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Welcome
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USP Compounding Standards Updates Summary and Impact

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Advisor Live® Webinar
USP Compounding Standards Updates Summary and Impacts

June 13, 2019

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NOTES
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QUESTIONS
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RECORDING
This webinar is being recorded.
View it later on-demand at premierinc.com/events.

Agenda

- Overview of USP Compounding Standards
- USP <797> Revisions
- USP <795> Revisions
- Premier Resources to Assist with USP Compliance
- Question & Answer

Please Note: This content is provided for informational and discussion purposes only and is not an official interpretation of the regulation.

Today's Speakers

Annie Lambert, PharmD

Director, Performance Partners

Chris Jones, R.Ph

Director, Pharmacy Automation & Technology

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USP Compounding Standards

Updated June 1, 2019

USP Compounding Standards

USP <795>: Non-sterile compounding

- Describes requirements for the compounding process, facilities, equipment, components, documentation quality controls and training to promote patient safety.

USP <797>: Sterile Compounding

- Helps to ensure patients receive quality preparations that are free from contaminants and are consistent in intended identity, strength and potency. It describes a number of requirements, including responsibilities of compounding personnel, training, environmental monitoring, storage and testing of finished preparations.

USP <800>: Hazardous Drugs

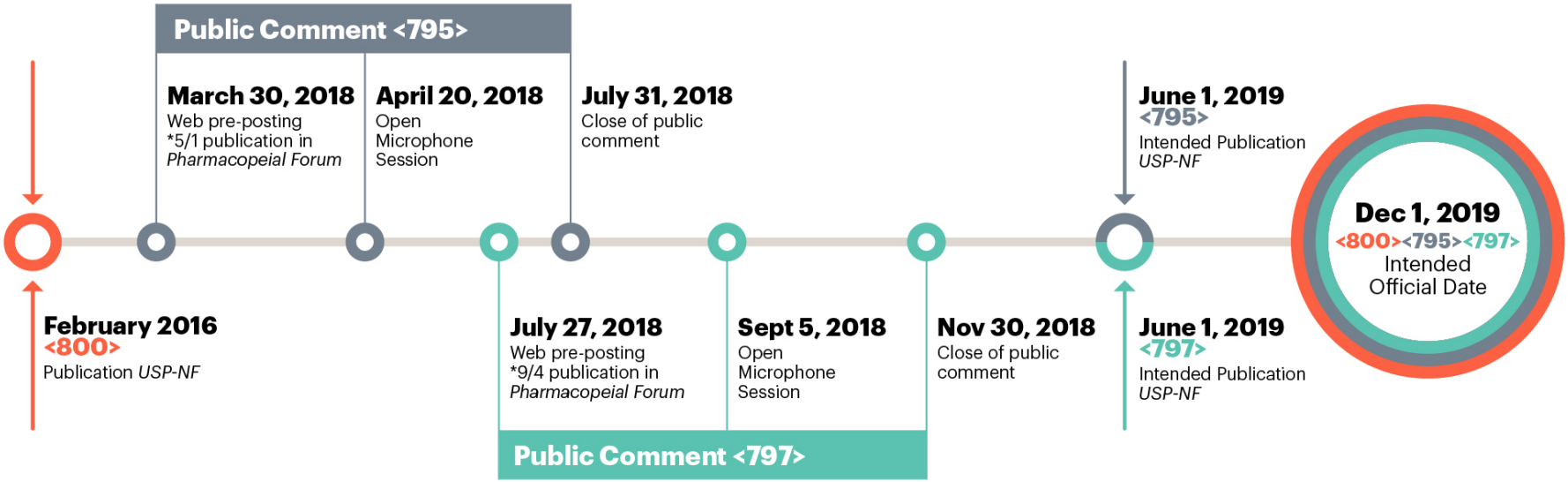
- Provides standards for safe handling of hazardous drugs to minimize the risk of exposure to healthcare personnel, patients and the environment.

USP <825>: Radiopharmaceuticals

- Provides the minimum standards for the preparation, compounding, dispensing, and repackaging of sterile and non-sterile radiopharmaceuticals for humans and animals that occur as part of state-licensed activities.

