Credentialing Guidelines and Requirements

A Candidate Guidebook

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Knowledge Domains and Areas	% of CSPT® Exam Content
1.0 Medications and Components	**17%**
1.1 Generic names, brand names, indications, side effects, and therapeutic classifications of medications used in sterile compounding	
1.2 Types of high-alert/narrow therapeutic index (NTI) medications used in sterile compounding (e.g., insulin, heparin, concentrated electrolytes, chemotherapy)	
1.3 Dosage (e.g., strength, dosage forms) and administration (e.g., routes, instructions) of compounded sterile preparations (CSPs)	
1.4 Drug-specific factors affecting stability of compounded sterile preparations (CSPs; e.g., containers, light, concentration, closure, temperature, agitation)	
1.5 Type, purpose, and use of technical and clinical references for sterile compounding (e.g., package inserts, Safety Data Sheets [SDSs])	
1.6 Factors (e.g., temperature, microbial limits of sterility, storage time, complexity of preparation, location of preparation) that influence the assignment of beyond-use dates (BUD) for compounded sterile preparations (CSPs)	
1.7 Physical and chemical compatibility criteria for components (e.g., medications, ingredients, base solutions, filters, tubing, closures)	
2.0 Facilities and Equipment	**22%**
2.1 Types and uses of primary engineering controls (PECs; e.g., laminar airflow workbenches [LAFW] and systems [LAFS], biological safety cabinets [BSC], compounding aseptic isolators [CAI], compounding aseptic containment isolators [CACI])	
2.2 Types of secondary engineering controls (SECs; e.g., anteroom, buffer area, segregated compounding areas [SCAs], containment segregated compounding areas [C-SCAs])	
2.3 Features of secondary engineering controls (SECs; e.g., air pressure differentials, HEPA filtration, ISO classification, air changes per hour [ACPH])	
2.4 Temperature, pressure, and humidity parameters and/or tolerances for facilities and controlled environments	
2.5 Procedures and requirements for conducting different types of environmental monitoring	
2.6 Action levels and parameters for assessing environmental monitoring results (e.g., surface sampling, viable air sampling, non-viable air sampling)	
2.7 Common factors contributing to out of specification environmental monitoring results	
2.8 Operational standards (e.g., food and drink restrictions, facility access) for maintaining the safety and sterility of sterile compounding environments	
3.0 Sterile Compounding Procedures	**53%**

3.1 Types, purpose, and procedures for conducting required personnel training and competency assessments (e.g., gloved fingertip sampling, media fill) and the minimum frequency with which they must occur
3.2 Equations and calculations used to prepare compounded sterile preparations (CSPs; e.g., infusion times, percent solutions, dilutions, alligations, dispensing quantities, days supply, ratios and proportions, quantities, doses, concentrations, conversions)
3.3 Personal health and hygiene requirements for sterile compounding (e.g., no active respiratory infections, rashes, weeping sores, visible jewelry, long or artificial nails, cosmetics)
3.4 Hand hygiene procedures
3.5 Types of garb and personal protective equipment (PPE)
3.6 Procedures for donning, doffing, and disposal of garb and personal protective equipment (PPE) for non-hazardous and/or hazardous drugs
3.7 Properties and usage indications for deactivating, decontaminating, cleaning, and disinfecting agents
3.8 Procedures and requirements for cleaning and disinfecting compounding equipment, primary engineering controls (PECs), and secondary engineering controls (SECs) for non-hazardous compounded sterile preparations (CSPs)
3.9 Procedures and requirements for deactivating, decontaminating, cleaning, and disinfecting compounding equipment, primary engineering controls (PECs), and secondary engineering controls (SECs) for hazardous compounded sterile preparations (CSPs)
3.10 Principles of aseptic manipulation and procedures for operating within horizontal and vertical air flow equipment (e.g., first air, zone of turbulence)
3.11 Types of and requirements for cleaning and disinfecting critical sites of components (e.g., vials, ampules, ports)
3.12 Safety procedures for handling sharps
3.13 Documentation and record-keeping requirements for sterile compounding (e.g., master formulation record, compounding record)
3.14 Procedures to accurately weigh and measure components; principles of volumetric and gravimetric accuracy
3.15 Procedures for compounding parenteral nutrition (PN)
3.16 Procedures for preparing specialized compounded sterile preparations (CSPs; e.g., epidurals, intrathecals, cassettes, ophthalmics, irrigations)
3.17 Procedures for compounding hazardous drugs (e.g., negative pressure technique, using closed system drug-transfer devices [CSTDs])
3.18 Procedures for compounding sterile preparations from non-sterile components (e.g., presterilization, terminal sterilization, filtration, aseptic preparation)
3.19 Potential signs of defective compounded sterile preparations (CSPs; e.g., discoloration, particulates, leaks, turbidity)
3.20 Conditions under which sterility, potency, and endotoxin testing are required
3.21 Procedures for interpreting results of sterility, potency, and endotoxin testing

4.0 Handling, Packaging, Storage, and Disposal	**8%**
4.1 Handling, labeling, packaging, storage, and disposal requirements for non-hazardous medications, components, sharps, and finished compounded sterile preparations (CSPs)	
4.2 Handling, labeling, packaging, storage, and disposal requirements for hazardous medications, components, sharps, and finished compounded sterile preparations (CSPs)	
4.3 Types of and requirements for supplies used in packaging and repackaging (e.g., bags, syringes, glass, PVC, latexfree, DEHP-free)	