

Board of Pharmacy Retail Sterile Compounding Questionnaire

INSTRUCTIONS AND DEFINITIONS

1. Unless otherwise specifically indicated, the following terms are defined as set forth below:

i. “Low-risk level compounded sterile preparations” means preparations compounded with aseptic manipulations entirely within ISO class 5 or better air quality using only sterile ingredients, products, components, and devices. The compounding process involves only assembling, transferring, measuring, and mixing, using no more than three commercially manufactured sterile products, and not more than two entries into one sterile container or package to make the compounded sterile preparations. The compounding process is limited to aseptically opening ampules, penetrating sterile stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products, and containers for storage and dispensing.

ii. “Medium-risk level compounded sterile preparations” means preparations compounded under low-risk level conditions but which require multiple individual or small doses of sterile products to be combined or pooled to prepare compounded sterile preparations that will be administered either to multiple patients or to one patient on multiple occasions. The compounding process includes complex aseptic manipulations other than single volume transfer, and requires an unusually long duration, such as that required to complete dissolution or homogeneous mixing.

iii. “High-risk level compounded sterile preparations” means preparations compounded from non-sterile ingredients or from ingredients that are incorporated using non-sterile equipment before terminal sterilization, or from commercially manufactured sterile products that lack effective antimicrobial preservatives and whose preparation, transfer, sterilization, and packaging is performed in air quality worse than ISO class 5 for more than one hour. Water-containing preparations that are stored for more than six hours before terminal sterilization are also classified as high-risk level compounded sterile preparations.

PLEASE PROVIDE A FULL AND COMPLETE ANSWER TO EACH QUESTION, ON A SEPARATE SHEET OF PAPER. EACH ANSWER SHOULD BE AS LENGTHY AS NECESSARY TO PROVIDE ALL THE INFORMATION REQUESTED. PLEASE READ, SIGN AND ATTACH A COPY OF THE ACCOMPANYING CERTIFICATION FOLLOWING THE LAST PAGE OF YOUR ANSWERS.

- 1) Provide a schematic drawing of the pharmacy, including the clean room (with identification of laminar airflow workbenches, biological safety cabinets, compounding aseptic isolators and compounding aseptic containment isolators) and the buffer area and ante area. Provide the total square footage of each area and indicate the maximum number of individuals who engage in compounding activities at any given time. Provide an explanation of any structural feature designed for the purpose of segregating any product that has the potential to cross-contaminate with other products (i.e. penicillin)
- 2) Does this pharmacy comply fully with all standards in USP 797, including but not limited to standards pertaining to personnel training and testing; environmental quality maintenance and monitoring; verification of the accuracy, purity, and sterility; and assignment of Beyond-Use Dates (BUDs) for Compounded Sterile Products (CSPs)? Do you make representations of compliance with USP 797 on a website or in promotional literature? Provide copies of such representations. If the pharmacy is not compliant, provide a detailed explanation of any deviation from those standards.
- 3) Does this pharmacy prepare High-Risk Level CSPs? If so, specify the products, the form in which they are produced (i.e. injectable syringes, IV bags, and oral doses) and approximately how many units of each product, in each format, are produced annually. Provide the Beyond-Use Dates (BUDs) for each product and the methodology used to establish that date. Indicate whether preservatives are used in the compounding of such products. What percentage of the product is tested for sterility, what is the nature of the testing performed, is such testing conducted on-site and by whom and how frequently is it performed? What percentage of the product is tested for stability, what is the nature of the testing performed, is such testing conducted on-site and by whom and how frequently is it performed? What percentage of the product is tested for potency, what is the nature of the testing performed, is such testing conducted on-site and by whom and how frequently is it performed? If any of the testing is not conducted on-site, provide the name of the person or entity conducting the testing and where it is performed.
- 4) Does this pharmacy prepare Medium-Risk Level CSPs? If so, specify the products, the form in which they are produced (i.e. injectable syringes, IV bags, oral doses) and approximately how many units of each product, in each format, are produced annually. Provide the Beyond-Use Dates (BUDs) for each product and the methodology used to establish that date. Indicate whether preservatives are used in the compounding of such products. What percentage of the product is tested for sterility, what is the nature of the testing performed, is such testing conducted on-site and by whom and how frequently is it performed? What percentage of the product is tested for stability, what is the nature of the testing performed, is such testing conducted on-site and by whom and how frequently is it performed? What percentage of the product is tested for potency, what is the nature of the testing performed, is such testing conducted on-site and by whom and how frequently is it performed? If any of the testing is not conducted on-site, provide the name of the person or entity conducting the testing and where it is performed.
- 5) Does this pharmacy prepare Low-Risk Level CSPs? If so, specify the products, the form in which they are produced (i.e. injectable syringes, IV bags, and oral doses) and approximately how many units of each product, and in each format, are produced annually. Provide the Beyond-Use Dates (BUDs) for each product and the methodology used to establish that date. Indicate whether preservatives are used in the compounding of such products. What percentage of the product is tested

