# USP <795> Readiness: What Health Systems Must Fix Before Joint Commission Enforcement Begins

**Acquella Brigham, PharmD**

Manager

Pharmacy Distribution Systems

University of Chicago Medical Center

**Kathleen J Kane, PharmD, MBA, BCSCP**

Assistant Director of Pharmacy

Compounding Integrity and Compounding Regulatory Compliance

University of Chicago Medical Center

2026 ICHP Annual Meeting

1

# Speaker Conflicts

- Speakers have no conflicts of interest with ineligible companies to disclose.

- As a Volunteer expert council member for both BPS and USP Dr. Kathleen J Kane, presents this topic in her own capacity and not as a member of these organizations.



# Learning Objectives

- Identify key gaps in nonsterile compounding practices related to USP <795> and Joint Commission expectations.
- Evaluate personnel training, documentation, and beyond use dating practices for compliance with revised standards.
- Implement practical remediation strategies to improve workflow, environmental controls, and survey readiness.
- Design sustainable competency and oversight systems that support safe, standardized nonsterile compounding.

# Background and Identifying Key Gaps

Learning Objective 1

Health systems preparing for Joint Commission enforcement should look at identifying gaps that directly impact safety, document integrity, and compliance with standards such as USP <795>

# Where to Start?

- Start by **reading** USP <795> and taking notes, then read it again.
- **Review** current practices against USP <795> “must” statements
- **Compare** documentation (MFRs, compounding records, BUD rationale) to regulatory requirements
  - Assess competency systems for completeness, validation, and role clarity
  - Evaluate workflow & environment for safety, organization, and compliance
  - Identify high-risk gaps that directly impact patient safety and survey readiness

# Overview of USP <795> key requirements

| Personnel Training & Competency | MFRs & Compounding Records | BUD Justification | Facility & Workflow Requirements | Quality Assurance& Oversight |
|---|---|---|---|---|
| Training | Formulations | Stability | Space | Audits |
| Competency | Records | Ingredients | Workflow | Quality |
| Validation | Accuracy | Packaging | Cleaning | Monitoring |
| Oversight | Documentation | Justification | Control | Improvement |



# How do Gaps Get Identified?

- **USP <795> "Must" Statement Checklist** – Line-by-line comparison of current practice to required standards
- **Joint Commission Medication Management Tracer** – valuates documentation integrity, workflow safety, and competency validation
- **Internal Compounding Audit Tool** — Standardized review of MFR completeness, record accuracy, and BUD justification
- **Process Mapping Worksheet** — Visualizes each step of the compounding process to identify bottlenecks and noncompliant actions
- **Fishbone (Ishikawa) Diagram Template** — Identifies root causes of recurring deficiencies (training, environment, documentation, materials)
- **Failure Mode & Effects Analysis (FMEA) Form** — Prioritizes high-risk steps in compounding workflows
- **Document Control Review Checklist** — Ensures MFRs, records, and SOPs are complete, current, and accessible
- **Competency System Audit Tool** — Evaluates training files, validation frequency, and role-specific competency criteria

2026 ICHP Annual Meeting

# Gap Analysis Tools used at UCMC

**GAP ANALYSIS SURVEY**
**COMPOUNDING NONSTERILE PREPARATIONS**
**(STATE FORMAT)**

**©International Journal of Pharmaceutical Compounding**
**122 N. Bryant**
**Edmond, Oklahoma 73034**

*Note: The purpose of this form is to conduct a preliminary assessment of the pharmacy to determine compliance with State Requirements for Compounding Nonsterile Preparations. Additional lines have been added to each section to accommodate additional survey questions. This document is provided in Microsoft Word so it can be easily modified to match your individual state requirements. It is patterned after the current USP <795> chapter.*

**Outline**

Introduction
Definitions
Categories of Compounding

Illinois Department of Financial and Professional Regulation
Division of Professional Regulation
Drug Compliance Unit
9511 Harrison Street, Suite LL 50, Des Plaines, IL 60016

Phone: (847) 294-4900

***(Read this Page Carefully)***

**NON-STERILE COMPOUNDING**

**Pharmacy Self-Inspection Form**

Illinois Law holds the Pharmacist-in-Charge (PIC) and all pharmacists on duty responsible for ensuring pharmacy compliance with all state and federal laws governing the practice of pharmacy.

