USP<797> 2022 Updates

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Objectives

Understand	Understand activities that do not fall within the scope of USP< 797>.
Identify	Identify key differences between USP<797> 2008 and USP<797>2022.
Explain	Explain the differences between Category 1, Category 2 and Category 3 CSP’s.

What is USP<797> ?

- USP General Chapters establish procedures, methods and practices that are utilized by practitioners to help ensure the quality of compounded preparations.

- USP General Chapter <797> is required and compendially applicable because it is:
- – Numbered below <1000> and referenced in the General Notices 3.10.30.

Dosage Forms

- USP<797> applies to all persons who prepare and to all places where CSP's are compounded for humans or animals.

- Injections, including infusions
- Irrigations for internal body cavities
- Ophthalmic dosage forms
- Aqueous preparations for pulmonary inhalation
- Baths and soaks for live organs and tissues
- Implants
-

Goals of USP<797>

Minimize harm, including death to human and animal patients that could result from:

Microbial contamination (non-sterility)

Excessive bacterial endotoxins

Variability from the intended strength of correct ingredients

Physical and chemical incompatibilities

Chemical and physical contaminants, and/or

Use of ingredients of inappropriate quality

Practices outside scope

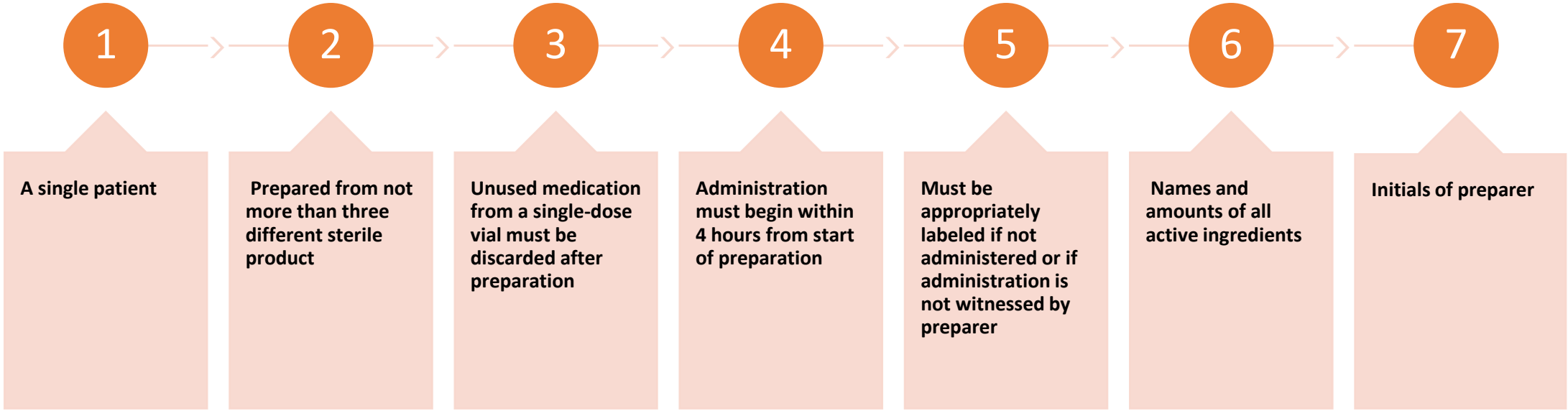
Docking and activation of proprietary bag and vial systems(not future activation).

Preparation per approved product labeling– For a single dose for an individual patient

Approved labeling must describe- Diluent, resultant strength, container closure system and storage time

Administration

Immediate Use CSP's



What is sterile compounding?

- combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance to create a sterile preparation

Objective number two

Identify key differences between USP<797> 2008 and USP<797>2022.

Review of USP 797 Inspection form.

Designated Person Responsibilities

Creating and implementing a training program for personnel

Ensuring that compounders, personnel who have direct oversight of compounders, and personnel who perform restocking or cleaning and disinfection duties are initially trained and qualified before being allowed to perform their job functions independently.

Maintenance of facilities

SOP’s

Training Program

- Training required for different personnel
- Frequency determined by role and compounding category
- Designated person may assign a trainer
- Training and observation must be documented
- SOP must define the roles and training required for each role
- SOP’s must be reviewed annually

Designated Person

Person must be identified who is responsible and accountable for the performance and operation of the facility and personnel involved in the preparation of CSPs.

[USP 797 Section 1.1.3]

Component BUD’s

SINGLE DOSE CONTAINERS

PHARMACY BULK PACKAGES

STOCK SOLUTIONS

Maintenance of Facilities

each area related to CSP preparation must meet the classified air quality standard appropriate for the activities to be conducted in that area.

ISO Class 5 areas are located, operated, maintained, monitored, and certified to have appropriate air quality

certification and recertification records are reviewed by the designated person(s)

microbiological air and surface sampling

Facilities and Engineering Controls

- ISO 8- 20 ACPH
- Temperature and humidity gauges must be calibrated per manufacturers recommendations
- Ante room must have line of demarcation
- No tacky mats in classified rooms

Misc

- Documentation of calibration of ACD’s

Personnel Training

Hand Hygiene and Garbing observational assessment must be completed and documented three times with Gloved Fingertip Testing after each.

