Certification Submission Form

This form must be completed, signed, and sent along with any required certification and/or viable sampling report submitted.

COMMENTS | *Clear Form*

1. Have all cleanrooms, laminar airflow workbenches, BSCs, CAIs, CACIs, and barrier isolators been certified? ○ Yes ○ No

2. List the number of individuals documented as being present during dynamic comprehensive viable environmental monitoring: Anteroom: #_____ Buffer room: #_____ HD buffer room: #_____

3. Does the cleanroom have an ISO Class 5 shielded laminar workflow area built into the room? ○ Yes ○ No

4. Is certification performed at least every 6 months, whenever the PECs are replaced or relocated; the physical structure of the buffer room or anteroom has been altered; or when any airflow or air quality is affected? ○ Yes ○ No

4a. Are certification reports available? ○ Yes ○ No
4b. Note the date(s) of certification failure, if applicable.

5. Has the cleanroom been independently certified using the requirements of USP Chapter 797 and when applicable, manufacturer specifications? ○ Yes ○ No

5a. Indicate the standards used as cited in the report:

6. Is the equipment used by the certifier calibrated and is the calibration in date? ○ Yes ○ No

7. Does each test on the certification report have a clear indication of pass or fail? ○ Yes ○ No

				COMMENTS
8.	Are the HEPA filtered air changes per hour (ACPH) measured for the compounding rooms?	Yes	No	
8a.	Are ISO Class 7 rooms certified as having a minimum of 30 ACPH with at least 15 ACPH of the total air change rate in the room from the HVAC through HEPA filters located in the ceiling?	Yes	No	
8b.	Are ISO Class 8 rooms certified as having a minimum of 20 ACPH with at least 15 ACPH of the total air change rate in the room from the HVAC through HEPA filters located in the ceiling?	Yes	No	
9.	Was air pattern analysis using smoke testing performed in each PEC?	Yes	No	
10.	Is smoke flow in the PEC described in the report for the various tests such as turbulent, sluggish, smooth, etc.?	Yes	No	
11.	Was a dynamic airflow smoke pattern test conducted inside each PEC (i.e., the direct compounding area) to demonstrate unidirectional airflow and sweeping action over and away from the preparations under dynamic operating conditions?	Yes	No	
12.	Was a visual smoke study test performed in the SECs to verify the absence of stagnant airflow?	Yes	No	
13.	If the cleanroom has an ISO Class 5 shielded laminar workflow area, are both static and dynamic smoke studies documented verifying continuous flow of HEPA-filtered air void of turbulence, dead air zones, and refluxing from the HEPA filters to and across the entire work area and to the air returns?	Yes	No	

				COMMENTS
14.	Was air pattern analysis conducted to confirm differential pressure at all points around all openings, doorways, and passthroughs?	Yes	No	
15.	Was air pattern analysis conducted around particle generating equipment while the equipment was in operation to confirm air flow?	Yes	No	
16.	Was the differential pressure measured to be at least 0.02" water column positive from the non-hazardous buffer room to the anteroom and from the anteroom to unclassified areas?	Yes	No	
17.	Was the differential pressure in the C-SCA/C-SEC measured to be between 0.01 and 0.03" water column negative to all adjacent areas?	Yes	No	
18.	Were particle counts measured at greater than or equal to 0.5 micrometers?	Yes	No	
19.	Were all particle counts taken during dynamic conditions and documented on certification reports?	Yes	No	
20.	Are ISO Class 5 areas certified as having less than 3,520 particles per cubic meter of air?	Yes	No	
21.	Are ISO Class 7 areas certified as having less than 352,000 particles per cubic meter of air?	Yes	No	
22.	Are ISO Class 8 areas certified as having less than 3,520,000 particles per cubic meter of air?	Yes	No	

					COMMENTS
23.	List the number of HEPA filters in each ISO certified room:	Anteroom: #_____	Buffer room: #_____	HD buffer room: #_____	
23a.	Was HEPA filter leak testing performed in the ISO certified rooms?	Yes	No		
23b.	If leaks were identified, were they repaired?	Yes	No		
23c.	If a repair was performed, was a smoke study performed in front of the repaired area?	Yes	No		
24.	List the number of PECs in each ISO certified room:	Anteroom: #_____	Buffer room: #_____	HD buffer room: #_____	
24a.	Was HEPA filter leak testing performed in all PECs?	Yes	No		
24b.	If applicable, was the BSC/CACI exhaust HEPA filter leak tested?	Yes	No		
24c.	If leaks were identified, were they repaired?	Yes	No		
24d.	If a repair was performed, was a smoke study performed in front of the repaired area?	Yes	No		
25.	Were viable air and surface sampling tests conducted?	Yes	No		
26.	Was a general microbiological growth media that supports the growth of bacteria and fungi used? List media used.	Yes	No		

				COMMENTS
27.	Was viable air sampling by active impaction using a volumetric air sampling device performed in all classified areas during dynamic operating conditions?	○ Yes	○ No	
28.	Was each air sample taken in ISO classified areas at least 1,000 liters in volume?	○ Yes	○ No	
29.	Was viable surface sampling performed in each classified area including each room, the interior of each ISO Class 5 PEC, and passthrough chambers connecting to classified areas using a risk-based approach?	○ Yes	○ No	
30.	Did any of the viable samples exceed action levels listed in USP Chapter <797>?	○ Yes	○ No	
31.	If the levels measured during sampling exceed action levels, was the cause investigated? List the corrective actions were taken.	○ Yes	○ No	
32.	If levels measured during sampling exceed action levels, was an attempt made to identify any microorganisms recovered to the genus level with the assistance of a microbiologist?	○ Yes	○ No	
33.	Do COAs from the manufacturer verify that the sampling media devices meet the expected growth promotion, pH and sterilization requirements?	○ Yes	○ No	

COMMENTS

34. Did the testing results report include the following information: ○ Yes ○ No

Media type
Media lot number
Media expiration date
Signature of the laboratory analyst and/or reviewer
Temperature of incubation
Dates of incubation

Printed Name of Designated Pharmacist conducting review:

_____

Signature of Designated Pharmacist: _____

Date: _____

Note: Performing incompetent or negligent work violates CGS Section 20-579(a)(15), and Section 21a-93(16) of the general statutes prohibits failing to demonstrate adherence to applicable provisions of United States Pharmacopeia, Chapter 797, Pharmaceutical Compounding – Sterile Preparations, as amended from time to time, concerning compounding or preparation of sterile drugs.