B C D E F

ashp Inpatient Care Practitioners — Compliance Sta 1, 2, or 3

**. INTRODUCTION AND SCOPE**

All personnel who compound or have direct oversight of compounding CNSPs must be initially trained and qualified by demonstrating knowledge and competency according to the requirements in this section (2. Personnel Training and Evaluation) before being allowed to perform their job functions independently.

esignated person(s) are responsible for creating and implementing a training program that describes the required training, the frequency of training, and the process for evaluating the ompetency of personnel. This program must equip personnel with knowledge and training in the required skills necessary to perform their assigned tasks. Personnel who compound or ave direct oversight of compounding personnel must complete training initially and at least every 12 months in appropriate compounding principles and practices as described in this section. Other personnel, who do not compound and only perform functions such as in-process checks, final verification, or dispensing of CNSPs, must undergo training as required by the facility's SOPs.

**. PERSONNEL TRAINING AND EVALUATION**

All personnel who compound or have direct oversight of compounding CNSPs must be initially trained and qualified by demonstrating knowledge and competency according to the requirements in this section (2. Personnel Training and Evaluation) before being allowed to perform their job functions independently.

# Common Gaps Found in Health Systems

1. Training & Competency Gaps
2. Documentation Gaps (MFRs & Records)
3. BUD Justification Gaps
4. Workflow & Environmental Gaps
5. Oversight & Governance Gaps
6. Quality Assurance Gaps



# Top 3 Common Gaps

| Training & Competency | Documentation | BUD Justification |
|---|---|---|
| • Incomplete<br>• Inconsistent<br>• Unvalidated<br>• Undocumented | • Missing<br>• Variable<br>• Inaccurate<br>• Nonstandard | • Unsupported<br>• Assumed<br>• Outdated<br>• Unjustified |



# Assessment Question 1

Which of the following represents a high-risk gap commonly identified using USP <795> readiness assessments?

a. Use of standardized master formulation records
b. Complete personnel training documentation
c. Inconsistent beyond-use dating justification
d. Routine competency validation performed annually

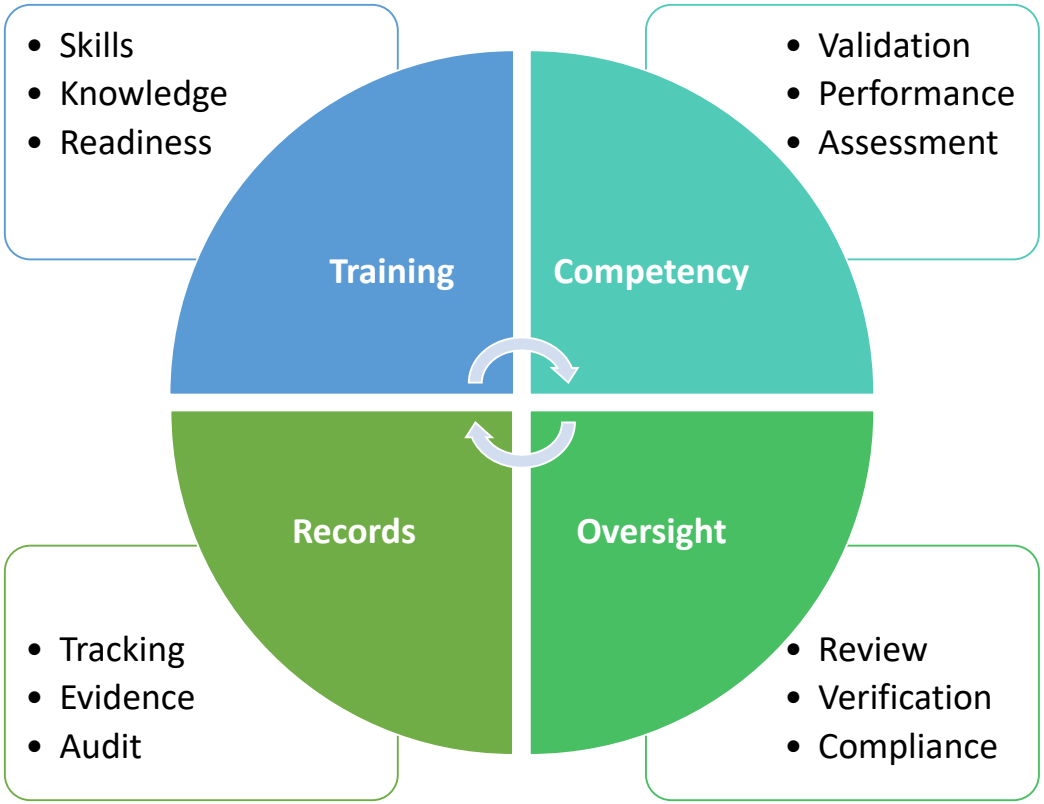
# Evaluate Training, Documentation, and BUD Practices

Learning Objective 2

Health systems preparing for Joint Commission enforcement should evaluate training, documentation, and BUD practices to ensure they meet the revised requirements of USP <795>.