for sterility, what is the nature of the testing performed, is such testing conducted on-site and by whom and how frequently is it performed? What percentage of the product is tested for stability, what is the nature of the testing performed, is such testing conducted on-site and by whom and how frequently is it performed? What percentage of the product is tested for potency, what is the nature of the testing performed, is such testing conducted on-site and by whom and how frequently is it performed? If any of the testing is not conducted on-site, provide the name of the person or entity conducting the testing and where it is performed.

6) Does this pharmacy compound commercially available FDA approved products that are currently available? If so, identify such products and explain the rationale for doing so.

7) Does the pharmacy repackage products? If so, identify such products and explain the rationale for doing so.

8) Is this pharmacy in good standing with all pertinent licensing and regulatory agencies including states to which it ships or delivers its medications (both CSPs and non CSPs)? If not, provide a detailed explanation as to why not and any communication it has received with respect to its standing in other jurisdictions. Provide a list of all jurisdictions into which the pharmacy is authorized to dispense.

9) Is the pharmacy registered as a manufacturer either with the U.S. Food and Drug Administration or any state agency? Is the pharmacy registered as a wholesaler in New Jersey or any other state? Provide the registration numbers, and the date that the registration was last renewed and when it will expire.

10) Is the pharmacy party to an agreement to conduct centralized prescription handling with another pharmacy, including institutional pharmacies, in New Jersey or with pharmacies or, including institutional pharmacies, in any other state? Provide copies of any current contractual agreements between this pharmacy and any other pharmacy to provide any of the services in central prescription handling. If the other pharmacy that is party to this contract is out-of-state, provide its registration number in New Jersey.

11) Provide the dates, over the course of the five (5) years preceding this Demand, on which this pharmacy was inspected by any regulatory agency. Identify the agency that performed the inspection and provide copies of any reports that it received as a result of such an inspection.

12) Over the course of the five (5) years preceding this Demand, has this pharmacy received any communication from a regulatory agency, assessing penalties, fines or other discipline, or providing warnings, advisories or guidance. If yes, provide such communication and provide a detailed explanation of the disposition, and what steps the pharmacy took to address the findings or observations noted by the regulatory agency.

13) Does this pharmacy have a comprehensive manual of standard operating procedures (SOPs)? Provide a copy of the current SOPs and indicate when it was last revised. Are all personnel responsible for compounding products provided with access to the SOPs? Are all personnel responsible for compounding products trained on the requirements as set forth in the SOPs and in what manner? If not, provide a detailed explanation as to why not.

14) Does this pharmacy have a formal process to document compliance with all of the procedures set forth in its SOPs? If yes, describe the documentation process.

15) Do any of the pharmacists or pharmacy technicians producing CSPs have any documentation attesting to completion of formal, specialized training in sterile compounding? If so, list the names

of pharmacists and pharmacy technicians, the type of training for each received and when, the training provider and the documentation maintained to demonstrate such training. Describe the nature of training that is provided, providing a summary of the curriculum covered. How frequently is training required? How frequently is training offered?

16) Provide a list of all personnel currently engaged in sterile compounding at the pharmacy and their respective license or registration numbers. (If there has been no change in such staffing since the pharmacy responded to the survey attached hereto, indicate that there has been no change.) Do you have a microbiologist on-site? Do you have microbiologist or a firm under contract or retainer to provide services and with what frequency? Identify the microbiologist or firm and provide a curriculum vitae or description of firm qualifications.

17) Does the pharmacy document the source, strength, and purity of each ingredient in each CSP? If yes, describe the system utilized to document these product characteristics. If not, provide a detailed explanation as to why such documentation is not created and maintained.

18) Does the pharmacy document that all of the active and inactive ingredients in CSPs are FDA approved for drug and nutrient use or are official articles in the currently official USP-NF? If yes, describe the system utilized to document the approval status of CSPs. If not, provide a detailed explanation as to why not.

19) Does the pharmacy require a patient-specific valid prescriptions or patient-specific medication orders to support the quantity of medication in advance of compounding? If a valid prescription or medication order is not required in advance of the compounding, what documentation does the pharmacy subsequently obtain to support the compounding performed, and within what timeframe must it be produced? How does the pharmacy obtain and maintain documentation of the history of prescribing to the patient which supports the quantity of medication compounded? How does the pharmacy obtain and maintain documentation of the ongoing prescriber-patient-pharmacist relationship for all products dispensed? If no such record is maintained, provide a detailed explanation as to why not.

