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	ISSUE DATE:	MONTH 00, YYYY	
	IMPLEMENTATION DATE:	MONTH 00, YYYY	
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TITLE : PERSONNEL – MANAGING – PROFESSIONAL DEVELOPMENT – COMPOUNDING PRACTICES (HD)

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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RELATED LOGS & FORMS

RECORD	SPECIFICATION / DESCRIPTION
USA - NS - L1.1.2.0	Competency and Training Log
USA - NS - F1.1.2.0	Personnel Roles and Responsibilities

RELATED STANDARD OPERATING PROCEDURES

SOP CODE	SOP TITLE
USA – NS – P0.1.1.0	Preamble – Implementing – Standard Operating Procedures – Compounding Practices
USA – NS – P0.2.1.0	Preamble – Customizing – Standard Operating Procedures – Compounding Practices
USA – NS – P0.3.1.0	Preamble – Recording – Good Documenting Practices – Compounding Practices
USA – NS – P0.4.3.1	Personnel – Managing – Hazard Communication Program – Compounding Practices (HD)
USA – NS – P1.1.2.0	Personnel – Managing – Professional Development – Compounding Practices
USA – NS – P1.2.3.1	Personnel – Managing – Medical Surveillance – Compounding Practices (HD)

RESPONSIBILITIES

1. Designated Person oversees this SOP.
2. Designated Person may perform training or assign another person the role of trainer.
3. Designated Person is responsible for competency assessments.
4. All compounding personnel must comply with this SOP.

PURPOSE

1. To establish and maintain record of continuous professional development training, competency assessments, and compliance assessments related to hazardous drug handling and compounding.

SCOPE

1. Applies to all compounding practices engaged in hazardous drug handling and compounding.
2. Applies to all compounding personnel (i.e., Designated Person, compounding pharmacists and pharmacy technicians).
3. Applies to theoretical training, competencies and ongoing compliance.
4. Applies to practical training, competencies and ongoing compliance.
5. Applies to specifically identified training, competencies and ongoing compliance.

DEFINITIONS

1. Closed System Transfer Device (CSTD): A drug-transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drugs or vapor concentrations from outside the system.
2. Competency: The documentation/proof of understanding of knowledge-based information or the ability to perform practice-based skills.
3. Compliance: The documentation/proof of performance of a compounding-related task.
4. Compounded Non-Sterile Preparation (CNSP): Compounded medication.
5. Designated Person: One or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel for the preparation of CNSPs.

6. Hazardous Drug (HD): Any drug identified by at least one of the following criteria; carcinogenicity, teratogenicity or other developmental toxicity, reproductive toxicity in humans, organ toxicity at low dose in humans or animals, genotoxicity, or new drugs that mimic existing HDs in structure or toxicity.

FREQUENCY

1. Complete initial theoretical and practical competency requirements prior to starting non-sterile hazardous drug handling and compounding.
2. Perform on an ongoing basis once personnel have completed and passed initial training program
3. Perform upon changes in requirements with respective regulatory boards and/or State or Federal regulations.
4. Complete a comprehensive refresher-training program with competency assessment every twelve months.
5. Perform retraining in the recognition of identified deficiencies or demonstrated errors in performance.
6. Perform retraining in the event of structural, functional and/or operational change to the compounding facility.

SPECIAL CIRCUMSTANCE

1. This SOP does not apply to non-hazardous drug compounding.

PROCEDURE

This SOP is divided into the following sections:

1. Applicability
2. Qualification
3. Training requirements
4. Competency Requirements
5. Compliance Requirements

1. Applicability
    1. Documentation, directly or indirectly, related to a standard operating procedure, or any other documentation requirements, must comply with all laws and regulations of the applicable regulatory jurisdiction.
2. Qualification
    1. Compounding personnel must receive initial training and demonstrate competencies in all aspects of non-sterile hazardous drug handling and compounding prior to commencement of these roles and responsibilities.
3. Training Requirements
    1. Compounding personnel must be able to demonstrate proficiencies in at least the following areas:
        a. Hazard Communication Program
        b. Hand hygiene
        c. Garbing (i.e., donning and doffing for hazardous drug handling and compounding)
        d. Receiving and storing procedures
        e. Use of appropriate containment engineering controls.
        f. Deactivating, decontaminating and cleaning.
        g. Handling and transporting components and CNSPs, which includes, however, may not be limited to:

i. Entering the compounding room.

ii. Transferring supplies between rooms (i.e., pass-through and doorways).

iii. Exiting the compounding room.

h. Measuring and mixing

i. Spill control

j. Waste management

k. Proper use of equipment and devices selected to compound CNSPs, which may include the use of CSTDs.

l. Documentation of the compounding process (e.g., Master Formulation Records and Compounding Records)

6. Compounding personnel must follow these steps in the training procedure:

a. Read and understand USP General Chapter 800, other applicable standards, and other relevant literature as identified by the Designated Person.

b. Understand and interpret Safety Data Sheets (SDSs) and, if applicable, Certificates of Analysis (COA)

c. Read and understand procedures related to their compounding duties.

4. Competency Requirements

1. Personnel must demonstrate competencies in the aforementioned subjects.

2. Personnel must document the competencies and their respective written assessments.

3. Upon completion of the training program, the Designated Person(s) and/or Trainer must document that the personnel has been trained and successfully completed competency assessments.

5. Compliance Requirements

1. Designated Person is responsible for the ongoing monitoring and observation of compounding activities and must include immediate corrective action if deficient practices are observed.

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VERIFICATION

1. Verify, using competency and compliance assessments, personnel performance…
    1. Routinely.
    2. In response to an error, incident, accident, complaint or adverse event.
    3. On an ongoing basis in accordance with regulatory agencies responsible for monitoring credentials and continuous professional development requirements of pharmacists and pharmacy technicians.
2. Verify the competency of all personnel as it applies to the Hazard Communication Program.

CORRECTIVE ACTIONS

1. Take appropriate corrective action in response to error, incident, accident, complaint or adverse event.

PREVENTIVE ACTIONS

1. Consider alteration/modification to the compounding practice's current training and competency assessment program.

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TECHNOLOGICAL RESOURCES

EQUIPMENT	MANUFACTURER	MAKE	MODEL	SERIAL NUMBER	ID CODE
Medisca United States					

EDUCATIONAL AND SERVICE RESOURCES

AVAILABLE OFFERINGS	
LP3 Network	Medisca Network
Non-Sterile Training - Home Studies	Specialized Consultation Services
Technician Training - Home Studies	Technical Support Services (TSS)
Non-Sterile Training - Live Event	
Technician Training - Live Event	
Hazardous Drug Compounding - Live Event	
eLearning	
Instructional videos	

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

REFERENCE SOURCE	REFERENCE CODE	REFERENCE DATE	SECTION CODE	SECTION DESCRIPTION
USP	795	01 MAY 18		Pharmaceutical Compounding – Nonsterile Preparations
USP	800	01 DEC 19		Hazardous Drugs – Handling in the Healthcare Setting
ACHC/PCAB	TCRX3-A	2018		
ACHC/PCAB	TCRX3-C	2018		
ACHC/PCAB	TCRX3-E	2018		
ACHC/PCAB	TCRX3-F	2018		
ACHC/PCAB	TCRX3-H	2018		
ACHC/PCAB	HDH1-A	2018		