*Source or Footnote = Arial Regular 8pt

USP Compounding Standards Timeline



Note: The current version of General Chapters <795> and <797> published in USP-NF are official.

*Source or Footnote = Arial Regular 8pt

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USP <797> Sterile Compounding

Summary of Updates and Potential Impacts

USP <797> General Information

- Chapter structure and summary tables
- Compounding definition
- New categories
- Clarified current practice → CGMPs

In Scope	Out of Scope
Repackaging	Radiopharmaceuticals
Allergenic extracts	Administration
	Preparation per approved labeling
Hazardous Drugs	

USP <797> Facilities

Clean room suite	Segregated Compounding Area (SCA)
ISO 5 PEC (any type)	ISO 5 PEC (any type)
ISO 7 room	N/A
ISO 7 or 8 ante room	N/A
Minimum 0.020”w.c.	No pressure requirement
≥ 20 or ≥ 30 ACPH (15 from HVAC)	No ACPH requirement
Cleanable surfaces and finishes	Cleanable surfaces and finishes
Sink placement clean or dirty side of LOD	Sink accessible but ≥ 1m from PEC and not within the perimeter of SCA
Category 1 or Category 2 CSPs	Category 1 CSPs only

USP <797> Categories and Beyond Use Dates (BUDs)

Table 10 establishes the longest permitted BUDs for Category 1 CSPs. Category 1 CSPs may be prepared in an SCA or cleanroom suite (see *4.2 Facility Design and Environmental Controls*).

Table 10. BUDs for Category 1 CSPs

	Storage Conditions	
	Controlled Room Temperature (20°–25°)	Refrigerator (2°–8°)
BUD	≤12 hours	≤24 hours

Table 11 establishes the longest permitted BUDs for Category 2 CSPs. Category 2 CSPs must be prepared in a cleanroom suite (see *4.2 Facility Design and Environmental Controls*).

Table 11. BUDs for Category 2 CSPs

Preparation Characteristics		Storage Conditions		
Compounding Method	Sterility Testing Performed and Passed	Controlled Room Temperature (20°–25°)	Refrigerator (2°–8°)	Freezer (–25° to –10°)
	No	Prepared from one or more nonsterile starting component(s): 1 day	Prepared from one or more nonsterile starting component(s): 4 days	Prepared from one or more nonsterile starting component(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
Aseptically processed CSPs	Yes	30 days	45 days	60 days
Terminally sterilized CSPs	No	14 days	28 days	45 days
	Yes	45 days	60 days	90 days

USP <797> Environmental Monitoring

Continuous with daily documentation:

- Pressure (if applicable), temperature, humidity

Minimum of every 6 months for classified areas:

- Airborne particle testing
- Viable airborne sampling

Minimum of monthly for classified areas:

- Viable surface sampling

Incubation standards: dual phase temperatures

Action levels:

- Same threshold levels, but no requirement to ID microorganism unless levels exceeded
- Corrective action plan regardless of findings

USP <797> Personnel Monitoring & Competency

For compounding personnel:

- Testing and demonstration initial and every 12 months
- Media fill initial and every 6 months
- Gloved fingertip and thumb sampling initial and every 6 months
- Same incubation standards as environmental monitoring

For other personnel:

- Training and demonstration required
- Frequency determined by training program
- Oversight by designated person

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USP <795> Non-Sterile Compounding

Summary of Updates and Potential Impacts

USP <795> General Information

Reorganized chapter

- Mirrors sections in USP <797> and <800>

In Scope	Out of Scope
Any alteration of a drug or bulk drug substance beyond the manufacturer's labeling	Radiopharmaceuticals
	Administration
	Reconstitution
	Repackaging
	Splitting tablets
Hazardous Drugs	

USP <795> Facilities

Designated area for nonsterile compounding:

- No carpet, cleanable surfaces
- Minimize cross-contamination
- Temperature monitoring
- Sink accessible and clean

Equipment:

