CORE CONCEPT

Hospital Sterile Compounding Course: IV Admixture, Cytotoxic Handling and USP 797/800 Practice

20 – 24 September 2027
Paris - Right Bank business hotel

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Introduction:

Hospital sterile compounding, covering IV admixture, cytotoxic handling and USP 797/800 practice, is a 1-week course for pharmacy compounding, oncology pharmacy and hospital quality leads that ends with a Sterile Compounding Unit Quality and Containment Plan for a case hospital. Hospitals face contaminated infusions, dose errors from manual syringe checks and staff exposure to hazardous drugs when clean areas, operator technique and verification steps drift. Nominees already supervise IV rooms or chemotherapy units, and the course is taught as an inspection walkthrough of a case compounding suite. CoreConcept Training Center delivers this hospital sterile compounding course.

Course Objectives:

- Classify the compounded sterile preparations and hazardous drugs a unit handles and record contamination, dosing and exposure risks in a gap review
- Map unit procedures against USP 797, USP 800 and the PIC/S PE 010 Guide for preparation in healthcare establishments
- Supervise aseptic technique, gloved fingertip sampling, media-fill tests and environmental monitoring for compounding staff and rooms
- Assign beyond-use dates and set compounding record, labelling and pharmacist final check steps for IV admixtures
- Control hazardous drug exposure through closed-system transfer devices, protective equipment, deactivation, cleaning and spill response
- Produce a Sterile Compounding Unit Quality and Containment Plan for a case hospital

Target Audience:

- Pharmacy management staff responsible for IV admixture and chemotherapy compounding services
- Compounding supervision staff responsible for daily cleanroom operation, rosters and preparation release
- Oncology pharmacy staff responsible for cytotoxic preparation and hazardous drug containment
- Hospital quality and patient safety staff responsible for compounding audits, error reports and corrective actions
- Infection prevention and occupational health staff responsible for monitoring review and staff exposure surveillance

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Course Outline:

Day 1: Sterile Compounding Risks, Unit Scope and Current-State Review

- Compounded Sterile Preparation Types for IV, Intrathecal and Intraocular Use
- Contamination and Dosing Failure Routes in Manual IV Admixture
- Hazardous Drug List Screening Against Carcinogenic and Genotoxic Criteria
- Compounding Unit Workload Map for Admixture and Chemotherapy Rooms
- Current-State Gap Review of a Hospital Compounding Unit

Day 2: USP 797, USP 800 and PIC/S PE 010 Requirements

- USP 797 Personnel, Facility and Storage Requirements Mapped
- USP 800 Engineering Control and Documentation Requirements Mapped
- PIC/S PE 010 Guide Preparation Principles for Healthcare Establishments
- ISO Class 5 Primary Engineering Controls Within Buffer Areas
- Biological Safety Cabinet Class II Types Versus Containment Isolators

Day 3: Aseptic Technique, Operator Qualification and Beyond-Use Dating

- Garbing Order, Hand Hygiene and Work Surface Disinfection Routine
- Gloved Fingertip Sampling and Media-Fill Test for Operators
- Viable Air, Surface Sampling and Particle Counts in Compounding Rooms
- Beyond-Use Date Assignment From Preparation Type and Storage
- Compounding Record, Label and Pharmacist Final Check Workflow

Day 4: Hazardous Drug Containment, Error Prevention and Excursion Handling

- Closed-System Drug-Transfer Device Use During Cytotoxic Reconstitution
- Chemotherapy Gloves, Gowns and Respiratory Protection Assignment
- Deactivation, Decontamination and Cleaning Agent Rotation for Hazardous Drugs
- Hazardous Drug Spill Kit Response and Exposure Reporting
- Gravimetric and Barcode Verification Replacing Syringe Pull-Back Checks

Day 5: Inspection Walkthrough of a Case Hospital Compounding Suite

- Case IV Admixture Room Walkthrough Against USP 797 Criteria
- Case Chemotherapy Suite Containment Check Against USP 800 Criteria
- Case Monitoring Excursion and Media-Fill Failure Review
- Case Compounding Error Log and Verification Workflow Redesign
- Sterile Compounding Unit Quality and Containment Plan Completion

Skills You Will Gain:

- Compounded Preparation Risk Classification
- Aseptic Technique Supervision
- Operator Qualification Review
- Environmental Monitoring Interpretation
- Beyond-Use Dating Rationale
- Hazardous Drug Containment Planning
- Spill Response Coordination
- Gravimetric Dose Verification

Why Attend This Course:

- Hand a Sterile Compounding Unit Quality and Containment Plan for a case hospital to the pharmacy director and the hospital quality committee for approval
- Decide whether an operator, room or set of preparations can continue after a failed fingertip sample, media-fill result or monitoring excursion
- Avoid contaminated infusions, wrong-dose chemotherapy and staff exposure to hazardous drugs that lead to patient harm and unit closure
- Coach compounding technicians and pharmacists on garbing, cabinet technique, transfer devices and spill response

Conclusion:

Once back at work, the participant presents the Sterile Compounding Unit Quality and Containment Plan to the pharmacy director, the quality committee and the occupational health lead. They use it to decide which rooms, cabinets and transfer devices to upgrade, how often operators requalify and which verification steps replace manual checks. After the first requalification round and the first quarter of monitoring results, the unit should compare excursions, compounding errors and exposure incidents with the baseline and revise the plan.

Frequently Asked Questions FAQ:

What should participants know before a hospital sterile compounding course?

Participants should already supervise or audit an IV admixture room, chemotherapy unit or compounding quality process and know their unit's garbing and labelling routines. Bringing an anonymised monitoring report, error log or room layout helps them apply the walkthrough to their own suite.

How does hospital sterile compounding differ from aseptic manufacturing in a pharmaceutical plant?

Hospital sterile compounding prepares patient-specific IV admixtures and cytotoxic doses in pharmacy cleanrooms under USP 797 and USP 800. Aseptic manufacturing fills large commercial batches on industrial lines with process validation, a subject this course touches only as background.

Why does hospital sterile compounding replace syringe pull-back checks with gravimetric and barcode verification?

Syringe pull-back checks are error-prone because they rely on visual confirmation after the fact. Barcode scanning confirms the right ingredient and gravimetric checks confirm the dose by weight, giving the pharmacist objective evidence before an IV admixture or cytotoxic dose leaves the unit.

What do participants take back from the hospital sterile compounding course?

Participants take back a Sterile Compounding Unit Quality and Containment Plan for a case hospital, with a gap review, operator qualification schedule, monitoring plan, beyond-use dating table, hazardous drug containment checklist and spill response procedure ready to adapt to their own unit.