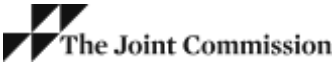
The Joint Commission

Glossary for the Medication Compounding Certification

clean room

A room in which the concentration of airborne particles is controlled through directional airflow and high-efficiency particulate air (HEPA)-filtered air supply to meet a specified airborne particulate cleanliness class. Microorganisms in the environment are monitored so that a microbial level for air, surface, and staff are not exceeded for a specified International Organization for Standardization (ISO)-classified space.

A drug transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapor concentrations outside of the system.

component

Any ingredient used in the compounding of a drug preparation, including any active ingredient or added substance that is used in its preparation.

compounded preparation

A nonsterile or sterile drug or nutrient preparation that is compounded in a licensed pharmacy or other health careï related facility pursuant to the order or anticipation of an order from a licensed prescriber.

compounded sterile preparation (CSP)

A preparation intended to be sterile that is created by combining, diluting, pooling, or otherwise altering a drug product or bulk drug substance. A product produced by reconstituting a conventionally manufactured

compounding

The preparation, mixing, assembling, altering, packaging, and labeling of a drug, drug-delivery device, or

critical site

A location that includes any component or fluid pathway surfaces (such as, vial septa, injection ports, and beakers) or openings (such as, opened ampules and needle hubs) that are exposed and at risk of direct contact with air (such as, ambient room or high-efficiency particulate air (HEPA)-filtered), moisture (such as, oral and mucosal secretions), or touch contamination.

disinfectant

A chemical agent used on inanimate surfaces and objects to destroy fungi, viruses, and bacteria, but not necessarily their spores.

engineering control

Primary, secondary, and supplemental devices designed to eliminate or reduce worker exposure to a

integrity test for filters

A test (for example, bubble-point test) performed after the filtration process to detect whether the integrity of a sterilizing-grade filter has been compromised.

International Organization for Standardization (ISO) class

An air-quality classification from the International Organization for Standardization.

isolator

master formulation record (MFR)

A documentation record (recipe) that includes the following:
- Official or assigned name, strength, and dosage of the preparation
- Calculations needed to determine and verify quantities of components and doses of active pharmaceutical ingredients
- Description of all ingredients and their quantities
- Compatibility and stability information, including references when available
- Equipment needed to prepare the preparation, when appropriate
- Mixing instructions as follows:
 1. Order of mixing
 2. Mixing temperatures or other environmental controls
 3. Duration of mixing
 4. Other factors pertinent to the replication of the preparation as compounded
- Sample labeling information, which should contain the following, in addition to legally required information:
 1. Generic name and quantity or concentration of each active ingredient
 2. Assigned beyond-use date (BUD)
 3. Storage conditions
 4. Prescription or control number, whichever is applicable
- Container used in dispensing
- Packaging and storage requirements
- Description of final preparation
- Quality control procedures and expected results

media-fill test

A simulation used to qualify processes and staff engaged in sterile compounding to ensure that the processes and staff are able to produce compounded sterile preparations (CSPs) without microbial contamination.

multiple-dose container

A container of sterile medication for parenteral administration (specifically, injection or infusion) that is designed to contain more than one dose of the medication. A multiple-dose container is usually required to meet the antimicrobial effectiveness testing criteria.

negative pressure room

A room that is at a lower pressure than the adjacent spaces and, therefore, the net flow of air is into the room.

pass-through

An enclosure with seals on interlocking doors that are positioned between two spaces for the purpose of minimizing particulate transfer while moving materials from one space to another.

personal protective equipment (PPE)

Items such as gloves, gowns, respirators, goggles, face shields, and others that protect individual workers from hazardous physical or chemical exposures.

preservative

A substance added to inhibit microbial growth or to prevent decomposition or undesirable chemical changes.

primary engineering control (PEC)

A ventilated device that provides a prescribed environment for the exposure of critical sites, and when desired, protects workers and the environment from exposure to the compounds under manipulation. PECs used for manipulation of hazardous drugs are designed for containment.

pyrogen-free

A substance lacking sufficient endotoxins or other fever-inducing contamination to induce a febrile or pyrogenic response.

quality assurance

A system of procedures, activities, and oversight that ensures that operational and quality standards are