2026 ICHP Annual Meeting

# Training and Competency Requirements




2026 ICHP Annual Meeting

# UCMC Remediation Approach: Training and Competency

- **Key Actions Implemented**
  - **Hands-on training class for all compounding staff**
    - Real-time practice with nonsterile compounding workflows
    - Standardized instruction across pharmacists and technicians
  - **Role-specific competency validation**
    - Skills demonstration aligned with USP <795> requirements
    - Documentation of knowledge, performance, and readiness
  - **Designated Person oversight**
    - Routine review of training records
    - Annual competency reassessment
- **Impact**
  - Eliminated variation in training quality
  - Ensured staff competency is documented, reproducible, and survey-ready
  - Strengthened compliance with Joint Commission expectations
- Linked concept: training requirements

# Documentation Systems

- **Aligned**
  - Uniform
  - Consistent
- **Whole**
  - Detailed
  - Thorough
- **Exact**
  - Precise
  - Verified
- **Ready**
  - Organized
  - Accessible
  - Legible

**Assessing Compounding Technique and Related Practices of Compounding Personnel For Suspension**

Name of Person:_____

Name of Facility or location: _____

**Technique, Safety, and Quality Assurance Practices:** The qualified evaluator checks each space for which the person being assessed has acceptably completed the described activity, prints N/A if the activity is not applicable to the assessment session or N/O if the activity was not observed.

____ Completes the hand hygiene and garbing competency assessment form
____ Performs proper hand hygiene, garbing, and gloving procedures according to SOPs
____ Cleans, sets up, and calibrates all equipment according to manufacturer's instructions
____ Disinfects direct compounding area with an appropriate agent
____ Inspects tools/glassware/utensils to be used in compounding prior to use
____ Correct ingredients were chosen for compound
____Uses solubilization, geometric dilution, and Levigation techniques correctly when applicable
____Calibrates beaker appropriately when required
____ Ingredients were thoroughly blended, and particles are dispersed uniformly, suspension is a free flowing liquid
____ pH is recorded when appropriate
____The proper container is selected, and labeled appropriately
____The outside of container is not contaminated with drug
____Documentation of compounding worksheet and log is complete
____ Dishes are washed in a timely manner
____ Once compounding is complete, disinfects compounding surface again with appropriate agent
____Disposes of sharps and waste according to policy and guidelines

*The person assessed is immediately informed of all unacceptable activities (i.e., Spaces lacking check marks, N/A, or N/O) and shown and informed of specific corrections.

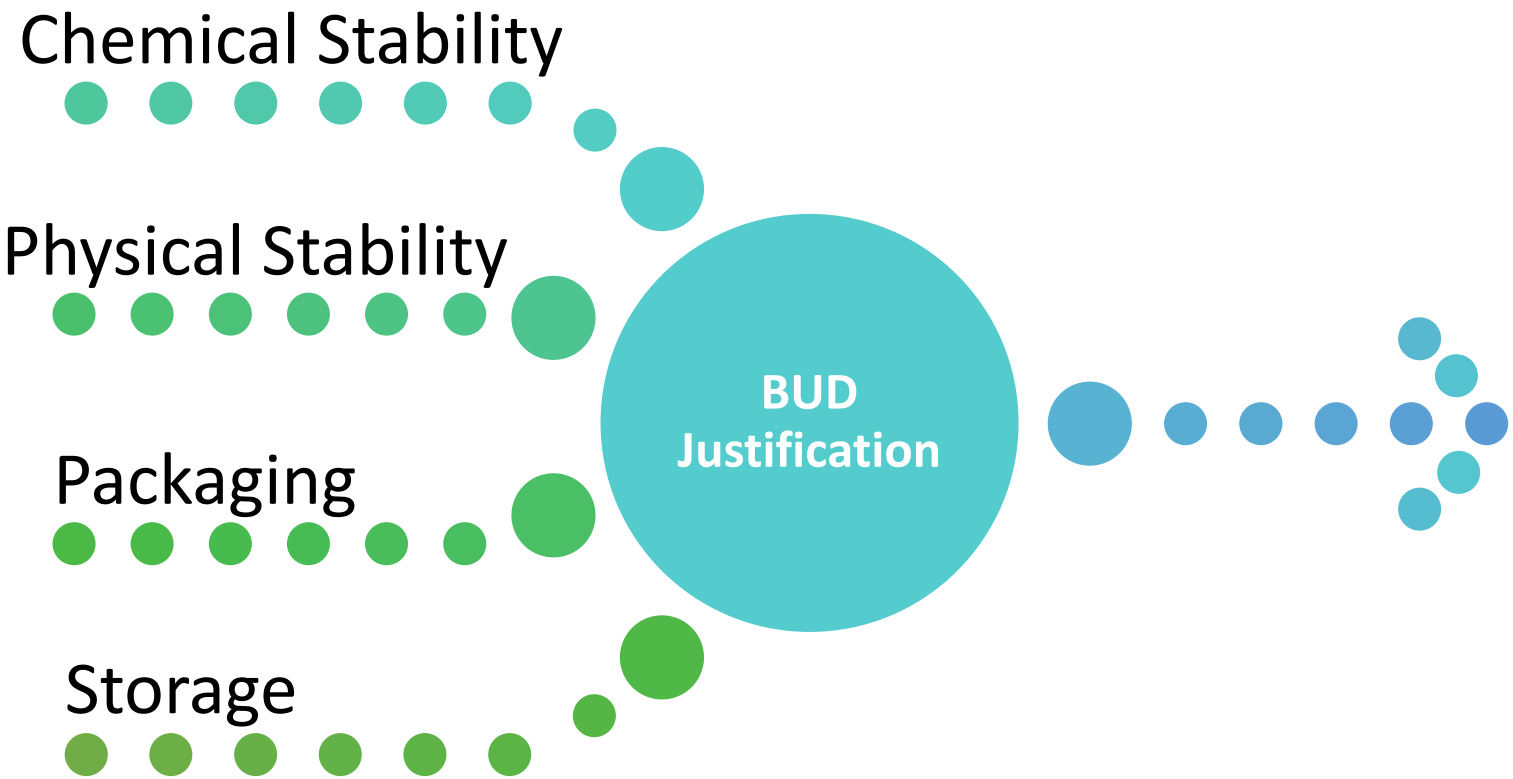
Signature of Person Assessed | Printed Name | Date

