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USP <795> Pharmaceutical Compounding Nonsterile Preparations: Journey to Compliance

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Disclosures

- The presenters have no real or perceived conflicts of interest related to this presentation

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Learning Objectives

At the end of this session, participants should be able to:

1. Identify the scope of USP <795> in various practice settings & the specific preparations to which the new regulations are to be applied.
2. Recall the required changes to meet compliance of the revised regulations.
3. Recognize strategies to streamline the quality & consistency of nonsterile compounded preparations to enhance patient safety.

USP <795>

Scope of USP <795> in Various Practice Settings

Definitions

- United States Pharmacopeia (USP)
  - Independent, scientific, nonprofit organization focused on safety & quality of medicines
    - "Standards build trust in medicines & a stronger supply chain"
- Pharmaceutical Compounding
  - Sterile (intravenous route of administration)
  - Nonsterile (oral, topical or rectal route of administration)
- Nonsterile compounding
  - Combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance to create a nonsterile preparation.

Source:
United States Pharmacopeia (USP) https://www.usp.org/about. Date accessed 5/16/2023.
United States Pharmacopeia (USP) chapter <795>: https://www.usp.org/compounding. Date accessed 2/13/2023.

Polling Question #1:

When do USP <795> & <797> updates become effective?

A. January 1, 2024
B. December 1, 2023
C. November 1, 2023
D. July 1, 2024

Current USP Regulatory Landscape

- Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations
  - Last revised 2014
- Chapter <797> Pharmaceutical Compounding – Sterile Preparations
  - Last revised 2008
- Chapter <800> Hazardous Drugs – Handling in Healthcare Settings
  - Last revised 2019
- USP <795> & <797> updates become effective 11/1/2023!

Source: United States Pharmacopeia (USP) https://www.usp.org/about. Date accessed 5/16/2023.

Purpose of USP <795> Regulations

- Focus on Patient Safety
- Prevent Patient Harm due to:
  - Incorrect Medication Concentration
  - Microbial Contamination
  - Wrong Active or Inactive Ingredients
  - Physical & Chemical Incompatibilities
  - Expired Medication
    - Low Potency
    - Toxicity

Source: United States Pharmacopeia (USP) chapter <795>: https://www.usp.org/compounding. Date accessed 2/13/2023.

Pharmaceutical Compounding Challenges

- Recent Published Data (includes all pharmaceutical compounding)
- Review of Compounding Errors in the U.S. from 1990 to 2020
  - 2,155 documented reports
    - Contamination
    - Suprapotency
    - Subpotency
  - 1,119 patients were harmed

Source: Journal of Medical Toxicology. 2021 April; 17 (2): 197-217. Pharmaceutical Compounding: a History, Regulatory Overview, and Systematic Review of Compounding Errors.

Exceptions to USP <795>

- Nonsterile radiopharmaceuticals
  - Follow USP <825> Radiopharmaceuticals
- Reconstitution
- Repackaging
  - Follow USP <1178> Good Repackaging Practices for oral solids
- Splitting tablets
- Administration
  - Preparation of single dose for single patient
  - Administration will begin within 4 hours

Source: USP General Chapter <825> Radiopharmaceuticals. https://www.usp.org/small-molecules/general-chapter-825

Polling Question #2:

What types of nonsterile preparations does your practice site regularly compound? (Select all that apply)

A. Lollipops/troches/lozenges
B. Topical ointments/creams/lotions
C. Oral solutions/suspensions
D. Vaginal/rectal suppositories
E. Others

Compounded Nonsterile Preparations (CNSPs)

- CNSPs for humans & animals, that are subject to USP <795> requirements:
  - Solid oral preparations
  - Liquid oral preparations
  - Rectal preparations
  - Vaginal preparations
  - Topical preparations (i.e., creams, gels & ointments)
  - Nasal & sinus preparations
  - Otic preparations

Source: United States Pharmacopeia (USP) chapter <795>: https://www.usp.org/compounding. Date accessed. 2/13/2023

Personnel & Settings Affected

- All persons who prepare CNSPs
- All places where CNSPs are prepared

Source: United States Pharmacopeia (USP) chapter <795>: https://www.usp.org/compounding. Date accessed. 2/13/2023

Assessment Question #1:

Which of the following is not within the scope of USP <795> regulations?

