MEETING THE NEW USP REQUIREMENTS, SIMPLIFIED

ACHCU SUPPORTS COMPLIANCE WITH LESS STRESS

COMPOUNDING PHARMACY

A valuable new resource for all compounding pharmacies.

Aligned with the latest versions of USP General Chapters <795>, <797>, and <800>, this comprehensive tool addresses everything your compounding pharmacy needs to establish and maintain compliance with USP. Available as a complete resource for all compounding services or as individual manuals focused on sterile or non-sterile, hazardous or non-hazardous compounding.

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DOCUMENTS

- **46** Policies and Procedures (P&P)
- **43** Standard Operating Procedures (SOP)
- **9** job descriptions
- **69** competencies
- **75** forms
- **1** acronym table
- **1** glossary

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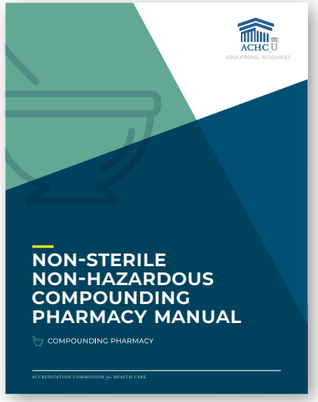
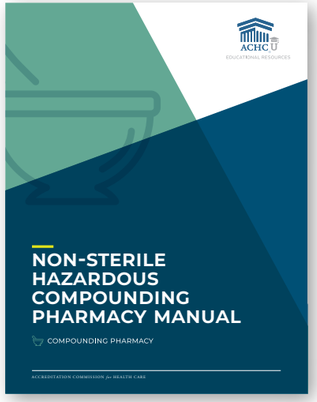
ACHCU compounding pharmacy manuals support compliance with less stress.



Non-Sterile Non-Hazardous Compounding



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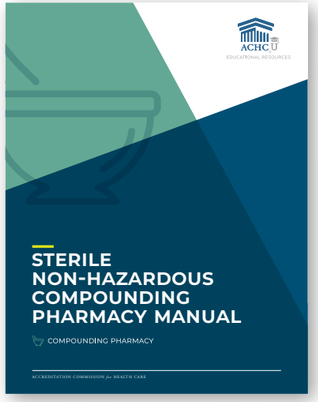
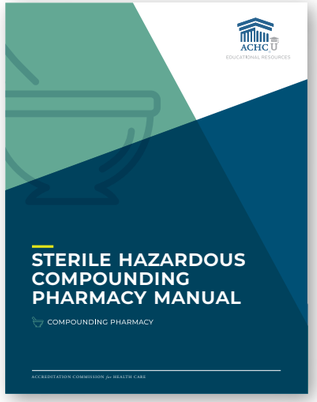


Sterile Non-Hazardous Compounding



Sterile Hazardous Compounding

POLICIES AND PROCEDURES

Authored by a team of professional pharmacists and pharmacy technicians with years of compounding experience, these are the foundational documents you need to establish quality practices for your compounding pharmacy.

STANDARD OPERATING PROCEDURES

Detailed, task-focused work instructions aligned with USP are ready to be customized to your processes. SOPs detail reports to run, required data fields (location, patient segment, e.g., active/discharged), and report handling. They note specific products in use, specific steps to be followed. In short, an SOP reflects an increased level of detail over a policy.

JOB DESCRIPTIONS

For roles specific to the compounding process (e.g., designated person, performance improvement coordinator), these descriptions align with the critical functions of your pharmacy.

COMPETENCY ASSESSMENTS

Detailed descriptions of the individual steps required to demonstrate competencies required for each type of compounding, including who performs the assessment, frequency of reassessment, etc. Representative items covered include:

For Non-Sterile Compounders

- Hand hygiene, gloving, gowning, and garbing.
- Compounding various dosage forms (e.g., liquid and semisolid, solid).
- The use of primary engineering controls (e.g., biological safety cabinet, containment ventilated enclosure).
- Cleaning and sanitizing the primary and secondary engineering controls.
- Ingredient/component receipt, evaluation, handling, storage, and selection.
- Equipment use.

