

## **SOP: Gowning for Entry into Biomanufacturing Suite**

### **Approvals:**

Preparer: Dr. Maggie Bryans

Date: 18FEB14

Reviewer: Jason McMillan

Date: 19FEB14

### **1. Purpose:**

- 1.1. To describe the proper gowning procedure for personnel entering the biomanufacturing suite to minimize the number of particles and viable microorganisms in the suite.

### **2. Scope:**

- 2.1. Applies to gowning performed in the gowning area prior to entering the biomanufacturing suite.

### **3. Responsibilities:**

- 3.1. It is the responsibility of the course instructor/lab assistant to ensure that this SOP is performed as described and to update the procedure when necessary.
- 3.2. It is the responsibility of the students/technicians to follow the SOP as described and to inform the instructor about any deviations or problems that may occur while performing the procedure.

### **4. References:**

- 4.1. Gowning for Aseptic Filling, Doxpub, Inc., Document number 02-0028-SOP-1.0

### **5. Definitions:** N/A

### **6. Precautions:**

- 6.1. 70% isopropyl alcohol is flammable and poisonous if ingested. Avoid creating excessive mist when using spray bottles with IPA.

### **7. Materials:**

- 7.1. disinfecting hand soap
- 7.2. sterile 70% (v/v) isopropyl alcohol (IPA)
- 7.3. head cover
- 7.4. hood (if needed)
- 7.5. facial hair cover (if needed)
- 7.6. cleanroom coverall, sterile Tyvek
- 7.7. shoe covers
- 7.8. non-powdered nitrile gloves
- 7.9. sterile gloves
- 7.10. lab tissues such as Kimwipes
- 7.10 boots
- 7.10 hood

### **8. Procedure:**

- 8.1. Employees should wear clean clothes that are not overly capable of shedding particulates (i.e., wool sweaters).
- 8.2. Gowning must occur only when no one is entering or exiting the gowning area. Likewise, do not enter the gowning area while someone is gowning.
- 8.3. Wearing makeup and jewelry is prohibited in the cleanrooms. If necessary, remove makeup and jewelry before proceeding to the Pre-Gowning Area.
- 8.4. **Pre-Gowning Area**
  - 8.4.1. Enter the pre-gowning area.
  - 8.4.2. Wash hands

## **SOP: Gowning for Entry into Biomanufacturing Suite**

- 8.4.3. Put on nitrile gloves. Choose gloves that have a snug but not overly tight fit.
- 8.4.4. Sanitize safety glasses with 70% (v/v) IPA, dry with a lab tissue, and place on face.
- 8.4.5. Don head cover. Use the mirror to verify that all hair is completely covered up to and including the hairline.
- 8.4.6. If applicable, don beard cover and place over facial hair. Use the mirror to verify that all hair is completely covered.
  - 8.4.6.1. If facial hair is still exposed, replace the head cover with a hood. Verify That all hair is completely covered.
- 8.4.7. Put on shoe covers
- 8.4.8. Proceed to gowning area.
- 8.5. Gowning Area**
  - Note: Avoid creating excess mist while using IPA throughout this procedure.
  - 8.5.1. Sanitize gowning bench with sterile 70% (v/v) IPA.
  - 8.5.2. Sanitize gloves with sterile 70% (v/v) IPA.
  - 8.5.3. Donning the hood and coverall
    - 8.5.3.1. Place hood on head taking care to touch only the inside
    - 8.5.3.2. Obtain a gowning package.
      - 8.5.3.2.1. Inspect the integrity of the package and verify that the package has been autoclaved.
    - 8.5.3.3. Open the package, Remove the coverall from the package and place on bench Note: Avoid touching the coverall to the floor at all times.
    - 8.5.3.4. Inspect the boots for rips or tears, place on bench
    - 8.5.3.5. Sanitize gloves with sterile 70% (v/v) IPA.
    - 8.5.3.6. Unzip the coverall.
    - 8.5.3.7. Gather the arms and one leg of the coverall together.
    - 8.5.3.8. Place leg in coverall and pull up the coverall. Repeat the process with the other leg. Do not allow the coverall to touch the floor.
    - 8.5.3.9. Pull the coverall up over the body and zip make sure base of hood is covered
    - 8.5.3.10. Sit on bench and put on a single boot.
    - 8.5.3.11. Swing leg over bench to clean side of gowning area. Apply other boot and stand on clean side of gowning area.
    - 8.5.3.12. Put on sterile gloves
    - 8.5.3.13. Sanitize gloves with sterile 70% (v/v) IPA.
- 8.6. After gowning, employees may enter the biomanufacturing area. While performing aseptic processing, resanitize gloves as needed. Reglove or regown if any adverse circumstances are observed or suspected that may affect the integrity of the gown components.
  - 8.6.1. Regown by exiting the biomanufacturing suite and repeating this SOP.
- 8.7. Exiting the biomanufacturing suite**
  - 8.7.1. Proceed to the exit area.
  - 8.7.2. Discard coverall and other cleanroom garb appropriately in the receptacle.
  - 8.7.3. Regown with fresh supplies when reentering the area.

### **SOP: Gowning for Entry into Biomanufacturing Suite**

8.8. Gowning qualifications for non-qualified personnel.

8.8.1. Non-qualified personnel (employees, outside contractors, or visitors) may not enter the biomanufacturing suite without permission from the Director of Manufacturing or QA/QC.

8.8.2. Upon permission, non-qualified personnel must gown with instructions and in the presence of a fully qualified operator and be monitored using applicable standard procedures.

8.8.3. All occurrences of non-qualified personnel entering the biomanufacturing suite between the time of room sanitization and completion of a batch must be documented using a discrepancy report.

**9. Attachments:** N/A

**10. History:**

Name	Date	Amendment
Deb Audino	22OCT05	Initial Release
Deb Audino	06FEB05	Changed donning gown from dirty side to clean side.
Deb Audino	17JUL08	College name change
Jason McMillan	19FEB14	College name change