20) Does the pharmacy batch-prepare compounded sterile medications for use by a licensed prescriber in professional practice? What documentation does the pharmacy obtain and maintain with respect to the compounding of sterile preparations intended for use by a professional in the course of professional practice? If no such record is maintained, provide a detailed explanation as to why not.

21) Are CSPs intended for administration by the epidural, intra-articular, intra-ocular, intraperitoneal, intrathecal, intravascular, and ophthalmic routes terminally sterilized in their final sealed containers by autoclaving or steam under pressure when contents, closures and containers are stable? If yes, specify the methods used. If not, provide a detailed explanation as to why not.

22) Is steam sterilization monitored and verified using biological and thermochemical indicators? If yes, describe the process used, setting forth the frequency of verification. If not, provide a detailed explanation as to alternate monitoring or verification processes.

23) Does the preparation of batches of CSPs that are divided into individual package forms (i.e. syringes, bags, vials) meet the requirements of USP General Chapter <71> Sterility Testing before the products are dispensed or shipped? If not, provide a detailed explanation as to why not.

24) Does the preparation of batches of official USP injectable CSP's that are divided into individual injectable doses (i.e. syringes, bags, vials) meet the requirements of the USP article

monograph and USP General Chapters <1> Injections and <85> Bacterial Endotoxins Test before the products are dispensed or shipped? If not, provide a detailed explanation as to why not.

25) Are sterile filters used to sterilize multiple package batches of CSPs intended for multiple patients observed and documented to pass the filter integrity bubble point test specified by the filter manufacturer or supplier before such CSPs are dispensed and administered?

26) Do the SOPs detail the process to be followed with respect to maintaining an audit trail with respect to all sterile products? If those practices and policies set forth in the manual of SOPs, provide the page number or section in which this issue is addressed. During the period addressed by the Demand, provide the number of times that this pharmacy undertook to investigate breaches of the audit trail process, and provide detail as to each such event and the steps undertaken as part of the investigation and the determination of the root cause of the breach. If no investigation was undertaken, provide a detailed explanation as to why not.

27) Do the SOPs detail the process to be followed with respect to the labeling of all products, and for assuring that the labeling process does not affect the sterility of the product? If those practices and policies set forth in the manual of SOPs, provide the page number or section in which this issue is addressed. During the period addressed by the Demand, provide the number of times that this pharmacy undertook to investigate labeling errors internally identified or reported by customers, and provide detail as to each such event and the steps undertaken as part of the investigation and the determination of the root cause of the breach. If no investigation was undertaken, provide a detailed explanation as to why not.

28) Do the SOPs detail the gowning or garbing techniques to be followed by all personnel engaged in activities relating to the compounding of sterile products? If those practices and policies set forth in the manual of SOPs, provide the page number or section in which this issue is addressed. During the period addressed by the Demand, provide the number of times that this pharmacy undertook to investigate breaches of the gowning or garbing policies, and provide detail as to each such event and the steps undertaken as part of the investigation. Describe what corrective and preventative action was undertaken. If no investigation or corrective or preventative action was undertaken, provide a detailed explanation as to why not.

29) Do the SOPs detail the gloving techniques to be followed by all personnel engaged in activities relating to the compounding of sterile products? If those practices and policies set forth in the manual of SOPs, provide the page number or section in which this issue is addressed. During the period addressed by the Demand, provide the number of times that this pharmacy undertook to investigate breaches of the gloving policies, and provide detail as to each such event and the steps undertaken as part of the investigation. Describe what corrective and preventative action was undertaken. If no investigation or corrective or preventative action was undertaken, provide a detailed explanation as to why not.

30) Do the SOPs detail the process to investigate out-of-limit environmental and personnel monitoring results specified in USP 797? If those practices and policies set forth in the manual of SOPs, provide the page number or section in which this issue is addressed. During the period addressed by the Demand, provide the number of times that this pharmacy undertook to investigate out-of-limit environmental or personnel monitoring results that failed to meet the standards set forth in USP 797, and provide detail as to each such event and the steps undertaken as part of the investigation and the determination of the root cause of the out-of-limit event. If no investigation was undertaken, provide a detailed explanation as to why not.

31) Do the SOPs detail the process to implement and verify corrective and preventative actions when out-of-limit environmental and personnel monitoring results specified in USP 797 occur? If

those practices and policies set forth in the manual of SOPs, provide the page number or section in which this issue is addressed. During the period addressed by the Demand, provide the number of times that this pharmacy undertook to implement and verify corrective and preventative actions to address out-of-limit environmental or personnel monitoring results that failed to meet the standards set forth in USP 797, and provide detail as to each such event and the steps undertaken as part of the implementation and verification process. If no steps were undertaken to implement corrective or preventative actions, provide a detailed explanation as to why not.

