Day One, February 7th, 2023

Opening
8:00 – 8:30 AM  Registration and Coffee

8:30 – 8:45 AM  Welcome and Introduction
Nurisha Wade, Vice President, Healthcare Quality and Safety, USP

8:45 – 9:00 AM  Workshop Goals and Anticipated Outcomes
Brian Serumaga, Senior Manager, Personalized Medicines, USP

Session I: USP Updates
Moderator:
Objective: This session will provide a historical perspective on the development of the compounding chapters and updates on USP’s ongoing activities for compounding.

9:00 – 9:45 AM  A Tale of Two Compounding Chapters
Selma Mitiche, USP

9:45 – 10:00 AM  Session I Discussion and Q&A

10:00 – 10:15 AM  Morning Break

Session II: Approaches to Implementing USP Compounding Standards: Practitioner Perspectives
Moderator:
Objective: This session will provide a platform for practitioners from various settings to share their experiences with preparing for the implementation of USP <795>, <797>, and <800>.

Key questions addressed will include:
   a) What innovative approaches have you taken to implement the requirements in USP compounding standards in your settings?
   b) What challenges did you face in this process and how did you go about trying to overcome these challenges?
   c) What are the lessons learned you would like to share and what recommendations can you make for workshop participants and stakeholders in general?
   d) What emerging needs did you identify in this process and what recommendations do you suggest for USP and other stakeholders?

10:15 – 10:45 AM  A Community Pharmacy Practitioner  
                   Rick Rhoads

10:45 – 11:15 AM  A Hospital/Health System Setting Practitioner  
                   Kevin Hansen

11:15 – 11:45 AM  Innovative Approaches to Implementing Category 3 Compounding  
                   Jim Gaither

11:45 – 12:15 PM  Session V Discussion and Q&A

12:15 – 1:00 PM   Lunch

Session III: 2023 Revisions — A Deep Dive into Special Topics

Moderator:

Objective: This session will cover specific topics in the 2023 compounding chapter revisions in greater detail.

This will include:
   a) Factors influencing the stability of compounded preparations
   b) Understanding preservative selection and the factors that influence antimicrobial effectiveness
   c) Selecting appropriate cleaning and disinfecting agents – approach and differences between agents
   d) What is <51> testing and how is it done?
   e) Understanding and applying sterility testing per USP <71> for compounded sterile preparations, including practical examples

1:00 – 2:00 PM   Panel: Compounded Preparation Development and Stability Testing  
                  Ed Elder, Peter Rice, Robert Shrewsbury

2:00 – 2:30 PM   Cleaning, Disinfecting, and Applying Sporicidal, Oh My!  
                  Mark Wiencek

2:30 – 3:00 PM   <51> Antimicrobial Effectiveness Testing & <71> Sterility Testing: When, Why, and How  
                  Brian Kelley
**Session IV: Panel Q&A Session**

**Moderator:**

**Objective:** Attendees will have an opportunity to ask a panel of USP Compounding Expert Committee members and guest speakers questions on the 2023 revisions and the topics presented in today's sessions.

3:30 – 4:30 PM  Q&A Session and Discussion on Implementing the 2023 Revisions  
*Expert Committee Members and Guest Speakers*

4:30 – 5:30 PM  Reception

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**Day Two, February 8th, 2023**

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**Opening**

8:00 – 8:45 AM  Registration and Coffee

8:45 – 9:00 AM  Welcome, Announcements, and Day 1 Recap

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**Session V: USP Compounded Preparation Monographs – 200 Year Evolution**

**Moderator:**

**Objective:** This session will inform workshop participants about the development, role, and application of USP Compounded Preparation Monographs (CPMs).

9:00 – 9:30 AM  Challenges in Developing and Implementing Monographs  
*Ed Elder*

9:30 – 10:00 AM  Navigating a CPM – How to Interpret, Use, and Apply a Monograph  
*Gigi Davidson*

10:00 – 10:30 AM  Panel – Challenges and Considerations in Selecting Quality Components and APIs  
*AJ Day, Hudson Polonini, Philip Smyth, Raman Sidhu*

10:30 – 10:45 AM  Session V Discussion and Q&A

10:45 – 11:00 AM  Morning Break
Session VI: Building Quality into the Compounding Process: Perspectives from Compounders

Moderator:

Objective: Panelists will discuss quality issues for sterile and nonsterile compounding as they apply to their individual practice sites.

The panelists will discuss the following:

a) What are the aspects of a compounding practice that can be modified to improve the quality of compounded preparations? How do you set up a compounding practice for continuous quality improvement?

b) What are the tools and resources needed to advance quality within their practice?

c) How do you set up your compounding practice to maximize the opportunities for quality improvement which may arise before, during, and after interactions with regulators, accreditors, certifiers, and other external parties?

11:00 – 11:30 AM   Before and After the Inspection: Perspectives from a Compounder
Lisa Ashworth

11:30 – 12:00 PM   Before and After the Inspection: Perspectives from a Surveyor
Kathleen Jackson

12:00 – 12:30 PM   Selecting and Managing Vendors in the Compounding Operation
Matthew Bernstein

12:30 – 12:45 PM   Session VI Discussion and Q&A

12:45 – 1:30 PM   Lunch

Session VII: Advancing Quality Compounding: Perspectives from Adopting Bodies

Moderator:

Objective: This session will inform workshop participants about regulatory changes and associated implications for compounding.

The session aims to address:

a) What are some of the policy considerations in balancing access, quality, and meeting a patient’s medical needs? What can we do to make sure the distinction between traditional compounding, outsourcing compounding, and manufacturing is not blurred over time?

b) What can we do to build practitioner awareness of appropriate circumstances and settings for compounding, including consistent procedures that promote patient safety?

c) What is the appropriate role of standards for quality in helping to assure quality compounded preparations?

d) Are there additional ways the federal government, states, and stakeholders can collaborate on addressing any quality gaps and in advancing compounding quality? What can we collectively do to address areas where regulatory requirements may be unclear or where gaps may exist?

1:30 – 2:00 PM   A State Perspective
Session VIII: Panel Q&A Session

**Moderator:**

**Objective:** Attendees will have an opportunity to ask a panel of USP Compounding Expert Committee members and guest speakers questions on the 2023 revisions and the topics presented in today’s sessions.

3:00 – 4:00 PM  Q&A Session and Discussion on Implementing the 2023 Revisions

*Expert Committee Members and Guest Speakers*

4:00 PM  End of Workshop

Adjourn