A. Solid oral preparations for humans
B. Liquid oral preparations for animals
C. Reconstitution per manufacturer labeling
D. Solid oral preparations for animals

Assessment Question #1 | Answer…

Which of the following is not within the scope of USP <795> regulations?

A. Solid oral preparations for humans

B. Liquid oral preparations for animals

C. Reconstitution per manufacturer labeling

D. Solid oral preparations for animals

USP <795>

Major Highlights & Changes Within the Regulations

Leadership & Oversight: Designated Person(s)

- One or more individuals to be responsible & accountable for the performance & operation of the facility & personnel for the preparation of CNSPs
  - Person(s) must be identified in the Standard Operating Procedure (SOP)
  - Example Responsibilities:
    - Oversee Training Program
    - Product Selection
    - Implement Policies & Procedures
    - Maintain Master Formula Database

Source: United States Pharmacopeia (USP) chapter <795>: https://www.usp.org/compounding. Date accessed. 2/13/2023

Personnel Training & Evaluation

- All personnel who participate in compounding CNSPs or have direct oversight, must be trained & competent
  - Knowledge & competency must be demonstrated initially & every 12 months in the following:
    - Hand hygiene
    - Garbing
    - Cleaning & sanitizing
    - Handling & transporting
    - Measuring & mixing
    - Proper use of equipment
    - Documentation of compounding

Source: United States Pharmacopeia (USP) chapter <795>: https://www.usp.org/compounding. Date accessed. 2/13/2023

Personnel Training & Evaluation, *continued*

- Steps to be included in training procedure:
  - Understand requirements of USP <795>
  - Understand & interpret safety data sheets (SDSs) & certificates of analysis (if applicable)
  - Read/understand procedures related to compounding responsibilities

Source: United States Pharmacopeia (USP) chapter <795>: https://www.usp.org/compounding. Date accessed. 2/13/2023

Hygiene & Garbing

- Personnel must maintain appropriate hand hygiene & cleanliness required for the kind of compounding
- Personnel must remove (at a minimum):
  - Personal outer garments
  - Jewelry/accessories that could interfere with garbing or hand hygiene
    - Examples: watches, rings, dangling jewelry
  - Headphones/earbuds

Source: United States Pharmacopeia (USP) chapter <795>: https://www.usp.org/compounding. Date accessed. 2/13/2023

Polling Question #3:

True or False: Alcohol-based hand sanitizer is adequate for hand hygiene prior to compounding nonsterile compounds

A. True
B. False

Hand Hygiene

- Personnel must perform the outlined hand hygiene procedures when entering the compounding area.
  - Wash hands with soap & water for at least 30 seconds
  - Completely dry hands with disposable towels or wipers
  - Wear gloves
- Alcohol-based hand sanitizers alone are not sufficient for hand hygiene.
- Gloves should be wiped or replaced before beginning a CNSP that contains different components.

Source: United States Pharmacopeia (USP) chapter <795>: https://www.usp.org/compounding. Date accessed. 2/13/2023

Garb & Glove Requirements

- Gloves must always be worn
- Other garb should be worn as appropriate to protect personnel & prevent CNSP contamination
  - e.g., shoe covers, head or hair covers, facial hair covers, face masks & gowns
- Garb must be replaced when visibly soiled or compromised
- All garb should be removed & discarded when leaving compounding area
  - May reuse gowns during same shift, but must remain in compounding area
- Reusable equipment must be cleaned & sanitized

Source: United States Pharmacopeia (USP) chapter <795>: https://www.usp.org/compounding. Date accessed. 2/13/2023

Polling Question #4:

True or False: Nonsterile compounding can be performed anywhere within the hospital or clinic.

A. True

B. False

Source: Add source of your data here in size 11 font.