32) What practices and procedures, including shipping monitoring studies, are used to ensure that particular CSPs retain their integrity and stability through the transportation or shipping cycle? How are the practices and procedures documented? If those practices and policies set forth in the manual of SOPs, provide the page number or section in which this issue is addressed. During the period addressed by the Demand, provide the number of times that this pharmacy was alerted to deviations from practices and procedures that had the potential to affect the integrity or stability of CSPs. Describe such deviations and the steps that the pharmacy took to implement and verify corrective and preventative actions to address such deviations. If no steps were undertaken to implement corrective or preventative actions, provide a detailed explanation as to why not.

33) What practices and procedures are to be followed if a customer alerts the pharmacy that a CSP is incorrectly compounded, incorrectly labeled or incorrectly packaged? How are the practices and procedures documented? If those practices and policies set forth in the manual of SOPs, provide the page number or section in which this issue is addressed. During the period addressed by the Demand, provide the number of times that a customer alerted the pharmacy to the fact that a CSP had been incorrectly compounded, incorrectly labeled or incorrectly packaged? Describe each such instance, identifying the CSP involved and nature of deviation, as well as the steps that the pharmacy took to implement and verify corrective and preventative actions to address the deviation and the ultimate disposition of the product. If no steps were undertaken to implement corrective or preventative actions, provide a detailed explanation as to why not.

34) Is each CSP accompanied by a notice at all times which provides the telephone number(s) of pharmacist(s) who supervised preparation or prepared each CSP to enable immediate reporting of adverse reactions of patients and observations of abnormal appearance of CSPs? What practices and procedures does the pharmacy employ to assure that the pharmacist will be available to receive such telephone calls? If no practices or policies, assure pharmacist availability, provide a detailed explanation as to why not.

35) What practices and policies are established to receive and document reports of adverse reactions of patients and observations of abnormal appearance of CSPs? How are these practices and procedures documented? If those practices and policies set forth in the manual of SOPs, provide the page number or section in which this issue is addressed. During the period addressed by the Demand, provide the number of times that the pharmacy received a report of an adverse patient reaction or an observation of an abnormal appearance of a CSP. Describe each such instance, identifying the CSP involved and nature of report, as well as the steps that the pharmacy took to investigate the root cause of the event and implement and verify corrective and preventative actions to address the reported issue, inform patients and prescribers of any recall, notify any regulatory agencies and handle the ultimate disposition of the product. Provide copies of any communications that were provided to patients, prescribers or regulatory agencies. If no steps were undertaken to investigate or implement corrective or preventative actions, provide a detailed explanation as to why not.

36) What practices and policies are established to investigate the cause and source of any potential finding of a contaminant (i.e. turbid broth, particulate matter) in a CSP? How are these practices and procedures documented? If those practices and policies set forth in the manual of SOPs, provide the

page number or section in which this issue is addressed. During the period addressed by the Demand, provide the number of times that the pharmacy internally identified or received a report of a contaminated CSP. Describe each such instance, identifying the CSP involved and contaminant found, as well as the steps that the pharmacy took to investigate the cause and source of the contaminant, inform patients and prescribers of any recall, notify regulatory agencies of the contaminant and the root cause to the extent identified. Specifically, identify any testing (microbial, endotoxin or otherwise) that was done, whether it was done on-site or off-site and by whom, and the results of that testing. Provide copies of any communications that were provided to patients, prescribers or regulatory agencies. If no such steps were undertaken, provide a detailed explanation as to why not.

37) What practices and policies are established to test personnel on the use of aseptic techniques and at what frequency are such tests performed? How are these practices and procedures documented? If those practices and policies set forth in the manual of SOPs, provide the page number or section in which this issue is addressed. During the period addressed by the Demand, provide the number of times that pharmacy personnel failed performance challenges. Describe each such instance, identifying the personnel involved, any retraining required, and/or any retesting performed and the results of such retesting. What steps were pursued to evaluate possible impact of the failed performance challenges on finished drug products and/or to retrieve product? Provide copies of any communications that were provided to personnel concerning failed performance challenges or to customer pertaining to the retrieval of finished product. If no such steps were undertaken, provide a detailed explanation as to why not.

38) When did the Registered Pharmacist In Charge last review the standards set forth in USP 797, and the requirements of USP General Chapter <71> Sterility Testing and the requirements of the USP article monograph and USP General Chapters <1> Injections and <85> Bacterial Endotoxins Test?

39)

CERTIFICATION

I certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

I hereby certify that the copies of any and all documents annexed hereto are true and complete copies.

Name (sign)

Name (print)

Title or Position: _____

Date: _____