NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: _____

NV Pharmacy or Outsourcing facility license # (if applicable): _____

Physical Address: _____

City: _____ State: _____ Zip: _____

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: _____ Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: _____ Contact Email: _____

Website: _____

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): _____

Supervising/Managing Pharmacist NV Pharmacist Registration #: _____

Name of Designated Person(s) as defined by revised USP-797 guidelines: _____

Email of Designated Person(s): _____

Telephone of Designated Person(s): _____

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

   ☐ Category 1 ☐ Category 2 ☐ Category 3

If you marked "**Category 3**", you must also complete **section 4**.

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ☐ Yes ☐ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ☐ Aseptic ☐ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ☐ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? _____

6. What is the frequency of the recertification for the ISO classified areas? _____

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ☐ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ☐ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? _____

10. Will you be performing sterile hazardous drug compounding? ☐ Yes ☐ No

If you marked "**Yes**", you must also complete **section 3**.

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

12. What laboratory performs your sterility or endotoxin testing?

Name: _____

Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____

13. What is your procedure for visual inspection of compounded sterile products?

14. How often do you perform glove fingertip and medial fill testing?

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

17. Who performs the sterile compounding process at your facility?

18. Who is responsible and accountable for the sterile compounding process at your facility?

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility?		
2. Are you complying with all USP 800 guidelines?	☐ Yes	☐ No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	☐ Yes	☐ No
4. Is your BSC or CACI vented 100% to the outside?	☐ Yes	☐ No
5. Do you have a negative pressure buffer room at your facility?	☐ Yes	☐ No
6. Will you be compounding with antineoplastic HDs or HD API?	☐ Yes	☐ No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☐ Yes	☐ No
8. Will you be utilizing a closed system transfer device?	☐ Yes	☐ No
9. If yes, list the name of the device:		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? ☐ Yes ☐ No

4. What is the frequency for completing volumetric active air sampling?

5. What is the frequency for completing surface sampling?		
6. What is the frequency for using sporicidal agents?		
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	☐ Yes	☐ No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	☐ Yes	☐ No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

_____

Name of Person who Completed the Form

_____

Title

_____ _____

Signature (copies or stamps not accepted) Date

Board Use Only	Date Received:_____ Date Approved: _____ Approved By: _____