| Your Company | SOP Title | Clean Room Gowning: Microbiological Qualification | SOP # | 04-2-147 |
|---|---|---|---|---|
| | Owner | | Version # | 16 |
| | Approver | | Effective date | |

# Clean Room Gowning Microbiological Qualification

**Purpose/scope**

The purpose of this procedure is to enable QC Sampler to verify that personnel are able to execute the aseptic gowning procedure as described in SOP 04-2-014. This procedure uses the observation of the gowning practices and the determination of microbiological burden after gowning to determine if personnel are qualified to enter the aseptic manufacturing area.

**Definitions**

Key terms used in this SOP are defined below.

| Term | Definition |
|---|---|
| CFU | Colony Forming Unit |
| TNTC | Too Numerous to Count (>250 CFU/plate) |
| Qualified Status | Indicates that a person has been trained and performed a successful gowning qualification test and access to the Class 100 and 10,000 clean room areas during product formulation and fill operations is approved. |
| Unqualified Status | Indicates that a person has failed to execute a successful gowning qualification test or has not been requalified during the re-qualification test period (expired). This person's access to the Class 100 and 10,000 clean room areas is denied until qualified status is attained. |
| Due Month | The month that an operator must perform a successful gowning requalification in order to continue to enter the Class 100 and 10,000 clean room areas. |

**Responsibility**

**Execution**

It is the responsibility of the Quality Control Sampler and Production Personnel to engage in this procedure and ensure that this procedure is executed as written.

**Record Maintenance**

The QC Microbiology department is responsible for maintaining all original files related to gowning qualification.

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# Clean Room Gowning Microbiological Qualification, Continued

**Equipment and Supplies**

Required equipment and supplies are:

- Sterile TSA (RODAC) Contact Plates
- 30-35°C Incubator
- Small plastic incubation bags and twist ties
- Sterile gloves
- Scrubs
- Hair, shoe and beard covers
- 70% sterile Isopropyl alcohol
- Face mask

**Testing frequency**

Qualification testing frequency is either annual or semi-annual as described below.

**Annual**

Personnel listed under annual qualification status are operators who regularly go into the clean room and have regular personnel monitoring at least once per quarter.

**Semi-annual**

Personnel listed under semi-annual qualification status are personnel who enter the clean rooms less than once per quarter. These people do not get regular exposure to the gowning procedures and therefore require more frequent qualification to confirm that their gowning techniques are sound.

**Testing schedule**

QC Microbi0logy will schedule gowning qualifications each month based on when the person was last qualified. QC will notify personnel due for requalification by e-mail that they are due.

**Maintain silence**

To prevent microbial contamination, neither the QC Sampler nor the person to be qualified should talk during the gowning.

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# Clean Room Gowning Microbiological Qualification, Continued

**Procedure**

Follow the steps in the table below to perform gowning qualification assessment in accordance with SOP 04-02-014.

***Warning:*** Terminate the procedure and document cause of termination on form FM:04-2-147A if at any time:

- the gowning room door are opened before the completion of plating,
- the aseptic gowning technique is breached in such a way that microbial contamination is likely, or
- the person to be qualified has excessive difficulty executing as per SOP.

| Step | Action |
|---|---|
| 1 | Enter the capping room (CL-8) before the person to be qualified enters. |
| 2 | Observe the capping process techniques of the person to be qualified. |
| 3 | Document any discrepancies on form FM:04-2-147A. |
| 4 | Exit CL-8 |
| 5 | Don a sterile face mask and sterile gloves |
| 6 | Enter the Gowning room (CL-5) before the person to be qualified enters. |
| 7 | Observe the aseptic gowning process of the person to be qualified |
| 8 | Document any discrepancies on form FM:04-2-147A. |

**Microbiological assessment**

Microbiological assessment for gowning qualifications shall be determined by surface viable sampling using RODAC plates on the goggles, right/left shoulders, right/left chest, right/left forearm, right/left wrist, and right/left fingertips in accordance with the method described in the SOP 03-2-001 – *Environmental Monitoring.*

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# Clean Room Gowning Microbiological Qualification, Continued

**Test specifications** Pass/Fail specifications are based on the alert levels for personnel monitoring that are defined in SOP 03-2-001

| Location | Pass | Fail |
|---|---|---|
| Goggle | < 3 CFU | ≥ 3 CFU |
| Shoulder | < 3 CFU | ≥ 3 CFU |
| Chest | < 3 CFU | ≥ 3 CFU |
| Forearm | < 3 CFU | ≥ 3 CFU |
| Wrist | < 3 CFU | ≥ 3 CFU |
| Fingertips | 0 CFU | ≥ 1 CFU |

**References**

| Document # | Description |
|---|---|
| SOP 02-1-002 | Aseptic Personnel Qualification Requirements |
| SOP 03-2-001 | Environmental Monitoring |
| SOP 04-2-014 | Gowning Requirements and Techniques |
| FM:04-2-147A | Gowning Qualification Data Sheet |
| FM:04-2-147C | Gowning Qualification Notification Form |
| FM:04-2-147D | List of Gowning Qualified Personnel |

**Approval**

| Name | Date |
|---|---|
| Prepared by: | |
| Production: | |
| Quality Control: | |
| Quality Assurance: | |