	SOP CODE:	USA – STRL – P1.4.1.0	REVISION NUMBER: 2 . 2 . 0
	ISSUE DATE:	MONTH 00, YYYY	
	IMPLEMENTATION DATE:	MONTH 00, YYYY	
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TITLE : PERSONNEL – GARBING – HAND HYGIENE AND PPE – COMPOUNDING PRACTICES

DRAFTED BY:	**SIGNATORY:**			
☐ n/a	**TITLE:**		SIGNATURE	DATE
VERIFIED BY:	**SIGNATORY:**			
☐ n/a	**TITLE:**		SIGNATURE	DATE
APPROVED BY:	**SIGNATORY:**			
	TITLE:	**DESIGNATED PERSON**	SIGNATURE	DATE
APPROVED BY:	**SIGNATORY:**			
☐ n/a	**TITLE:**	**DESIGNATED PERSON**	SIGNATURE	DATE

COMPENDIAL APPLICABILITY OF THE USP GENERAL CHAPTER <800>

"On December 1, 2019, USP's standard on the safe handling of hazardous drugs, General Chapter <800>, became official. General Chapter <800> is informational and not compendially applicable. USP General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings describes practice and quality standards for handling hazardous drugs. USP is committed to maintaining patient access to medicines, while supporting patient safety, healthcare worker safety, and environmental protection when handling HDs (hazardous drugs) in healthcare facilities." (USP Publication: Compendial Applicability of USP 800).

Please see the document titled, compendial-applicability-of-usp-800.pdf in the folder titled, 10 – Supplemental Documentation\References and Standards for additional details.

To determine the regulatory applicability of the USP General Chapter <800>, you must contact your State Board of Pharmacy.

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TITLE : PERSONNEL – GARBING – HAND HYGIENE AND PPE – COMPOUNDING PRACTICES

RELATED LOGS & FORMS

RECORD	SPECIFICATION / DESCRIPTION
USA – STRL – F1.4.1.0	Hand Hygiene and Garbing Assessment - Non-HD

RELATED STANDARD OPERATING PROCEDURES

SOP CODE	SOP TITLE
USA – STRL – P0.1.1.0	Preamble – Implementing – Standard Operating Procedures – Compounding Practices
USA – STRL – P0.2.1.0	Preamble – Customizing – Standard Operating Procedures – Compounding Practices
USA – STRL – P0.3.1.0	Preamble – Recording – Good Documenting Practices – Compounding Practices
USA – STRL – P1.4.1.1	Personnel – Garbing – Hand Hygiene and PPE – Compounding Practices (HD)

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TITLE : PERSONNEL – GARBING – HAND HYGIENE AND PPE – COMPOUNDING PRACTICES

RESPONSIBILITIES

1. Designated Person oversees this SOP.
2. All personnel are responsible for performing this SOP.
3. All service providers performing inspections, certifications, and/or repairs requiring entry into controlled environments or ISO classified environments are responsible for performing this SOP.

PURPOSE

1. To ensure the proper donning of personal protective equipment.
2. To ensure the proper doffing of personal protective equipment.
3. To ensure proper hand hygiene and gloving requirements are met.

SCOPE

1. Applies to non-hazardous substance handling and sterile compounding, which includes, however, may not be limited to:
    a. Receiving inventory.
    b. Stocking and inventory control.
    c. Collecting and disposing non-hazardous compounding waste.
    d. Immediate cleaning and disinfecting of direct compounding areas.
2. Applies to donning of personal protective equipment for non-hazardous sterile drug compounding.
3. Applies to doffing of personal protective equipment in non-hazardous sterile drug compounding.
4. Applies to proper hand hygiene and gloving for non-hazardous sterile drug compounding.

DEFINITIONS

1. Breakthrough Time: The time between when a harmful chemical liquid touches the outside of a glove or other personal protective equipment, and when it breaks the surface to reach the skin.
2. Compliance Indicator: A document used to assess the performance of compounding personnel on a per task basis.
3. Compounded Sterile Preparation (CSP): Compounded medication prepared in a sterile compounding facility.