Signature of Qualified Evaluator | Printed Name | Date

# UCMC Remediation Approach: Documentation

- **Key Actions Implemented**
  - **Complete redesign of all Master Formulation Records (MFRs)**
    - Updated to meet **Pharmacy Practice Act** requirements
    - Fully aligned with **USP <795> "must" statements**
  - **Standardized templates across all sites**
    - Required fields: ingredients, calculations, packaging, labeling, BUD rationale
    - No blank fields permitted
  - **Verification & audit readiness**
    - Math double-checked
    - Records organized and accessible for surveyors
- **Impact**
  - Eliminated documentation variability
  - Ensured MFRs meet regulatory and accreditation standards
  - Improved traceability and reproducibility of compounding records
- Linked concept: documentation systems

# BUD Assignment Requirements




2026 ICHP Annual Meeting

# UCMC Remediation Approach: BUD Justification

- **Key Actions Implemented**
  - **Annual literature review for all compounded preparations**
    - Conducted collaboratively with technicians and students
    - Ensures references reflect the most current stability data
  - **Standardized BUD justification process**
    - Chemical & physical stability
    - Packaging & storage conditions
    - Ingredient assessment
  - **Documentation of evidence sources**
    - References added directly to MFRs
    - Clear rationale for each assigned BUD
- **Impact**
  - Removed unsupported or assumed BUD assignments
  - Ensured BUDs are defensible during Joint Commission surveys
  - Strengthened patient safety through accurate stability-based dating
- Linked concept: BUD justification

# Case Example: BUD Evaluation- Omeprazole

2026 ICHP Annual Meeting

| Literature Stability | Internal/Extended Stability | USP <795> Default BUD |
|---|---|---|
| Published study: **14 days refrigerated** | Some institutions use **21–30 days refrigerated** | Water-containing oral formulation: **14 days refrigerated** |
| Chemical stability only | Only valid if matching *your exact* formulation, packaging, and storage | Applies when stability data does not fully match your preparation |
| Does not address container, excipients, or microbial risk | | |

# Assessment Question 2

When evaluating compliance with revised USP <795>, which documentation element is required to demonstrate appropriate beyond-use dating practices?

A. List of all compounded preparations being dispensed
B. Evidence supporting stability and BUD assignment
C. Technician work schedules
D. Pharmacy inventory records

# Implementation Remediation Strategies

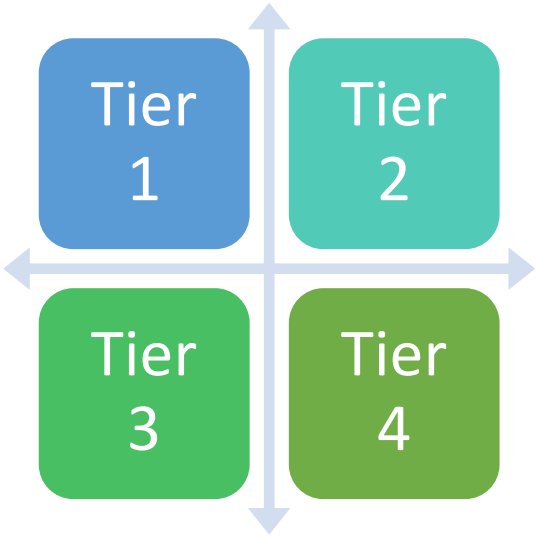
Learning Objective 3

Health systems preparing for Joint Commission enforcement should apply structured remediation methods to strengthen workflow organization, environmental controls, and record accuracy.