For Sterile Compounders

- Hand hygiene, gloving, gowning, and garbing.
- Aseptic technique.
- The use of primary engineering controls (e.g., biological safety cabinet, laminar airflow workbench, compounding aseptic isolator).
- Cleaning and disinfecting the primary and secondary engineering controls.
- Ingredient/component receipt, evaluation, handling, storage, and selection.
- Equipment use.
- Environmental monitoring for air and surface sampling.
- Sterilization and depyrogenation techniques.
- Method suitability, sterility testing, bacterial endotoxin testing.

For Hazardous Compounding

- Hand hygiene, gloving, gowning, and garbing.
- Deactivating and decontaminating the primary and secondary engineering controls.
- The use of primary engineering controls (e.g., biological safety cabinet, compounding aseptic containment isolator, containment ventilated enclosure).
- Spill management.
- Hazardous waste disposal.
- Environmental wipe sampling.

FORMS

Efficient logging of USP requirements, including:

- Orientation and training.
- Environmental monitoring.
  - Temperature, humidity, and pressure differentials.
  - Glove fingertip and media fill testing for sterile compounding.
  - Air and surface sampling.
  - Certification and recertification of the primary and secondary engineering controls.
  - Cleaning and maintenance of the primary and secondary engineering controls.
- Master formulation record and compounding record.
- Equipment cleaning and maintenance.
- Reports for monitoring.
- Complaints/grievances/concerns.
  - Adverse events/risk events.
  - Product recalls, internal and external.
  - Performance Improvement activities.
- Hazardous-related.
  - Hazardous Drug Acknowledgment.
  - Assessment of risk.
  - Hazardous communication plan.
  - Hazardous drug list.
  - Hazardous drug exposure report.

Connecting the dots.

A CASE STUDY

Your Cleaning and Disinfection **Policy** requires use of an EPA-registered disinfecting agent.

Your **SOP** identifies the specific product and how it is used.

Analysis of your environmental monitoring **documentation** indicates an increase in failures for gloved fingertip testing.

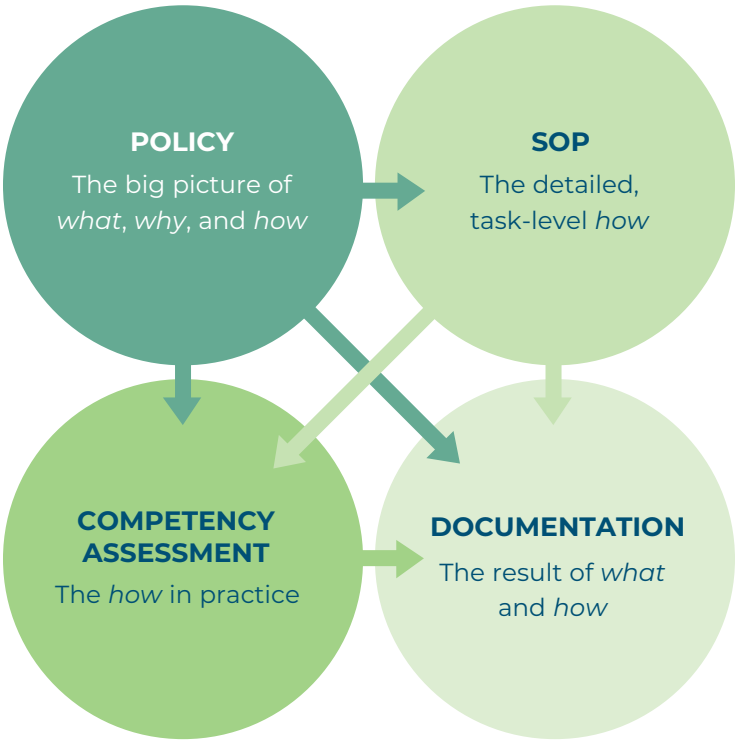
Begin investigation.

Competency Assessments indicate appropriate garbing and gloving technique.

SOP shows a recent change in the disinfecting product used. Corrective action restores use of previous product.

Documentation shows improvement.

Policy is revised to require segregated testing of new products prior to SOP changes.



Customized to be practical.

If you have already invested the time and effort to create your own policies and SOPs addressing USP changes, choose competency documents and procedure tracking logs and forms as individual, stand-alone resources, bundled by compounding type.

Ensure your readiness for a visit from the State Board of Pharmacy while developing sustainable excellence in compounding practices.

We're ready to help.

ACHCU is ready to create an educational solution for your organization.
Contact us to get a quote today.

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