Compounding Area

- Must specifically designate an area for nonsterile compounding
  - Must be described in SOPs
- Must be well lit, clean, orderly, sanitary & in good state of repair
- Should not have carpet in designated compounding area
- Area must allow enough space to prevent mix-ups

Source: United States Pharmacopeia (USP) chapter <795>: https://www.usp.org/compounding. Date accessed. 2/13/2023

Storage Area

- Must monitor temperature in storage area daily on days that facility is open
- Temperature monitoring equipment must be calibrated/verified for accuracy every 12 months (or per manufacturer recommendations)
- Evaluate temperature excursions for compromised integrity of products
  - Must discard compromised products

Source: United States Pharmacopeia (USP) chapter <795>: https://www.usp.org/compounding. Date accessed. 2/13/2023

Cleaning & Sanitizing

Site	Minimum Frequency
Work Surfaces	• Beginning & end of shift on days when compounding occurs • Spills • Surface contamination is known or suspected
Floors	• Daily on days when compounding occurs • Spills • Surface contamination is known or suspected
Walls	• Visibly soiled • Spills • Surface contamination is known or suspected
Ceilings	• Visibly soiled • Surface contamination is known or suspected
Storage shelves	• Every 3 months • Spills • Surface contamination is known or suspected

Source: United States Pharmacopeia (USP) chapter <795>: https://www.usp.org/compounding. Date accessed. 2/13/2023

Equipment

Compounding equipment **must** be:

- Suitable for type of compounding
- Stored in a way to minimize the risk of contamination
- Located to facilitate use, maintenance & cleaning
- Be inspected before use
- Verified for accuracy every 12 months or as recommended by manufacturer (whichever is more frequent)

Compounding equipment surfaces **must not**:

- Be reactive, additive or absorptive
- Alter the quality of compound

Source: United States Pharmacopeia (USP) chapter <795>: https://www.usp.org/compounding. Date accessed. 2/13/2023

Closed System Processing Devices

- Process evaluation must be performed if weighing, measuring, otherwise manipulating components could generate airborne chemical products.
- Types of close system processing devices:
  - Biological Safety Cabinets (BSCs)
  - Containment Ventilated Enclosures (CVEs)
  - Single-use containment glove bags
- BSCs & CVEs must be certified every 12 months

Source: Photo property of Michael Epshteyn. Please do not reproduce without permission

Source: United States Pharmacopeia (USP) chapter <795>: https://www.usp.org/compounding. Date accessed. 2/13/2023

Equipment Cleaning & Sanitizing Frequency

Equipment	Frequency
Biological safety cabinet	• Beginning & end of shift on compounding days • Spills/surface contamination is known or suspected • Horizontal work surface between CNSPs with different components
Containment ventilated enclosures	• Beginning & end of shift on compounding days • Spills/surface contamination is known or suspected • Horizontal work surface between CNSPs with different components
Other devices/ equipment	• Before first use • According to manufacturer's recommendation • If no recommendation, between CNSPs with different components

Source: United States Pharmacopeia (USP) chapter <795>: https://www.usp.org/compounding. Date accessed. 2/13/2023

Components

- Regarding components, the facility **must**:
  - Address component selection & inventory control in SOPs
  - Have Safety Data Sheets (SDSs) readily available
  - Instruct personnel on how to locate & interpret SDSs
  - Have designated person responsible for component selection

Source: United States Pharmacopeia (USP) chapter <795>: https://www.usp.org/compounding. Date accessed. 2/13/2023

Component Selection

- Active Pharmaceutical Ingredients (APIs)
  - Must comply with criteria in USP-NF monograph (if exists)
  - Must have certificate of analysis
  - If facility within the United States:
    - Must be manufactured by an FDA-registered facility
  - If facility outside the United States:
    - Must follow laws & regulations for appropriate regulatory jurisdiction
- Water
  - Purified water or better quality must be used in CNSPs when the formula includes water

Source: United States Pharmacopeia (USP) chapter <795>: https://www.usp.org/compounding. Date accessed. 2/13/2023

Component Receipt

- Must review the Certificate of Analysis (COAs) of non-conventionally manufactured products, to ensure it meets criteria per the USP-NF monograph (if exists)
- If component is deemed to be of unacceptable quality, it must be clearly labeled as rejected & separated from stock to prevent use
  - Examine same component from same vendor to ensure other lots are not defective

Source: United States Pharmacopeia (USP) chapter <795>: https://www.usp.org/compounding. Date accessed. 2/13/2023

Component Receipt

- Must document:
  - Receipt date
  - Quantity received
  - Supplier name
  - Lot number
  - Expiration date
  - Results of any testing performed (in-house or third party)
- Components without vendor expiration date
  - Date of receipt must be marked on component package
  - Maximum beyond-use date (BUD) of **3 years** from date of receipt
  - Assign shorter date if used in sterile compounding or known degradation

Source: United States Pharmacopeia (USP) chapter <795>: https://www.usp.org/compounding. Date accessed. 2/13/2023