- Closed system processing device i.e. Containment Ventilate Enclosure (CVE), Biologic Safety Cabinet (BSC), single use glove bag
  - Evaluate need and develop SOP for use
  - Certify every 12 months
  - Cleaning SOP

USP <795> Categories and BUDs

- Eliminated categories of compounded products related to complexity
- Expanded requirements for extending BUD beyond regs in absence of data
- Provisions for shorter or extended BUD

Table 3. Maximum BUD by Type of Preparation in the Absence of a *USP-NF* Compounded Preparation Monograph or CNSP-Specific Stability Information

Type of Preparation	BUDs (days)	Storage Temperature[a]
Non-preserved aqueous dosage forms[b]	14	Refrigerator
Preserved aqueous dosage forms[b]	35	Controlled room temperature or refrigerator
Nonaqueous dosage forms[c]	90	Controlled room temperature or refrigerator
Solid dosage forms[d]	180	Controlled room temperature or refrigerator

[a] See *Packaging and Storage Requirements* ⟨659⟩.
[b] An aqueous preparation is one that has an Aw of > 0.6 (e.g., emulsions, gels, creams, solutions, sprays, or suspensions).
[c] Any preparation other than solid dosage forms that have a reduced Aw of ≤0.6 (e.g., suppositories, ointments, fixed oils, or waxes).
[d] Capsules, tablets, granules, powders.

USP <795> Policies and Procedures

- Training and demonstration of core competencies every 12 months
- Hand hygiene and garbing
  - Gloves required, additional PPE per SOP
- Cleaning and sanitizing

Table 1. Minimum Frequency for Cleaning and Sanitizing Surfaces in Nonsterile Compounding Area(s)

Site	Minimum Frequency
Work surfaces	• At the beginning and end of each shift, after spills, and when surface contamination is known or suspected • Clean and sanitize the work surfaces between compounding CNSPs with different components
Floors	Daily, after spills, and when surface contamination (e.g., splashes) is known or suspected
Walls	Every 3 months, after spills, and when surface contamination (e.g., splashes) is known or suspected
Ceilings	When visibly soiled and when surface contamination is known or suspected
Storage shelving	Every 3 months, after spills, and when surface contamination (e.g., splashes) is known or suspected

USP <795> / <797> / <800>

Policies and Procedures

- Document, document, document!

Master Formulation Records (MFR) and Compounding Records (CR)

- MFR: Describes procedures for preparation, BUD, references
- CR: Documents the steps and components used

Designated Person

- Oversight of compliance with all aspects of each chapter

QA and QC Plan

- Adherence to SOPs
- Prevention and detection of errors and other quality problems
- Evaluation of complaints and adverse events
- Investigations and corrective actions