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4. Compounding Aseptic Containment Isolator (CACI): A type of RABS that uses HEPA filtration to provide an ISO class 5 unidirectional air environment designed for the compounding of sterile HDs.
5. Compounding Aseptic Isolator (CAI): A type of RABS that uses HEPA filtration to provide an ISO class 5 unidirectional air environment designed for compounding of sterile non-HDs.
6. Designated Person: Equivalent to Compounding Supervisor. One or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel for the preparation of CSPs.
7. Doffing: is the act of removing personal protective equipment.
8. Donning: is the act of putting on personal protective equipment.
9. Personal Protective Equipment (PPE): is clothing designed to protect the wearer's body from injury and chemical exposure. PPE includes, however, may not limited to masks, goggles, gowns, head covers, gloves, hairnets, shoe covers and boot covers.
10. Pharmaceutical Isolator: An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air operated at a continuously higher pressure than its surrounding environment and is decontaminated using an automated system. It uses only decontaminated interfaces or rapid transfer ports for materials transfer.
11. Restricted-Access Barrier System (RABS): An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air that allows for the ingress and/or egress of materials through defined openings that have been designed and validated to preclude the transfer of contamination, and that generally are not to be opened during operations. Examples of RABS include CAIs and CACIs.
12. SDS: Safety Data Sheets, which help determine PPE requirements on a per active pharmaceutical ingredient basis.

FREQUENCY

1. Don non-hazardous personal protective equipment in recognition of:
    1. Entry into any classified secondary engineering control designated for non-hazardous drug compounding.
    2. During non-hazardous drug compounding.
    3. Handling non-hazardous chemicals or unfinished (i.e., unsealed) container-closures.

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SPECIAL CIRCUMSTANCE

1. **This SOP does not address donning of personal protective equipment for hazardous drug handling or compounding.**
2. **This SOP does not address donning of personal protective equipment for the sanitization of the compounding facility (i.e., controlled and classified rooms).**
3. Qualification: If using a Restricted-access barrier system (RABS), such as a CAI or CACI, disposable gloves (e.g., cotton, sterile) should be worn inside gloves attached to the RABS sleeves. Sterile gloves must be worn over gloves attached to the RABS sleeve.
    1. The RABS sleeves and gloves and the pharmaceutical isolator gauntlet sleeves and gloves should be changed as per the manufacturer's recommendations.
4. Qualification: The following procedure may or may not be appropriate for all compounding facility physical layouts. Adjustments may be required.
    1. The order of hand washing and garbing is dependent upon the placement of the sink used during hand hygiene procedures.

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PROCEDURE

This SOP is divided into the following sections:

1. General requirements
2. Hand Hygiene and Glove Requirements
3. Hand Sanitizing Procedures – Skin
4. Hand Sanitizing Procedures – Gloves
5. Personal Protective Equipment Requirements
6. Donning Personal Protective Equipment for Non-Hazardous Drug Compounding
7. Doffing Personal Protective Equipment for Non-Hazardous Drug Compounding

1. General Requirements:
    1. Ensure the NIOSH hazardous drug list and Safety Data Sheet (SDS) for each chemical substance in the sterile compounding facility is logged, reviewed and risk classified, which includes compounding and sanitizing agents.
        a. Determine the PPE requirements and the dangers presented by the chemical prior to receiving that chemical substance.
        b. The selection of PPE must be made based on a comprehensive risk assessment.
    2. Ensure that only authorized personnel enter classified or controlled environments.
    3. Ensure that donning and doffing of PPE never occur at the same time in the anteroom or segregated compounding area.
    4. Prohibit food (including chewing gum) and drink in the compounding environment and areas where chemicals or preparations are present.
    5. Ensure personnel are free from medical conditions that can result in contamination of finished preparations.
    6. Ensure PPE is stored in a manner that minimizes contamination (e.g. away from sinks to avoid splashing).
        a. In the case of a sink, a minimum of one (1) meter space is required.
    7. Verify Process Development, Master Formulation and Compounding Records all indicate required personal protective equipment.
    8. Ensure that potable hot and cold water used for hand washing is compliant with the Environmental Protection Agency's (EPA) national primary drinking water regulations.