Component Evaluation Before Use

- Must visually re-inspect all components for:
  - Container breakage
  - Cap/container closure
  - Deviation from expected appearance
  - Deviation of texture
- Must reject component, if component identity, strength, purity & quality cannot be verified
  - Clearly label as rejected & segregate from active stock

Source: United States Pharmacopeia (USP) chapter <795>: https://www.usp.org/compounding. Date accessed. 2/13/2023

Component Handling

- Must be handled per manufacturer's instruction
  - Or per law & regulations of regulatory jurisdiction
- Handling must minimize:
  - Risk of contamination
  - Mix-up errors
  - Deterioration
- If component is removed from the original container & not used during compounding, it should be discarded

Source: United States Pharmacopeia (USP) chapter <795>: https://www.usp.org/compounding. Date accessed. 2/13/2023

Component Spill & Disposal

- Must maintain current chemical hazard & disposal information such as SDSs
- Must address nonhazardous spills & disposal in SOPs
- Must have spill kit in compounding area
- Must train personnel who are expected to remediate spills
  - Training must occur every 12 months

Source: United States Pharmacopeia (USP) chapter <795>: https://www.usp.org/compounding. Date accessed. 2/13/2023

Master Formulation Records (MFR)

- Detailed record of how to prepare the Compounded Nonsterile Preparation (CNSP)
- One must be created for each unique formulation of a CNSP
- Changes must be approved & documented per SOP

Drug Name	Route	Dosage Form	Concentration
Folic acid	Oral	Suspension	100 mcg/mL

Formula Qty: 20 mL	Beyond-Use Date (BUD): Refrigerate: 60 days

Equipment needed: mortar and pestle, graduated cylinder, stirring rod, plastic amber bottle

Auxiliary Labels/Storage: shake well; refrigerate; protect from light

Directions:

- Crush folic acid tablets in mortar and grind to a fine powder
- Wet powder with a minimal amount of Simple Syrup and mix to form a viscous, but smooth and uniform paste
- Continue adding Simple Syrup in incremental proportions, mixing well after each addition
- Transfer to a calibrated bottle
- QS to final volume with Simple Syrup, shake well
- Labels: "Shake well, Refrigerate"
- Stable for 60 days Refrigerated

Ingredients:	QS	Quantity	Units
Folic acid 1 mg tablets		2	tablets
Simple Syrup	X	20	mL

References:

Gunasekaran GH, Jusoh NH, Saridin N. The Stability of Folic Acid Suspension. Int J Sci Res Publ. 2015;5:1-9.

Nahata MC, Pai VB, and Hipple TF. *Pediatric Drug Formulations*, 5th ed, Cincinnati, OH: Harvey Whitney Books Co, 2004

USP <795> Pharmaceutical Compounding—Nonsterile Preparations. US Pharmacopeial Convention; Jan 2014.

Source: United States Pharmacopeia (USP) chapter <795>: https://www.usp.org/compounding. Date accessed. 2/13/2023

