts
* Complex Non-Sterile Compounding License, as applicable
* Pharmacist, Pharmacy Intern, and Pharmacy Technician Licenses & Registration Cards
* Technician Trainee hours
* Other (DCP, FDA, etc.)

# Policy and Procedure Manual:

* Environmental Monitoring (e.g. Temperature, Humidity, etc.)
* Certification based tests for PECs and SECs, as applicable
* Proper Storage, handling, shipping, packaging, transportation, and delivery
* Final release checks and verification of non-sterile compounded preparations
* Quality assurance program including RCA and CAPA
* Change control, validation of new or changed facilities, equipment, or processes
* Hand hygiene and garbing processes
* Patient monitoring and adverse event reporting, including recalls of CSPs
* Maintenance, calibration, and cleaning intervals
* Response to broken, damaged, or spilled non-sterile compounded preparation
* Compounding procedures specific to each risk level
* Quality control testing requirements and procedures (pH testing, capsule variance, etc.)
* Assignment of BUD
* Proper waste handling and disposal Equipment maintenance program

# Personnel Training, Competency, and Proficiency Tests:

* Training program for new and veteran compounding personnel
* Hand Hygiene and Garbing competencies for compounding personnel and external staff members
* Cleaning and Disinfection competencies for compounding personnel and external staff members

# Quality Related Documentation:

* Environmental monitoring results including trending analysis and sampling map
* Certification report for compounding environment
* Example of Out of Specification reports for Environment, Personnel and Product including Root Cause Analysis (RCA) and Corrective Action Preventative Action CAPA.
* Compounding Master Formulation Record and Individual Compounding Record
* Cleaning and Disinfection Log, Temperature and Humidity Log
* Extended Stability Analytical Testing Reports
* List of Non-Sterile Compounds Produced and/or Outsourced
* List of Non-Sterile Compounds Recalled, for any Reason
* Equipment Maintenance Log