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2. Hand Hygiene and Glove Requirements
    1. Prior to compounding, personnel must:
        a. Remove all hand, wrist, and other exposed jewelry.
        b. Remove visible debris from underneath fingernails under warm running water using a disposable nail cleaner.
        c. Wash hands and forearms up to the elbows with soap and water for at least 30 seconds.
            i. Ensure the use of a closed and non-refillable soap dispenser.
            ii. Brushes must **not** be used for hand hygiene.
        d. Dry hands and forearms to the elbows completely with low-lint disposable towels or wipers.
            i. Hand dryers must **not** be used to dry forearms and hands[1].
        e. Allow hands and forearms to dry thoroughly before donning gloves.
        f. Alcohol sanitizers alone are not sufficient.
    2. Gloves must be worn during all compounding related activities and be:
        a. Resistant to chemicals actively being used.
        b. Checked for holes or rips (they must be replaced immediately if detected).
        c. Changed between compounds.
        d. Changed if visibly soiled.
    3. Sterile gloves must be donned in…
        a. An ISO classified room, or…
        b. Segregated compounding area or room.
    4. Hands must be sanitized with alcohol based hand rub before donning sterile gloves.
3. Hand Sanitizing Procedures - Skin
    1. Apply an alcohol-based hand rub to dry skin following the manufacturer's instructions for the volume of product to use.
    2. Apply product to one hand and rub hands together, covering all surfaces of hands and fingers, until hands are dry.
    3. Allow hands to dry thoroughly before donning sterile gloves.

[1] Hand dryers are allowed by current standards but it is strongly recommended to use low-lint disposable towels or wipers only.

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Hand Sanitizing Procedures - Gloves

1. Gloves must be sterile and powder free.
2. Application of sterile 70% Isopropyl alcohol to gloves must occur regularly throughout the compounding process.
    a. Includes whenever non-sterile surfaces are touched.
3. All gloves must be inspected for holes, punctures, or tears and must be replaced immediately if such defects are detected.
    a. If using a RABS, then its sleeves and gloves should be changed as per the manufacturer's recommendations.
    b. If using a pharmaceutical isolator, then its gauntlet sleeves and gloves should be changed as per the manufacturer's recommendations.

5. Personal Protective Equipment Requirements:
    1. Ensure the following minimum requirements for garb are met:
        a. Low-lint garment with sleeves that fit snugly around the wrists and that is enclosed at the neck (e.g., gowns or coveralls).
            i. Use of a sterile gown or coveralls is strongly recommended.
        b. Low-lint, disposable covers for shoes.
            i. Use of sterile, second pair of boot covers, is strongly recommended
        c. Low-lint, disposable covers for head that cover the hair and ears, and if applicable, disposable cover for facial hair.
            i. Use of sterile, second head cover, is strongly recommended.
        d. Face mask.
        e. Sterile powder-free gloves.
    2. Ensure PPE provides adequate and appropriate:
        a. Personnel protection from the physical or health hazard in question.
        b. Personnel protection as per Safety Data Sheet (SDS).
        c. Protection of the environment or preparation from contamination by personnel, where applicable.
    3. Assess personal protective equipment for degradation, breakthrough time and permeability characteristics.

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6. Donning Personal Protective Equipment for Non-Hazardous Drug Compounding:

    1. Ensure personnel have removed outer garments (e.g. bandanas, coats, hats, jackets) and earbuds/headphones.
    2. Donning and doffing garb must not occur in the segregated compounding area or anteroom at the same time.
    3. Don dedicated shoes, and then enter the ISO classified environment.
    4. In the ISO classified environment starting on the dirty side of the line of demarcation, don hair cover and facemask (beard cover if necessary), and then shoe covers as feet cross the line of demarcation.
    5. Under warm running water, clean the fingernails with a pick, wash the hands and forearms to the elbow with soap, and rinse the hands and arms so water flows from hand to elbow.
    6. Dry the arms utilizing a lint free disposable towel from hands to elbow.
    7. Don the appropriate gown or coverall minimizing contact with its outer surface. Avoid contact between outer surface of coverall with hands or floor. (Coveralls may stop at the neck, wrists, and ankles).

        a. Use of sterile gown or coverall is strongly recommended.

