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Gowning and Hygiene in Manufacturing Areas

Category: Production/Manufacturing

Standard Operating Procedure (SOP)

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Department: Production

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1.0 PURPOSE

This Standard Operating Procedure (SOP) outlines the procedures for gowning and maintaining personnel hygiene within NovaThera Pharmaceuticals' manufacturing areas. This SOP ensures that personnel entering manufacturing areas follow defined practices to minimize the risk of product contamination and maintain the required environmental conditions for pharmaceutical manufacturing.

2.0 SCOPE

This SOP applies to all personnel, including employees, contractors, and visitors, who are required to enter NovaThera Pharmaceuticals' manufacturing areas. This SOP covers all personnel entering manufacturing areas involved in the production of all pharmaceutical products, regardless of batch size or dosage form. It encompasses all manufacturing areas classified as controlled environments, including but not limited to, dispensing, granulation, compression, coating, filling, and packaging areas. It does NOT cover areas outside of designated manufacturing zones such as office spaces, cafeterias, or general storage.

3.0 RESPONSIBILITY

QC Inspector:

- Verifies the integrity and cleanliness of gowns and other Personal Protective Equipment (PPE) before use.
- Monitors personnel gowning procedures to ensure compliance with this SOP.
- Documents any deviations from the SOP in the appropriate logbook.
- Reports any observed hygiene deficiencies to the Production Supervisor.

Production Supervisor:

- Ensures that all personnel entering manufacturing areas are trained on this SOP.
- Provides adequate supplies of clean gowns and other PPE.
- Monitors personnel adherence to this SOP and enforces corrective actions as needed.
- Maintains gowning room cleanliness and order.
- Investigates and documents any deviations from this SOP.

QA Manager:

- Reviews and approves this SOP and any revisions.
- Monitors the effectiveness of this SOP through audits and inspections.
- Ensures that all deviations from this SOP are properly investigated and addressed.
- Provides guidance and support to the Production Supervisor on matters related to gowning and hygiene.

Head of QA:

- Provides final approval for this SOP and any revisions.
- Oversees the overall quality system, including gowning and hygiene practices.
- Ensures that this SOP is in compliance with all applicable regulations and guidelines.

4.0 MATERIALS & EQUIPMENT

PPE:

- Hairnet/Head Cover (disposable, lint-free)
- Beard Cover (disposable, lint-free, if applicable)
- Facial Mask (disposable, bacterial filtration efficiency (BFE) ≥ 95%)
- Manufacturing Gown (launderable, low-linting, full-body coverage)
- Dedicated Manufacturing Shoes or Shoe Covers (launderable or disposable, non-slip)
- Gloves (nitrile, powder-free, sterile or non-sterile as required by the manufacturing process)
- Eye Protection (safety glasses or goggles, as required by the manufacturing process)

Equipment:

- Gowning Room Bench (stainless steel or other easily cleanable material)

- Gowning Room Mirror
- Hand Sanitizer Dispenser (alcohol-based, ≥ 70% alcohol)
- Waste Receptacles (clearly labeled for disposal of used PPE)
- Designated Storage for Clean Gowns and PPE
- Air Shower (if applicable, with appropriate filter integrity testing SOP; refer SOP-ENG-005 for Air Shower Maintenance)
- Sticky Mat (at the entrance to manufacturing areas)

Documentation:

- Gowning and Hygiene Logbook (Form-PROD-001)
- Training Records (Form-HR-002)
- SOP Training Record (Form-QA-001)
- Deviation Report Form (Form-QA-003)

5.0 PROCEDURE

5.1 Pre-Gowning Requirements

1. Remove all jewelry, including rings, watches, necklaces, and earrings, and store them in a personal locker outside the gowning area.
2. Remove all visible dirt or contamination from hands.
3. Wash hands thoroughly with soap and water for at least 30 seconds following proper handwashing technique per SOP-GEN-002, Hand Washing Procedure. Pay particular attention to areas between fingers, under fingernails, and the back of hands.
4. Dry hands thoroughly with lint-free paper towels.
5. Inspect hands for any cuts, abrasions, or skin conditions. If present, report to the Production Supervisor before proceeding. The Production Supervisor will assess the situation and determine if the individual is fit to enter the manufacturing area. If approved, ensure cuts or abrasions are covered with a waterproof bandage and appropriate gloves.

5.2 Gowning Procedure - General Manufacturing Areas (Grade D/C)

1. Enter the designated gowning room.
2. Sit on the gowning bench, keeping street shoes on the floor side.
3. Put on the hairnet/head cover, ensuring all hair is completely covered. If applicable, put on the beard cover, ensuring all facial hair is completely covered.
4. Put on the facial mask, ensuring it covers the nose and mouth securely. Adjust the nose clip for a snug fit.

5. Put on dedicated manufacturing shoes or shoe covers. If using shoe covers, ensure they completely cover street shoes.
6. Stand up and step over the bench to the clean side.
7. Don the manufacturing gown. Ensure the gown is properly fastened, covering all street clothing.
8. Put on gloves. If the manufacturing process requires sterile gloves, follow the sterile gowning procedure (Section 5.3). If non-sterile gloves are sufficient, ensure the gloves cover the cuffs of the gown sleeves.
9. If required by the manufacturing process, put on eye protection (safety glasses or goggles).
10. Inspect your gowning to ensure complete coverage and proper fit. Use the gowning room mirror to assist with the inspection. The QC Inspector will verify proper gowning procedure.
11. Walk across the sticky mat at the entrance to the manufacturing area to remove any loose particles from footwear.
12. Record the date and time of entry into the manufacturing area in the Gowning and Hygiene Logbook (Form-PROD-001).