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Premier Resources

Support Services for USP Compliance

Get Ready and Stay Ready with Premier's Support

General advice and updates

- Blog posts and webinars

Subject Matter Experts

- Resource, references and FAQs

Preparation Checklists

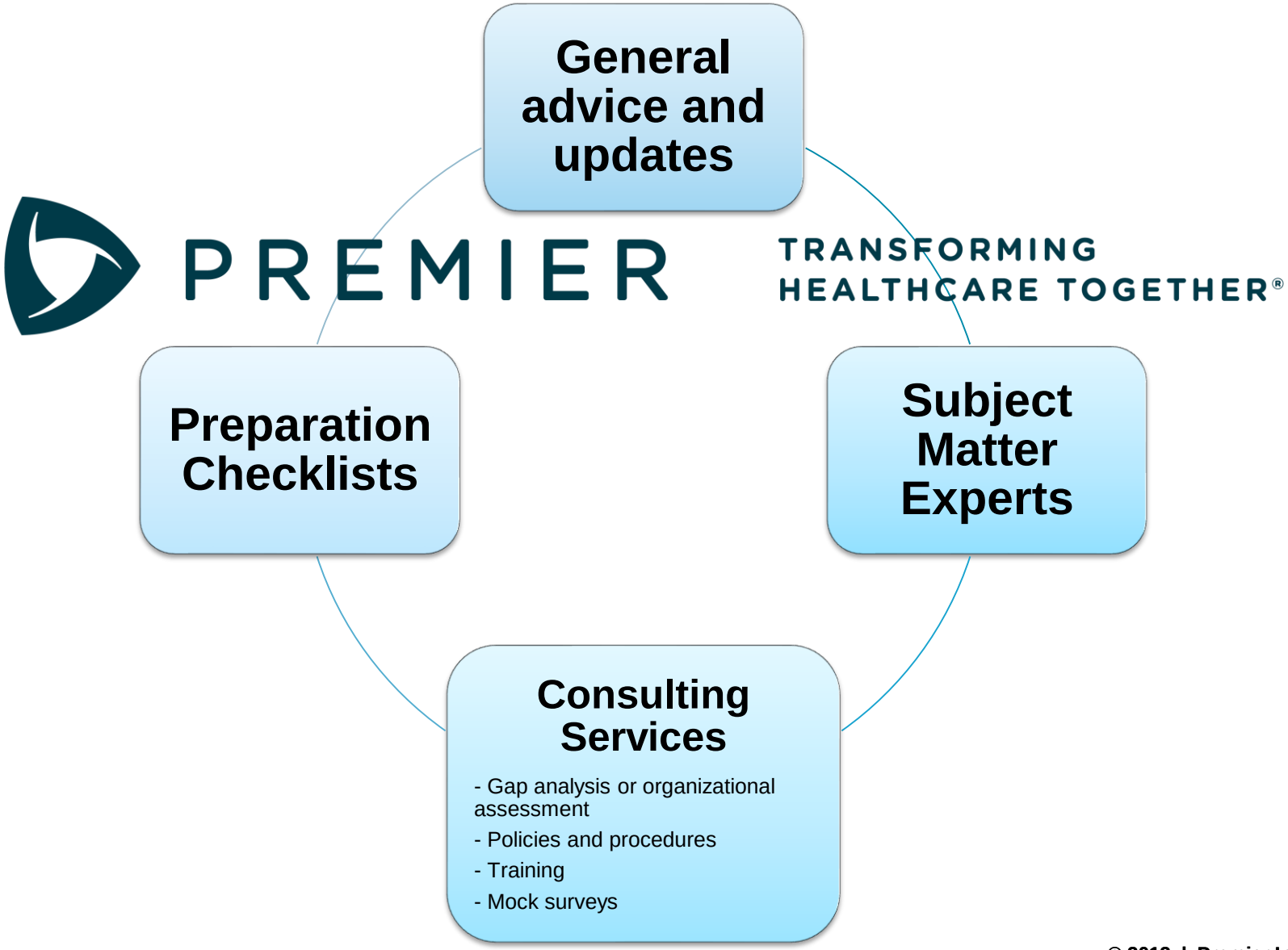
- Quick reference tools

Consulting services

- Gap analysis or organizational assessment
- Policies and procedures
- Training
- Mock surveys

innovatix PREMIER INC. COMPANIES | ESSENSA | PREMIER Alternate Site Programs

Get Ready and Stay Ready with Premier's Support



Cleanroom PPE, Cleaning Supplies, and Consumables

Current Suppliers:

- Acute Care Pharmaceuticals (PPPH21ACP01)
- Contec, Inc. (PPPH21CON01)

Current Supplies Include:	
Shoe covers, non-shedding	Beard covers
Hair covers/hair bonnets	Masks, sterile
Goggles	Coats, non-shedding
Coveralls, non-shedding	Gloves, sterile
Gloves, chemotherapy, sterile	Gowns, non-shedding
Wipes, lint-free	Alcohol pads/wipes
70% sterile isopropyl alcohol	Sporicidals
Other disinfectant agents	Media fill kits
Floor mops, non-shedding	Chemo spill kits
Floor wipers, non-shedding	

Capital Equipment- Primary Engineering Controls

Current Suppliers:

- The Baker Company (PPPH22BAK01)
- NuAire, Inc. (PPPH22NUA01)

Includes:

