

Getting started

Three priorities to prepare for non-sterile compounding





Priority 1

Assessing risk and gaps

Existing pharmacies must be compliant by January 1, 2020

What compounds are you making or planning to make? Are changes to your infrastructure necessary?

- Review the [Standards for Pharmacy Compounding of Non-sterile Preparations \(SPCNP\)](#) and [Guidance Document for Pharmacy Compounding of Non-sterile Preparations \(GPCNP\)](#) and complete a gap analysis of all areas to assist with planning/prioritizing overall implementation.
- Identify the compounding supervisor who will develop, organize and oversee all activities (GPCNP 5.1.2).
- Identify all personnel who will require skills and training assessment (GPCNP 5.1.3-5.2.2).
- Determine what non-sterile compounded preparations and services you are providing.
- Use the algorithm (GPCNP Diagram 1) to identify the levels of requirements for the compounds you are preparing (GPCNP 4.1-4.3).
 - Complete a risk assessment for each non-sterile compound that you are preparing.
 - Ensure the master formulations are comprehensive and evidence-based with Safety Data Sheets (SDS) for each chemical used (GPCNP 6.2).
 - Refer to the National Institute for Occupational Safety and Health (NIOSH) list and SDS for Workplace Hazardous Materials Information System (WHMIS) and Globally Harmonized System (GHS) Health Hazards (Section 2 of the SDS) to determine the level of risk to the compounding personnel (GPCNP 4.3).
 - Identify the need for (and sources for) personal protective equipment (PPE) and safety equipment (GPCNP 9.4, 9.2.3)
- Have a pharmacist review and approve Beyond-Use Dates (BUDs) for all compounds as a part of the risk assessment (GPCNP 6.1.1).
- Determine the gaps for which additional training (compounding and cleaning personnel) will be needed.
- Determine the gaps for which facility improvements are required, given the time and planning needed to make structural changes.
- Identify the cleaning supplies required and identify suppliers.
- Identify the need for policies and procedures regarding staff compliance with hygiene requirements (e.g., no makeup, no jewelry, suitable work clothing, etc.)
- Develop and implement an action plan to address identified gaps.
 - Plan for risk mitigation where possible in the interim (GPCNP 9).



Priority 2

Compounding and cleaning, personnel training, and quality assurance

Existing pharmacies must be compliant by January 1, 2020

What kind of training, evidence of and assessment of training, and policies and procedures do you have in place to support you in meeting the standards?

- Review policies and procedures and identify gaps based on the findings from Priority 1.
- Refer to the checklist regarding responsibilities for pharmacy personnel (regulated and non-regulated) and delineate these responsibilities. Note the responsibilities for non-hazardous and hazardous non-sterile compounding (GPCNP 5.2.1 and 5.2.1.1).
- Assess the skills required for cleaning personnel (GPCNP 5.2.2).
- Complete the skills assessment checklist and determine the document skills training program required to address gaps and maintain quality practice.
- Revise or develop policies and procedures including a quality assurance program (GPCNP 7.6). Ensure that your quality assurance program addresses
 - verification and maintenance of equipment,
 - environmental control of facilities and primary engineering control,
 - environmental monitoring of chemical contamination for hazardous products, and
 - quality assurance of compounded non-sterile preparations (protocol, compliance with prescription, and documentation).
- Ensure your policies and procedures address proper hygiene for personnel (GPCNP Template 1, 6.5).
- Master formulation records should include all necessary information to compound a non-sterile preparation (GPCNP Template 2).
- Ensure that near misses, drug incident and accident reporting, investigation, and follow up are addressed (GPCNP Template 3, 9.4).
- For hazardous compounding, ensure that procedures for receiving, unpacking, and storing hazardous products as well as a waste management program are established and documented (SPCNP 9.5; GPCNP 9.1.4-9.1.5).



Priority 3

Facilities and equipment

Existing pharmacies must be compliant by July 1, 2020

Are your facilities and equipment in compliance with respect to the preparation of hazardous and nonhazardous nonsterile compounds that may require specific handling requirements?

- Ensure that hoods are certified every six months, hazardous material is stored appropriately, and cleaning and decontamination equipment and supplies are in place for hazardous compounding (SPCNP 9.2, GPCNP 9.3, 9.6.1). NB: Containers should not be reused.
- Ensure that your facility and equipment meet the requirements for lighting, heating, ventilation and air conditioning systems, water supply, work surfaces, furniture, walls, and flooring (SPCNP 9.1).
- Establish protocols and schedules for cleaning facilities and equipment to maintain the quality and integrity of the final preparations (GPCNP 5.4.1.6).
- Ensure routine maintenance of the facility and all equipment including the cleaning of specialized equipment. This must be documented in the general maintenance log (GPCNP 5.4.2.1).
- Finalize your quality assurance program and ensure that it addresses
 - facility,
 - equipment,
 - personnel metrics,
 - final compounded non-sterile preparations, and
 - documentation (GPCNP 7).
- For facilities that compound hazardous preparations, ensure that proper deactivation, decontamination, and cleaning procedures are addressed (GPCNP 9.3).
- Ensure that an environmental monitoring plan is in place (GPCNP 9.6.3).