# Overview: Remediation Strategy Framework

- **What remediation means in USP <795> readiness:**
  - Correcting gaps identified in Section 1
  - Strengthening systems evaluated in Section 2
  - Prioritizing fixes that directly impact safety and survey readiness
  - Standardizing processes across all sites
- Not all gaps are equal
- Some directly affect patient safety
- Some drive regulatory noncompliance
- Some are operational inefficiencies
- Remediation must be prioritized, not random

# Criteria for Prioritizing Gaps




Tier 1:
High Risk / High Frequency
→ **Fix immediately**
These are the gaps that pose direct patient safety risk and occur often.

Tier 2:
High Risk / Low Frequency
→ **Fix quickly**
These are dangerous but less common — still high priority.

Tier 3:
Low Risk / High Frequency
→ **Fix soon**
These create inefficiency, rework, or survey annoyance.

Tier 4:
Low Risk / Low Frequency
→ **Fix when feasible**
These are cosmetic or minor issues.

# UCMC Classification of Largest Gaps

| Type of Risk | Classified Gaps |
|---|---|
| High Risk/ High Frequency | Unsupported BUDs across multiple sites<br>Missing fields in MFRs<br>Incomplete competency validations |
| High Risk/ Low Frequency | Workflow steps that create contamination risk<br>Incorrect ingredient selection or substitution |
| Low Risk/High Frequency | Inconsistent labeling formats<br>Non-Standard documentation templates |
| Low Risk/Low Frequency | Minor workspace organization issues<br>Cosmetic formatting inconsistencies |