5.3 Gowning Procedure - Aseptic Processing Areas (Grade A/B)

1. Follow steps 1-5 of Section 5.2 (Pre-Gowning Requirements).
2. Enter the designated gowning room (may be multiple stages, with increasing levels of cleanliness).
3. Sit on the gowning bench, keeping street shoes on the floor side.
4. Put on the hairnet/head cover, ensuring all hair is completely covered. If applicable, put on the beard cover, ensuring all facial hair is completely covered.
5. Put on the facial mask, ensuring it covers the nose and mouth securely. Adjust the nose clip for a snug fit.
6. Put on dedicated manufacturing shoes or shoe covers. If using shoe covers, ensure they completely cover street shoes.
7. Step over the bench to the clean side.
8. Don the first layer of the manufacturing gown (under-gown). Ensure the gown is properly fastened, covering all street clothing.
9. Wash and sanitize hands thoroughly with alcohol-based hand sanitizer. Allow hands to dry completely before proceeding.
10. Don sterile gloves. Ensure the gloves cover the cuffs of the under-gown sleeves.
11. Don the second layer of the manufacturing gown (sterile over-gown). Ensure the gown is properly fastened, covering the under-gown.
12. Put on sterile gloves. Ensure the gloves cover the cuffs of the over-gown sleeves.
13. If required, put on sterile eye protection (safety glasses or goggles).
14. Enter the air shower, if applicable. Follow the air shower operating procedure (refer SOP-ENG-006, Air Shower Operation) to remove any loose particles from the gowning.

15. Inspect your gowning to ensure complete coverage and proper fit. The QC Inspector will verify proper gowning procedure.
16. Walk across the sticky mat at the entrance to the aseptic processing area to remove any loose particles from footwear.
17. Record the date and time of entry into the manufacturing area in the Gowning and Hygiene Logbook (Form-PROD-001).

5.4 Hygiene Requirements within Manufacturing Areas

1. Maintain good personal hygiene practices at all times while in the manufacturing area.
2. Avoid touching your face, hair, or any exposed skin while wearing gloves.
3. If gloves become damaged or contaminated, replace them immediately. Wash and sanitize hands before putting on new gloves.
4. Do not eat, drink, chew gum, or apply cosmetics in the manufacturing area.
5. Keep workspaces clean and organized.
6. Report any spills or accidents immediately to the Production Supervisor.
7. Adhere to all applicable Standard Operating Procedures (SOPs) for the manufacturing process.
8. If required to handle product directly, change gloves after any activity not directly related to the process, even if they are not visibly soiled.
9. Ensure that fingernails are kept short and clean. Nail polish and artificial nails are prohibited in manufacturing areas.
10. Personnel exhibiting symptoms of illness, such as coughing, sneezing, or fever, should not enter the manufacturing area. Report any illness to the Production Supervisor.

5.5 De-Gowning Procedure

1. Before exiting the manufacturing area, record the date and time of exit in the Gowning and Hygiene Logbook (Form-PROD-001).
2. Remove eye protection (if applicable).
3. Remove gloves and discard them in the designated waste receptacle. Wash and sanitize hands.
4. Remove the manufacturing gown. Hang the gown on the designated rack for re-use (if applicable and as determined by the cleaning frequency schedule) or discard in the designated laundry hamper. For aseptic processing areas, discard the over-gown and gloves into the designated waste receptacles after each entry/exit.
5. Remove dedicated manufacturing shoes or shoe covers. If using shoe covers, discard them in the designated waste receptacle.
6. Remove the facial mask and discard it in the designated waste receptacle.
7. Remove the hairnet/head cover and beard cover (if applicable) and discard them in the designated waste receptacle.
8. Exit the gowning room.

9. Wash and sanitize hands again after exiting the gowning area.

6.0 POST-PROCEDURE ACTIVITIES

- The Production Supervisor ensures that the Gowning and Hygiene Logbook (Form-PROD-001) is reviewed daily for completeness and accuracy.
- The Production Supervisor ensures that used gowns are laundered according to the established schedule and SOP-FAC-001, Laundry Procedure for Manufacturing Gowns.
- The Production Supervisor ensures that the gowning room is cleaned and sanitized daily according to SOP-CLN-001, Cleaning and Sanitization of Manufacturing Areas.
- The QC Inspector performs periodic audits of gowning and hygiene practices to ensure compliance with this SOP.
- The QA Manager reviews the Gowning and Hygiene Logbook and audit reports periodically to identify any trends or potential issues.
- Any deviations from this SOP are documented on a Deviation Report Form (Form-QA-003) and investigated by the Production Supervisor and QA Manager. Corrective and Preventive Actions (CAPA) are implemented as necessary.

7.0 SAFETY PRECAUTIONS

- Ensure that all PPE is in good condition before use. Report any damaged or defective PPE to the Production Supervisor.
- Do not wear loose-fitting clothing or jewelry that could pose a hazard in the manufacturing area.
- Be aware of your surroundings and avoid tripping hazards.
- Use caution when handling chemicals or equipment.
- In case of an emergency, follow the established emergency procedures.
- If using sanitizers containing alcohol, ensure proper ventilation. Keep away from open flames.
- Report any allergic reactions to PPE materials (e.g., latex gloves) to the Production Supervisor immediately. Alternative PPE will be provided.

8.0 APPROVALS

Prepared By: Production Supervisor

Reviewed By: QA Manager

Approved By: Head of QA

Date:

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