

Exhibit 3-41 A

Definitions (adapted from United States Pharmacopeia (USP 797) Glossary)

Anteroom: An ISO Class 8 or cleaner room with fixed walls and doors where hand hygiene, garbing procedures, and other activities that generate high particulate levels may be performed. The anteroom is the transition room between the unclassified area of the facility and the buffer room.

Aseptic technique: A set of methods used to keep objects and areas free of microorganisms and thereby minimize infection risk to the patient.

Beyond-use date (BUD): The date, or hour and the date, after which a CSP must not be used, stored, or transported. Administration time is not considered a part of the BUD.

Buffer room: An ISO Class 7 or cleaner room with fixed walls and doors where PEC(s) that generate and maintain an ISO Class 5 environment are physically located. The buffer room may only be accessed through the anteroom or another buffer room.

Category 1 CSP: A CSP that is assigned a BUD of 12 hours or less at controlled room temperature or 24 hours or less refrigerated.

Category 2 CSP: A CSP that may be assigned a BUD of greater than 12 hours at controlled room temperature or greater than 24 hours refrigerated.

Classified area: An area that maintains an air quality classification based on the ISO standards.

Cleaning: The process of removing substances from objects and surfaces, normally accomplished by using water with detergents or enzymatic products.

Compounded sterile preparation (CSP): A preparation intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance.

Compounding: The process of combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance to create a sterile preparation.

Designated Person: One or more persons assigned to be responsible and accountable for the performance and operation of the facility and personnel as it relates to preparation of CSPs. The designated person(s) may assign trainers or designees to assist in carrying out functions as described in facility SOPs.

Disinfectant: A chemical or physical agent used on inanimate surfaces and objects to destroy fungi, viruses, and bacteria. Sporicidal disinfectants are considered a special class of disinfectants that also are effective against bacterial and fungal spores.

Dynamic airflow smoke pattern test: A PEC test in which a visible source of smoke is used to observe air patterns within the unidirectional space under dynamic operating conditions.

Dynamic operating conditions: Conditions in the compounding area in which operating personnel are present and simulating or performing compounding. The conditions should reflect the largest number of personnel and highest complexity of compounding expected during routine operations as determined by the designated person(s).

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

Primary engineering control (PEC): A device or zone that provides an ISO Class 5 air quality environment for sterile compounding.

Restricted-access barrier system (RABS): An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air that allows for the ingress and/or egress of materials through defined openings that have been designed and validated to preclude the transfer of contamination, and that generally are not to be opened during operations. Examples of RABS include compounding aseptic isolators (CAIs) and compounding aseptic containment isolators (CACIs).

Secondary engineering control (SEC): The area where the PEC is placed (e.g., a cleanroom suite or an SCA). It incorporates specific design and operational parameters required to minimize the risk of contamination within the compounding area.

Segregated compounding area (SCA): A designated space, area, or room that is not required to be classified and is defined with a visible perimeter. The SCA must contain a PEC and is suitable for preparation of Category 1 CSPs only.

Unclassified Area: A space not required to meet any air cleanliness classification based on the ISO.