# Prioritizing Remediation

**Immediate Fixes**

- Training
- Competency
- BUD Justification

**Foundational Systems**

- Documentation Systems
- MFR Standardization
- Record Completeness

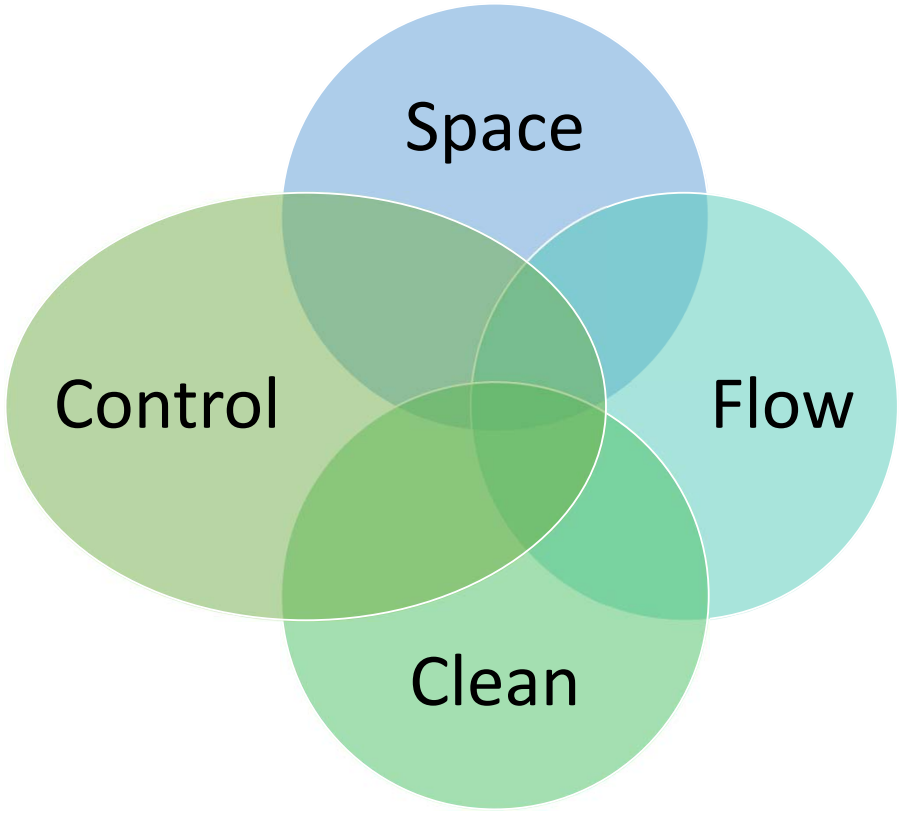
**Optimization**

- Workflow Organization
- Environmental Controls
- QA cycle improvements

**Compliance**

2026 ICHP Annual Meeting

# Workflow & Environmental Controls




2026 ICHP Annual Meeting

# UCMC Remediation: Workflow Controls

- **Space Utilization**
  - Assess whether the compounding area supports **unidirectional flow**
  - Remove unnecessary items from active work surfaces
  - Ensure adequate **staging zones** for ingredients, equipment, and final products
  - Use visual cues (tape boundaries, labeled zones) to reduce ambiguity
- **Process Flow**
  - Map the current workflow step-by-step to identify backtracking or cross-traffic
  - Standardize the sequence: weigh → measure → mix → package → label → document
  - Separate incompatible tasks (e.g., weighing powders vs. mixing liquids)
  - Reduce handoffs and unnecessary movement between stations
- **Material Handling**
  - Establish consistent placement of scales, syringes, spatulas, and containers
  - Use dedicated bins for “clean,” “in-use,” and “to be cleaned” items
  - Implement FIFO for ingredients to prevent expired stock from entering workflow

# UCMC Remediation: Environmental Controls

- **Cleanliness Standards**
  - Daily cleaning of surfaces before and after compounding
  - Weekly deep cleaning of shelves, storage areas, and equipment
  - Monthly environmental checks (dust, clutter, residue)
  - Use validated cleaning agents appropriate for nonsterile compounding
- **Organization & Clutter Reduction**
  - Remove personal items, excess supplies, and outdated materials
  - Keep only active ingredients and tools in the immediate compounding zone
  - Use labeled drawers and bins to reduce search time and prevent mix-ups
- **Storage & Environmental Conditions**
  - Verify temperature and humidity ranges for ingredient stability
  - Ensure proper segregation of hazardous vs. non-hazardous materials
  - Store finished products in clearly defined areas with no cross-contamination risk
- **Separation of Activities**
  - Designate specific areas for weighing, mixing, packaging, and labeling
  - Prevent simultaneous incompatible activities (e.g., cleaning while compounding)
  - Use physical or visual barriers to maintain separation

# Documentation Remediation

**Standardize**

- Create Uniform Templates
- Align across all sites
- Remove Variation

**Complete**

- Ensure all “Musts” are included
- No fields left empty
- Add reference for BUD

**Verify**

- Math
- Commercial Availability
- Ingredients
- Labeling

2026 ICHP Annual Meeting

# UCMC Remediation: Documentation

- **Excel-Based Template Development**
  - Created a locked, structured template with required USP <795> fields
  - Included math verification, ingredient specifications, and workflow steps
  - Added drop-downs to reduce free-text variability
  - Ensured formatting consistency across all preparations
- **Item-by-Item Literature Evaluation**
  - Reviewed stability references for each ingredient
  - Compared literature findings to USP default BUDs
  - Updated instructions to ensure they were measurable and reproducible
  - Documented reference sources directly in the MFR

# UCMC Remediation: Documentation Cont.

- **Locked-Down Recipes**
  - Only the Designated Person can modify formulations
  - Prevents unauthorized edits or site-specific variations
  - Ensures consistency across all locations
  - Supports audit readiness and traceability
  - Reduces risk of incorrect or outdated instructions being used
- **Version Control & Change Management**
  - Every update is documented with date, reason, and reference
  - Old versions archived but not accessible for use
  - Ensures surveyors see a clean, controlled documentation system

# Assessment Question 3

Which remediation action most effectively addresses workflow-related nonsterile compounding deficiencies before Joint Commission survey enforcement?

A. Increasing batch size to reduce preparation frequency
B. Standardizing workflow steps and correcting environmental barriers
C. Delegating compounding tasks exclusively to pharmacists
D. Eliminating master formulation records to simplify documentation