Source: Master formulation template from Medical City Heart & Spine Hospitals

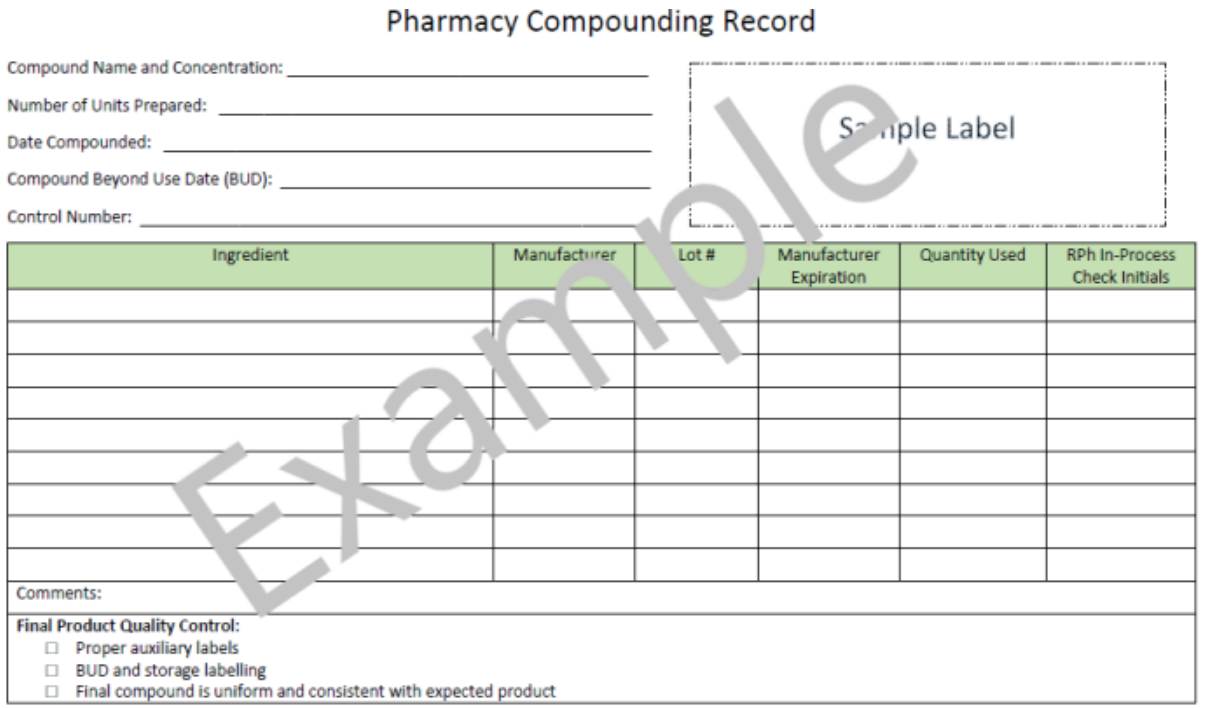
Master Formulation Records

- Must include:
  - Name, strength & dosage form
  - Identities & amounts of all components
  - Container closure system
  - Complete instructions to prepare CNSP
  - BUD & storage requirements
  - Reference source for assigned BUD
  - If applicable, calculations to determine & verify quantities & concentrations of components
  - Quality control (QC) procedures & expected results
  - Other information needed to describe compounding process & ensure repeatability

Source: United States Pharmacopeia (USP) chapter <795>: https://www.usp.org/compounding. Date accessed. 2/13/2023

Compounding Records

- Required for compounding of each CNSP
- Must be completed before release of CNSP
- Must allow for traceability in case of a recall or quality issue



Pharmacy Compounding Record

Compound Name and Concentration: _____

Number of Units Prepared: _____

Date Compounded: _____

Compound Beyond Use Date (BUD): _____

Control Number: _____

Sample Label

Ingredient	Manufacturer	Lot #	Manufacturer Expiration	Quantity Used	RPh In-Process Check Initials

Comments:

Final Product Quality Control:

- ☐ Proper auxiliary labels
- ☐ BUD and storage labelling
- ☐ Final compound is uniform and consistent with expected product

Source: Compounding template from Medical City Heart & Spine Hospitals

Source: United States Pharmacopeia (USP) chapter <795>: https://www.usp.org/compounding. Date accessed. 2/13/2023

Compounding Records

- Must include:
  - Name, strength, dosage form
  - Date, or date & time of preparation
  - Assigned internal identification number
  - Method to identify individuals involved
  - Name, vendor/manufacturer, lot number & expiration date of each component
  - Total quantity
  - Assigned BUD & storage requirements
  - If applicable, calculations to determine & verify quantities & concentrations of components
  - Physical description of final CNSP
  - Results of quality control procedures
  - MFR reference

Source: United States Pharmacopeia (USP) chapter <795>: https://www.usp.org/compounding. Date accessed. 2/13/2023

Labeling

- Label on CNSPs **must** legibly display:
  - Assigned internal identification number
  - Active ingredient(s) including:
    - Amount(s)
    - Activity(ies), or
    - Concentration(s)
  - Storage conditions, if other than controlled room temperature
  - BUD
  - Dosage form
  - Total amount/volume, if not obvious

Source: United States Pharmacopeia (USP) chapter <795>: https://www.usp.org/compounding. Date accessed. 2/13/2023

Labeling, *continued*

- Label on CNSPs **should** legibly display:
  - Route of administration
  - Indication
  - Any special handling instructions
  - Any warning statements
  - Compounding facility name & contact information, if to be sent outside of the facility/healthcare system