    8. Don boot covers on the outside of the coverall.

        a. Use of sterile boot covers is strongly recommended

    9. Don a hood (head cover) on the outside of the coverall.

        a. Use of sterile hood (head cover) is strongly recommended.

    10. Don form fitted goggles.
    11. Perform a second person inspection, or use a mirror located inside the anteroom to inspect donned garb for proper fitting, as well as punctures or rips in the hair net, shoe covers, or gown.

        a. Apply the no skin exposed rule (i.e., any exposed skin implies an error in your garbing technique).

    12. Don sterile gloves on the outside of the coverall.
    13. Wipe any materials entering the pre-sterilization room (3-room suite) or buffer room (2-room suite) from the anteroom with 70% Sterile Isopropyl Alcohol wetted sterile lint free disposable wipes.
    14. Sanitize the gloves with 70% SIPA and enter the buffer room.
    15. Replace the previously donned pair of sterile gloves with a new pair of sterile gloves.
    16. Apply sterile isopropyl alcohol to the gloves and rub as if to moisturize hands.

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7. Doffing Personal Protective Equipment for Non-Hazardous Drug Compounding:

    1. Remove all disposable PPE (e.g. gloves, gown, shoe covers, boot covers, hairnets and masks) prior to leaving the compounding room (secondary engineering control; SEC) and discard in appropriate waste bag or container.

        a. Disposable PPE must not be re-used.

        b. Reusable PPE must be decontaminated and cleaned after use.

    2. Treat soiled PPE as chemical waste.

    3. Clean and sanitize reusable PPE (e.g. goggles) with isopropyl alcohol 70%, as appropriate.

    4. Gowns that are not visibly soiled may be re-used within the same shift if the gown is maintained inside the perimeter of a segregated compounding area (SCA)

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VERIFICATION

1. Inspect PPE routinely for any tears, abrasions or notable visual contamination by visual inspection.
2. Verify the quality of the water used during hand hygiene procedures by performing microbial contamination tests.

CORRECTIVE ACTIONS

1. In the event that PPE fails visual inspection, remove and replace PPE affected.
2. In the event of a spill or splash, remove and replace lab coat/gown, gloves, and other affected PPE.

PREVENTIVE ACTIONS

1. Perform visual inspections using compliance indicators to assess:
    1. Hand hygiene procedures.
    2. Hand sanitizing procedures.
    3. Donning personal protective equipment.
        a. Includes gloving.
    4. Doffing personal protective equipment.
2. Seek additional and/or updated information on a regular basis on the subject of personal protective equipment from the following organizations, which includes, however, may not be limited to the:
    1. American National Standard Institute (ANSI).
    2. American Society for Testing and Materials (ASTM).
    3. International Organization of Standardization (ISO).
    4. Occupational Safety and Health Administration (OSHA).
    5. National Institute of Occupational Safety and Health (NIOSH).
    6. National Institute of Standards and Technology (NIST).
    7. United States Pharmacopeia (USP).

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TECHNOLOGICAL RESOURCES

EQUIPMENT	MANUFACTURER	MAKE	MODEL	SERIAL NUMBER	ID CODE
Coveralls					
Foot Covers/Boots					
Mask					
Gloves					
Safety glasses/goggles					

EDUCATIONAL AND SERVICE RESOURCES

AVAILABLE OFFERINGS	
LP3 Network	Medisca Network
	Specialized Consultation Services
	Technical Support Services (TSS)

SPECIFICATION DOCUMENTS

DOCUMENT NUMBER	DOCUMENT NAME	SOURCE	DESCRIPTION

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REVISION HISTORY

REVISION NUMBER	IMPLEMENTATION DATE	TERMINATION DATE	SUMMARY OF CHANGE TO CURRENT VERSION

REGULATORY COMPLIANCE GUIDELINES AND STANDARDS OF PRACTICE

REFERENCE SOURCE	REFERENCE CODE	REFERENCE DATE	SECTION CODE	SECTION DESCRIPTION
USP	797	2008		Pharmaceutical Compounding – Sterile Preparations

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