SOP Title:	**Personnel Health Restrictions in Product-Contact Environments**
SOP Number:	**21706**
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TABLE OF CONTENTS

1. PURPOSE

This procedure describes the criteria for restriction of personnel from product-contact environments due to the adverse health of employees.

2. SCOPE

This procedure applies to personnel working in GMP environments where contact with product raw materials, containers and closures, in-process, bulk, or final products may occur (product-contact surface areas). This procedure does not apply to Process Analytic (PA) testing areas.

3. BACKGROUND

21 CFR 211 requires:

- **21 CFR 211.28 (b)** Personnel shall practice good sanitation and health habits.
- **21 CFR 211.28 (d)** Any person shown at any time (either by medical examination or supervisory observation) to have an apparent illness or open lesions that may adversely affect the safety or quality of drug products shall be excluded from direct contact with components, drug product containers, closures, in-process materials, and drug products until the condition is corrected or determined by competent medical personnel not to jeopardize the safety or quality of drug products. All personnel shall be instructed to report to supervisory personnel any health conditions that may have an adverse effect on drug products.
- **21 CFR 600.10(c)** Persons whose presence can affect adversely the safety and purity of a product shall be excluded from the room where the manufacture of a product is in progress.

4. RESPONSIBILITIES

4.1 Director of Regulatory Compliance

- Defines the procedure.

4.2 BDP Personnel

- Reports to supervisor whenever an employee's physical condition, other health condition, or presence has the potential to have a negative adverse effect on the product's safety or purity. (Personnel who have access to product or product-contact surface areas).

4.3 Supervisor

- Notifies BQA if an employee be restricted from working with an open product or in product-contact surface areas and when they have been allowed to return to work in such an area.

4.4 BQA

- Provides quality oversight of this procedure.
- Notifies supervisor if a concern arises over an individual’s health condition for possible restriction from working in a production area."

5. CRITERIA FOR RESTRICTION

5.1 Personnel shown to have, by medical examination or supervisory observation, the following conditions or other apparent illness, shall be restricted from working with open raw materials, product containers and closures, or in-process, bulk, or final drug substance or product, and product contact surfaces.

5.1.1 Eye drainage or crusting.

5.1.2 Open lesions including cold sores, open wound, severe burns, or other draining lesions of the skin.

5.1.3 Acute upper respiratory symptoms, which include: Sore throat, rhinorrhea (runny nose), cough, sneezing, or fever.

5.1.4 Acute gastrointestinal illness, such as vomiting and/or diarrhea with or without associated symptoms such as fever, nausea, and abdominal pain.

5.1.5 Severely peeling skin.

5.1.6 Use of antibiotics (beta-lactams and cephalosporin).

5.1.7 Any other condition that has a potential to contaminate product or product contact surfaces.

5.2 Employees may be requested to visit Occupational Health Services (OHS) for a medical evaluation in order to help evaluate the likelihood of product risk from the employee's condition.

6. EXCEPTIONS

Exception to these restrictions must be in writing and approved by Production and BQA Management. The justification must state the reason why there will be no product impact.

7. RELEASE FROM RESTRICTION

7.1 Employees will confer with their Supervisor following restriction to gain permission to return to work in a product-contact environment.

7.2 The Supervisor may request a written release from OHS in order to determine whether the employee is able to return to work in product or product-contact surface areas.

7.3 The Supervisor notifies BQA when an employee is removed from restriction.

8. REFERENCES AND RELATED DOCUMENTS

Document Number	Title
21 CFR 211	Current Good Manufacturing Practice for Finished Pharmaceuticals
21 CFR 600	Biological Products: General