Must occur where gloves are donned.

GFT Incubation- 30-35 for minimum of 48 hours followed by 30-35 for 5 days.

> 0 cfu. per both hands is a failure, must have 3 consecutive passing tests.

Purpose: indicate that staff member can don gloves without contaminating them

Personnel Training

Aseptic Technique observational assessment followed by media fill, surface sample and post media fill GFT.

Incubation for 7 days at 20-25 and 30-35, order of incubation must be defined in SOP's.

Visual turbidity during incubation period indicates a failure.

> 3 cfu on surface sample or GFT represents a failure.

Purpose: Indicate that staff member can keep microbial bioburden on their gloves low when compounding.

Personnel

- Garbing according to SOP.
- No ear buds, headphones

Frequency of training

Determined by function and Category compounded.

Category 1 and 2:

Persons with direct oversight of compounding-every 12 months

Compounders-every 6 months

Category 3:

Persons with direct oversight of compounding-every 12 months

Compounders-every 3 months

Documentation Requirements

Documentation requirements for GFT and Media Fill:

- name of the person evaluated
- evaluation date and time
- media and components used to include manufacturer, expiration date, and lot number
- starting temperature for each interval of incubation
- dates of incubation
- results and identification of the observer and personnel reading and documenting the results

Microbiological Surface sampling

Category 1 and 2: Monthly

Category 3: Weekly, prior to assigning BUD longer than Category 2.

Action levels

ISO 5>3

ISO 7>5

ISO 8>50 (previously>100)

If action levels exceeded, all effort should be made to identify any micro-organism to the genus level

No statement about pathogenic organisms

Microbiological Air Sampling

Category 1 and 2-every 6 months

Category 3-Within 30 days before start of compounding and monthly

Incubate at 30-35 C for no less than 48 h then incubate at

20-25 C for no less than 5 additional days

May use 2 sampling media, not required

Cleaning and Disinfecting

Cleaning, disinfecting and sporicidal agents used within the PEC must be sterile.” Sterile water must be used when diluting concentrated agents for use in the PEC.

Category 1 and 2- Sporicidal use monthly

Category 3- Sporicidal use weekly

SOP’s

- appropriate and implemented.
- person(s) must follow up to ensure that corrective actions are taken if problems, deviations, failures, or errors are identified.
- the corrective action must be documented.
- reviewed every 12 months by the designated person(s) to ensure that they reflect current practices, and the review must be documented.
- changes or alterations to an SOP must be made by the designated person(s) and must be documented.
- changes must be communicated to staff.

QA and QC Program

Formal Program that must be reviewed every 12 months and ensure

- adherence to procedures
- prevention and detection of errors and other quality problems
- evaluation of complaints and adverse events
- appropriate investigations and corrective actions
- recall procedures

Category 1

PEC in unclassified space- Category 1 only

BUD: 12 hours room temperature, 24 hours refrigerated

No sterility testing

Aseptically compounded

Includes CAI or CACI in unclassified space

Category 2

- PEC in classified space
- Aseptic processing
- Sterility testing required depending on BUD
- Endotoxin testing- required for injectables with non-sterile starting components and sterility testing required.
- BUD from table 13

Category 2 BUD

Preparation Characteristics		Storage Conditions		
Compounding Method	**Sterility Testing Performed and Passed**	**Controlled Room Tempera- ture (20°-25°)**	**Refrigerator (2°-8°)**	**Freezer (−25° to −10°)**
Aseptically processed CSPs	No	Prepared from one or more nonsterile starting compo- nent(s): 1 day	Prepared from one or more nonsterile starting compo- nent(s): 4 days	Prepared from one or more nonsterile starting compo- nent(s): 45 days
		Prepared from only sterile starting components: 4 days	Prepared from only sterile starting components: 10 days	Prepared from only sterile starting components: 45 days
	Yes	30 days	45 days	60 days
Terminally sterilized CSPs	No	14 days	28 days	45 days
	Yes	45 days	60 days	90 days

Category 3

PEC IN CLASSIFIED SPACE

ASEPTIC PROCESSING

OR TERMINAL STERILIZATION

STERILITY TESTING REQUIRED

ENDOTOXIN TESTING- REQUIRED FOR INJECTABLES

BUD FROM TABLE 14

Category 3

- Antimicrobial Effectiveness Testing
- Particulate Testing
- Container Closure Studies
- Stability Indicating Assays
- Max Batch Size-250

Category 3 BUD

Preparation Characteristics	Storage Conditions		
Compounding Method	Controlled Room Temperature (20°–25°)	Refrigerator (2°–8°)	Freezer (–25° to –10°)
Aseptically processed, sterility tested, and passing all applicable tests for Category 3 CSPs	60 days	90 days	120 days
Terminally sterilized, sterility tested, and passing all applicable tests for Category 3 CSPs	90 days	120 days	180 days