

SOP: Operator Hygiene and Gowning Requirements

This SOP establishes **operator hygiene and gowning requirements** to maintain a clean and safe working environment. It outlines proper handwashing techniques, use of personal protective equipment (PPE), gowning protocols, and restrictions on jewelry and personal items. The procedure aims to prevent contamination, ensure product quality, and protect both operators and equipment in controlled environments.

1. Purpose

To define the procedures for operator hygiene and gowning requirements in order to minimize risks of contamination within controlled environments.

2. Scope

This SOP applies to all personnel entering or working within cleanrooms, production, packaging, and laboratory areas.

3. Responsibility

- **Operators:** Must comply with all hygiene and gowning requirements as described in this SOP.
- **Supervisors:** Ensure all personnel adhere to established hygiene and gowning protocols.
- **Quality Assurance:** Periodically audit compliance and update SOP as needed.

4. Definitions

Term	Definition
PPE	Personal Protective Equipment
Gowning	The donning of approved garments and equipment prior to entry into controlled areas

5. Procedure

- 1. Personal Hygiene Requirements**
 - Shower or bathe daily before reporting to work.
 - Maintain clean, short fingernails without polish or artificial enhancements.
 - Abstain from strong perfumes, lotions, or cosmetics.
 - Report any skin conditions, open wounds, or illnesses to supervisor prior to entry.
- 2. Handwashing Procedure**
 1. Wet hands and forearms with water.
 2. Apply approved handwashing soap.
 3. Scrub all areas thoroughly for at least 30 seconds, including between fingers and under nails.
 4. Rinse thoroughly with water.
 5. Dry hands completely using a clean, disposable towel or air dryer.
- 3. PPE and Gowning Protocol**
 1. Don hair and beard cover (if applicable).
 2. Wear approved cleanroom gown/coverall, ensuring full body coverage.
 3. Put on face mask and, if required, safety goggles or face shield.
 4. Wear dedicated footwear or shoe covers before entry.
 5. Don sterile gloves, ensuring hands remain gloved within controlled areas.
 6. Check all PPE for damage or contamination; replace as necessary.
- 4. Jewelry and Personal Items**
 - Remove all jewelry, including watches, rings, necklaces, piercings, and bracelets.
 - Secure all personal items (phones, keys, pens) in designated storage areas outside controlled zones.
- 5. Entry and Exit**
 - Perform gowning in the designated gowning area only.
 - Follow unidirectional flow and avoid contact with surfaces after gowning.
 - Upon exit, remove PPE in correct sequence and dispose of or store as appropriate.
 - Wash hands after gown removal and before leaving gowning area.

6. Training

All personnel must complete initial and annual refresher training on hygiene and gowning requirements. Training records must be maintained.

7. Documentation

- Handwashing, gowning, and PPE compliance should be monitored and documented as per facility requirements.

- All deviations must be reported and documented according to deviation handling procedures.

8. References

- Facility Hygiene Policy
- GMP Guidelines
- PPE Usage Manual

9. Revision History

Version	Date	Description	Approved by
1.0	2024-06-01	Initial SOP release	QA Manager