- Laminar airflow workbenches
- Compounding aseptic isolators (CAI)
- Compounding aseptic containment isolators (CACI)

Key Considerations:

- Warranty and service guarantees
- Size configurations
- Accessories

Capital Equipment- Refrigeration & Monitoring

Wireless Temperature and Air Pressure Monitoring- various Suppliers

Medication and Laboratory Grade Refrigerators & Freezers

- Helmer- (PPPH20HLM01)
- NorLake- (PPPH20NLK01)

Capital Equipment- Cleanroom Automation

Cleanroom workflow software Suppliers:

- DoseEdge- Baxter (PPPH20BAX05)
- i.v.Soft- Omnicell (PPPH20OMN01)

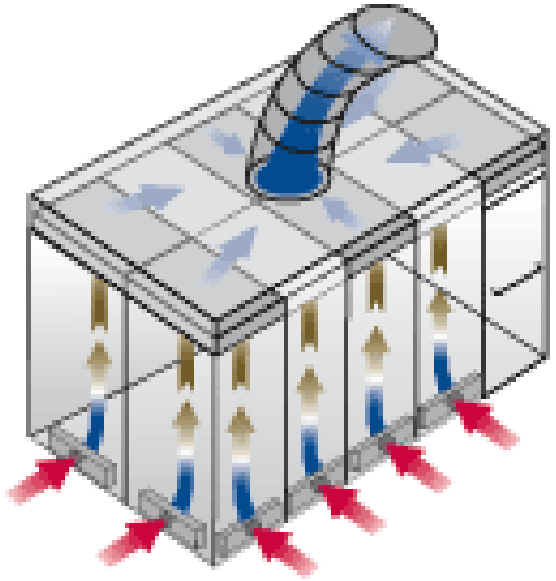
Cleanroom compounding robotic Suppliers:

- i.v.Station- Omnicell (PPPH20OMN01)
- i.v. Station- ONCO- (PPPH20OMN01)
- RIVA- ARxIUM cGMP robot- (pending)

Outsourced Services- Air Quality Testing and Certification

Air Quality Certification and Testing Services:
Medical Technology Associates-MTA (PPPH21ETN01)
Technical Services Solutions-TSS (PPPH21TSS01)

Outsourced Services: Cleanroom Planning & Design



Cleanroom Planning and Design:

- Aseptic Enclosures- (PPPH21APK01)
- Carter Health- (PPPH21CTR01)

Outsourced Services- 503A and 503B Compounding

Outsourced I.V. Admixture Service Suppliers:

- AIS Healthcare- (PPPH21AIS01)- 503A intrathecal pain pump refills
- CAPS- (PPPH21BBM01)- 503A for TPN and 503B injectables
- Fagron Sterile Services- (PPPH21FSS01)- 503B ophthalmics and drug shortages
- Leiters- (PPPH21LTR01)- 503B injectables, ophthalmic meds, drug shortages
- Nephron- (PPPH21NAP01)- 503B injectables and drug shortages
- PharMEDium- (PPPH21PMD01)- 503B injectables
- QuVa- (PPPH21QVA01)- 503B injectables and drug shortages
- SCA- (PPPH21SCA01)- 503B injectables and drug shortages

Questions?

Resources

Preparation Checklists for USP <795> <797> <800>

GPO Contracts

USP Compliance Services for Non-Acute Sites of Practice

Premier Experts:

- Annie Lambert, PharmD – acute sites of practice
- Jennifer Valentine – non-acute sites of practice
- Chris Jones, RPh – GPO contracts
- Soumi Saha, PharmD, JD – advocacy

General Inquiries: solutioncenter@premierinc.com

Speakers Contact Information

Annie Lambert, PharmD

Director, Performance Partners

Premier

253.651.2288

Annie_Lambert@Premierinc.com

Chris Jones, R.Ph

Director, Pharmacy Automation & Technology

Premier

704.816.5783

Christopher_Jones@Premierinc.com

Additional Resource

Jennifer Valentine - Program Manager, Specialty Pharmacy Management

jennifer_valentine@innovatix.com 212.901.1328