Source: United States Pharmacopeia (USP) chapter <795>: https://www.usp.org/compounding. Date accessed. 2/13/2023

Establishing Beyond-Use Dates

- Beyond-use dates are the date or the hour & date, that a preparation can no longer be used
- Should be established conservatively to ensure the CNSP maintains the required characteristics to minimize risk of **contamination** or **degradation**
- Must consider parameters that may affect quality, including:
  - Chemical & physical stability
  - Compatibility & degradation of container
  - Microbial growth potential
  - Deviations from essential compounding steps

Source: United States Pharmacopeia (USP) chapter <795>: https://www.usp.org/compounding. Date accessed. 2/13/2023

Beyond-Use Dates

- BUDs in table below are based on water activity (A_w), in the absence of a USP-NF compounded preparation monograph or CNSP specific stability information
  - Aqueous dosage form = $a_w \geq 0.60$
  - Nonaqueous dosage form = $a_w < 0.60$

Type of Preparation	BUD (days)	Storage Temperature
Non-preserved aqueous dosage forms	14	Refrigerator
Preserved aqueous dosage forms	35	Controlled room temperature or refrigerator
Oral liquids (nonaqueous)	90	Controlled room temperature or refrigerator
Other nonaqueous dosage forms	180	Controlled room temperature or refrigerator

Source: United States Pharmacopeia (USP) chapter <795>: https://www.usp.org/compounding. Date accessed. 2/13/2023

Packaging & Transportation

- Packaging
  - Must be addressed in SOPs
  - Select packaging materials that will support integrity & stability of the product (both physically & chemically)
- Transportation
  - If transporting, must be addressed in SOPs
    - Mode of transportation
    - Special handling instructions
    - Temperature monitoring?

Source: United States Pharmacopeia (USP) chapter <795>: https://www.usp.org/compounding. Date accessed. 2/13/2023

Assessment Question #2:

Due to the recent changes, new requirements to meet compliance for the minimum frequency of the cleaning work surfaces should be?

A. Daily on compounding days
B. Beginning & end of each shift on compounding days & between compounding with different components
C. Only when visibly soiled or if surface contamination is known or suspected
D. Every 3 months

Assessment Question #2 | Answer…

Due to the recent changes, new requirements to meet compliance for the minimum frequency of the cleaning work surfaces should be?

A. Daily on compounding days

B. Beginning & end of each shift on compounding days & between compounding with different components

C. Only when visibly soiled or if surface contamination is known or suspected

D. Every 3 months

USP <795>

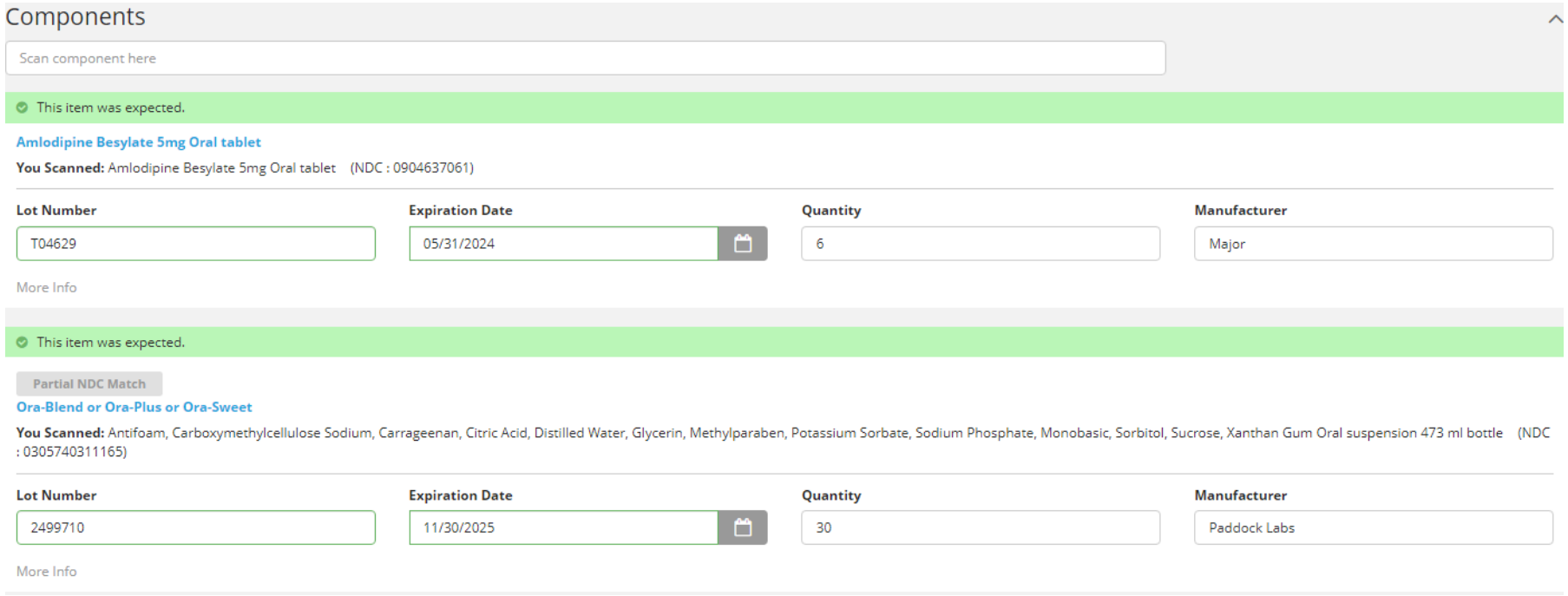
Strategies to Streamline the Quality & Consistency of CNSPs