# Design Sustainable Competency & Oversight Systems

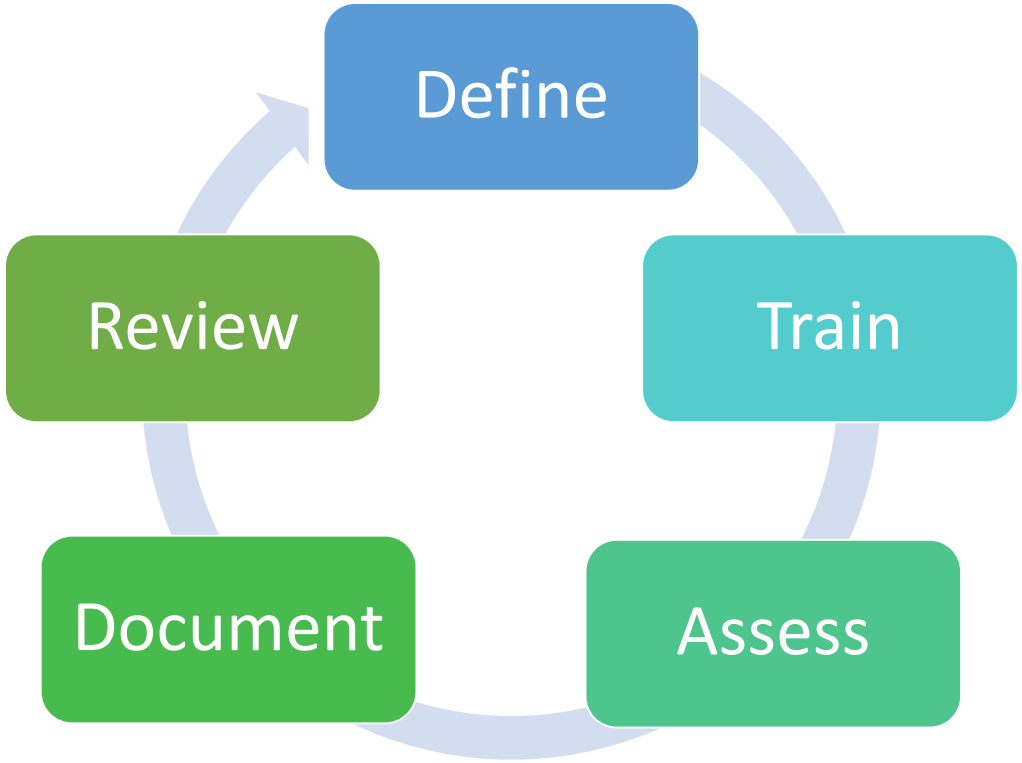
Learning Objective 4

Health systems preparing for USP <795> compliance should design sustainable competency and oversight systems that ensure safe, standardized nonsterile compounding across all sites.

# What Sustainable Competency Really Means

- **Role-specific competency criteria** — Clear expectations for pharmacists, technicians, students, and supervisors
- **Initial and ongoing validation** — Not just onboarding; annual or semiannual refreshers
- **Hands-on demonstration of skills** — Technique observation, weighing accuracy, workflow discipline
- **Documentation of competency outcomes** — Pass/fail criteria, remediation plans, signatures, dates
- **Integration with training systems** — Competency tied directly to training content and MFR updates

# Building a Competency Program




2026 ICHP Annual Meeting

# Oversight Systems That Make Competency Stick

- **Centralized oversight** — One DP or committee reviewing competency, documentation, and MFR updates
- **Controlled document management** — Locked MFRs, version control, change approval workflows
- **Routine audits** — Monthly or quarterly checks of records, workflow, and environment
- **Feedback loops** — Findings → corrective action → follow-up → competency reinforcement
- **Enterprise standardization** — All sites use the same templates, same training, same competency criteria

# UCMC Competency Template

- **Enterprise-wide 4-day hands-on training** — A standardized competency program delivered off-site to ensure consistency and focus
- **Structured curriculum** — Nonsterile compounding, sterile technique fundamentals, calculations, hazardous handling, spill cleanup, workflow discipline
- **Technique-based validation** — Mortar and pestle use, suspension preparation, pediatric dilution, aseptic technique practice, CSTD handling
- **Measurable competency outcomes** — Written quizzes, practical demonstrations, observation checklists
- **Senior staff leveling** — Sending more experienced employees through the same program to eliminate variability and align practice across the enterprise

# Why UCMC Designed Competency This Way

- **Dedicated learning environment** — No workflow interruptions, no distractions
- **Controlled space** — You control the layout, flow, cleanliness, and equipment
- **Standardized experience** — Every employee receives the same training, in the same order, with the same expectations
- **Enterprise consistency** — Eliminates site-specific habits, shortcuts, or legacy practices
- **Better retention** — Staff learn technique through repetition, not observation



# Role of the Designated Person

| Oversight | Training | Documentation | Quality |
|---|---|---|---|
| Guide | Teach | Record | Audit |
| Monitor | Coach | Check | Review |
| Lead | Assess | Track | Improve |

# Designated Person

**The DP as a System not a Person**

- Centralized oversight
- Controlled documentation
- Standardized competency cycles
- Routine audits and feedback loops
- Enterprise alignment
- Continuous improvement