Utilizing Technology for Workflow Documentation

- Preparations move from step to step as the user completes compounding & takes images

- Steps requiring pharmacist approval
  - Approve Components
  - Approve Final Product

Scanning of Components Assures Patient Safety



Source: Pharmacy workflow documentation template from Medical City Dallas Hospital

Compounding Quality Assurance & Quality Control

Source: United States Pharmacopeia (USP) chapter <795>: https://www.usp.org/compounding. Date accessed. 2/13/2023

Quality Assurance & Quality Control

- Implement a written QA & QC program that supports:
  - Adherence to procedures
  - Prevention & detection of errors & quality issues
  - Evaluation of complaints & adverse events
  - Appropriate investigations & corrective actions

Source: United States Pharmacopeia (USP) chapter <795>: https://www.usp.org/compounding. Date accessed. 2/13/2023

Release Inspections & Testing

- All release inspections must be documented
- All CNSPs must be visually inspected:
  - For expected physical appearance (e.g., color, texture, physical uniformity)
  - To confirm CNSP & label matches the compounding record for the prescription/medication order
  - For proper container closure
- CNSPs that are not dispensed on the same day of preparation, must be visually inspected before being released

Source: United States Pharmacopeia (USP) chapter <795>: https://www.usp.org/compounding. Date accessed. 2/13/2023

Variance Occurrence Reporting

- SOPs must address the process for handling complaints/variances
- If determined that there is a potential quality issue, must complete a thorough investigation
  - Determine if a recall is required
  - Consider to stop all nonsterile compounding until root cause identified & rectified
- Complaint handling process must be documented & retrievable via occurrence reporting system

Source: United States Pharmacopeia (USP) chapter <795>: https://www.usp.org/compounding. Date accessed. 2/13/2023

Recalls

- Develop procedures to:
  - Determine when to initiate recalls
  - Recall all unused dispensed CNSPs & segregation of remaining stock in the pharmacy
  - Investigate other lots

Source: United States Pharmacopeia (USP) chapter <795>: https://www.usp.org/compounding. Date accessed. 2/13/2023

Annual Tasks & Documentation Summary

- Personnel Training & Evaluation (initial & every 12 months)
- Equipment Calibration & Testing
  - Balance
  - Biological Safety Cabinets (BSCs)
  - Temperature monitoring equipment
- Review Commercially Available Products
  - DO NOT compound medications that are commercially manufactured

Source: United States Pharmacopeia (USP) chapter <795>: https://www.usp.org/compounding. Date accessed. 2/13/2023

Assessment Question #3:

Which of the following strategies can be used to streamline documentation for preparation of nonsterile compounds?

A. Utilizing image-capture technology for each compounding workflow step

B. Developing procedures to determine when to initiate recalls

C. Implementing a written quality assurance & quality control program

D. Reporting occurrences of variance

Assessment Question #3 | Answer…

Which of the following strategies can be used to streamline documentation for preparation of nonsterile compounds?