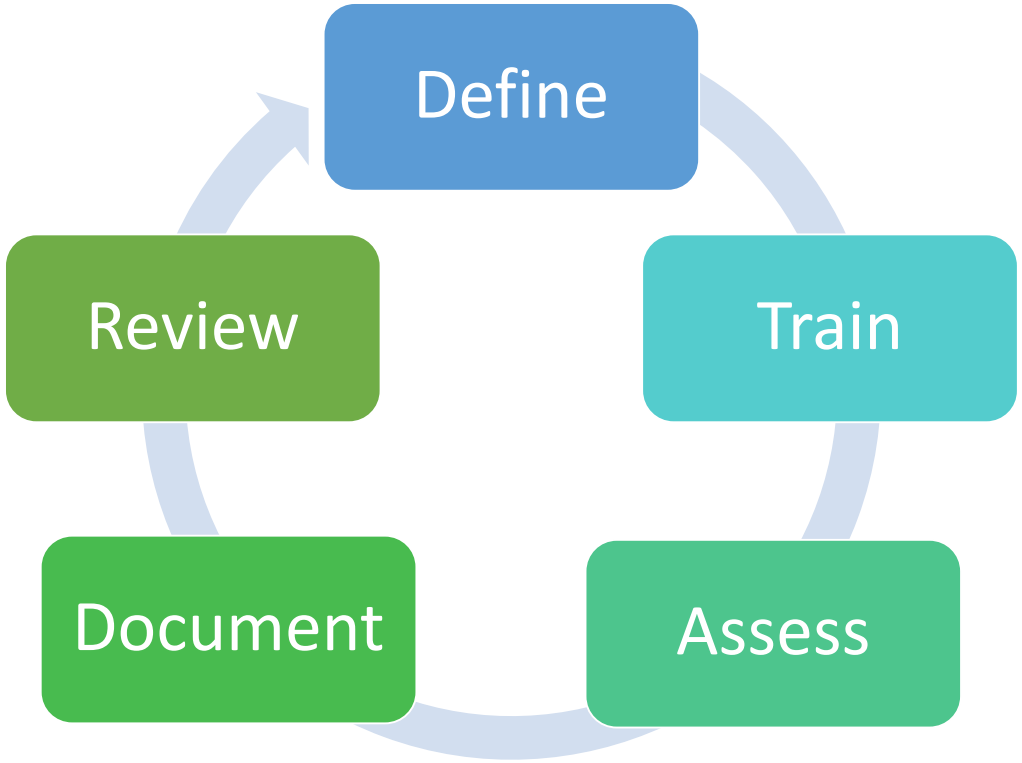
**What the DP Enables**

- Predictable onboarding
- Reproducible technique
- Controlled documentation
- Defensible BUDs
- Reduced variability
- Strong survey readiness
- Long-term operational stability

# UCMC Example

- Locked-down MFRs
- Enterprise-wide templates4-day hands-on training
- Senior staff leveling
- Annual literature review
- Controlled change management
- Centralized competency records

# Building a Competency Program




2026 ICHP Annual Meeting

# Creating Sustainable Systems

- **Define** — Clear, measurable compounding competencies
- **Train** — Your 4-day hands-on program
- **Validate** — Technique observation, quizzes, practical demonstrations
- **Document** — Controlled records, signatures, outcomes
- **Review** — Annual literature review, MFR updates, competency refreshers

- *Improve — Audit findings → training updates → competency reinforcement*



# Assessment Question 4

Which component is essential for a sustainable competency-based training program aligned with USP <795> expectations?

A. Annual review of pharmacy policies only
B. Observation-based assessments without documentation
C. Role-Specific competency validation with documented performance criteria
D. Informal peer feedback during compounding activities

# References


- United States Pharmacopeial Convention. (2023). USP 795: Pharmaceutical compounding—Nonsterile preparations. United States Pharmacopeia.
- United States Pharmacopeial Convention. (2023). USP 800: Hazardous drugs—Handling in healthcare settings. United States Pharmacopeia.
- Allen, L. V. (2020). The art, science, and technology of pharmaceutical compounding (6th ed.). American Pharmacists Association.
- Trissel, L. A. (2021). Trissel's stability of compounded formulations (6th ed.). American Pharmacists Association.
- Illinois General Assembly. (2024). Pharmacy Practice Act (225 ILCS 85). https://www.ilga.gov


# USP <795> Readiness: What Health Systems Must Fix Before Joint Commission Enforcement Begins

**Acquella Brigham, PharmD**

Manager

Pharmacy Distribution Systems

University of Chicago Medical Center

**Kathleen J Kane, PharmD, MBA, BCSCP**

Assistant Director of Pharmacy

Compounding Integrity and Compounding Regulatory Compliance

University of Chicago Medical Center

2026 ICHP Annual Meeting