A. Utilizing image-capture technology for each compounding workflow step

B. Developing procedures to determine when to initiate recalls

C. Implementing a written quality assurance & quality control program

D. Reporting occurrences of variance

SUMMARY

- USP Chapter <795> “Pharmaceutical Compounding-Nonsterile Preparations” becomes effective & enforceable on November 1, 2023
- Patient safety is a primary focus
- Updated USP <795> publication provides uniform guidelines for healthcare facilities for non-sterile compounding
- Following USP <795> requirements will lead to improved quality & safety of compounded products

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References

- United States Pharmacopeia (USP): https://www.usp.org/about. Date accessed 5/16/2023.
- United States Pharmacopeia (USP) Chapter <795> Pharmaceutical Compounding-Nonsterile Preparations: https://www.usp.org/compounding. Date accessed 2/13/2023.
- Journal of Medical Toxicology. 2021 April; 17 (2): 197-217. Pharmaceutical Compounding: a History, Regulatory Overview, and Systematic Review of Compounding Errors.
- United States Pharmacopeia (USP) Chapter <1178> Good Repackaging Practices: http://www.uspbpep.com/usp31/v31261/usp31nf26s1_c1178.asp. Date accessed 5/1/2023
- United States Pharmacopeia (USP) Chapter <825> Radiopharmaceuticals: https://www.usp.org/small-molecules/general-chapter-825

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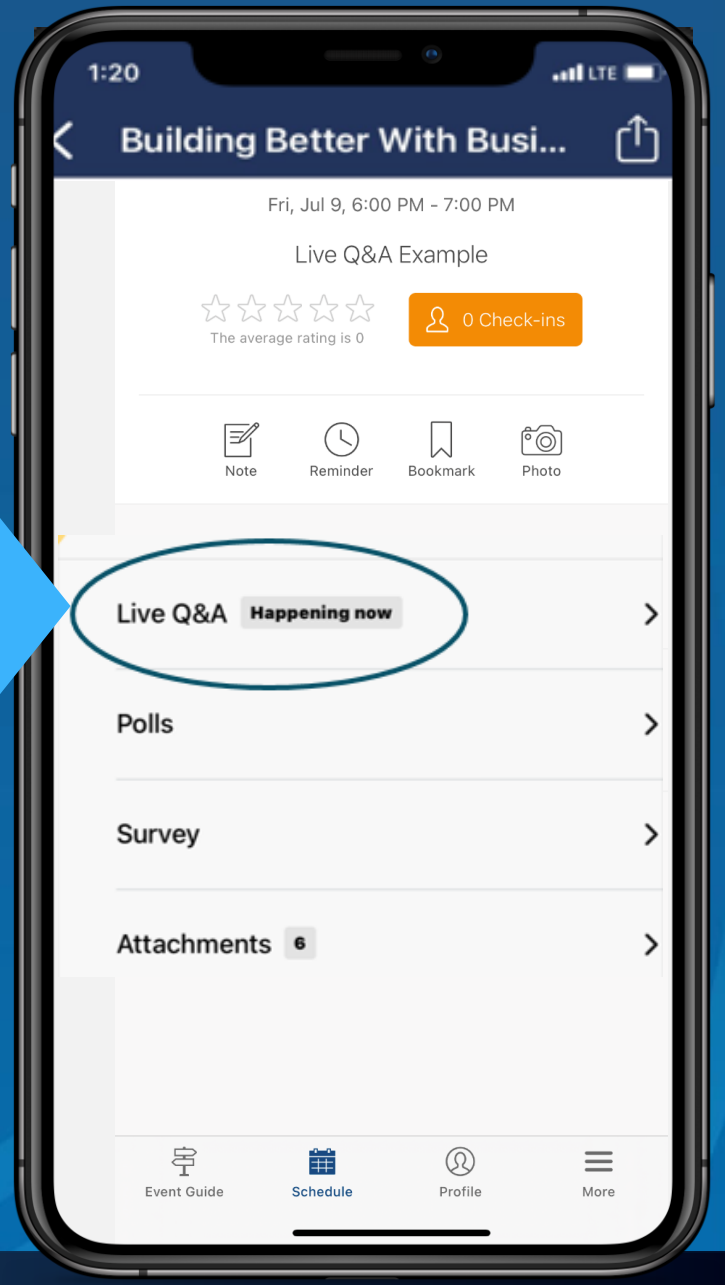

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Thank you...

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