Inaugural USP Workshop on Evolution and Advances in Compounding
Final Agenda

DAY ONE: May 21, 2018

8:00 – 8:30 am **Registration and Coffee**

8:30 – 8:45 am **Welcome and Introduction**
Jaap Venema, *Executive Vice President/Chief Science Officer, USP*

8:45 – 9:00 am **Workshop Goals and Anticipated Outcomes**
Brian Serumaga, *Science Program Manager, HealthCare Quality Systems, USP*

9:00 – 9:30 am **Keynote speaker**
Dr. Thomas C. Kupiec, *CEO, ARL Bio Pharma and DNA Solutions Inc.*

Session I: USP Updates

Objective: This session will provide updates to workshop participants on USP ongoing activities for quality compounding.

Time	Topic	
9:30 – 10:00 am	Updates on USP <795>, USP <797> and USP <800>	Rick Schnatz *USP*
10:00 – 10:30 am	Compounded Preparation Monograph (CPM) development and The USP CPM Donation Program	Brian Serumaga *USP*
10:30 – 10:45 am	Session I Discussion and Q&A	

10:45 – 11:00 am **Morning Break**

Session II: Enhancing the safety of compounded preparations through standardization: implications for compounders

Moderator: Dr. Gus Bassani, *Member: USP Compounding Expert Committee*

Objective: This session will focus on inter-professional efforts to reduce errors and improve quality of compounded preparations. Such efforts include standardization of concentrations of the most commonly compounded medicines.

Key question addressed will include:

a) What is the history and purpose of efforts to standardize concentrations of commonly compounded medicines?
b) What are the lessons learned from designing and implementing such initiatives at the state level?

Time	Topic	
11:00 – 11:30 am	The ASHP Standardize4safety Initiative	Michael Ganio *ASHP*
11:30 – 12:00 pm	Implementing statewide standard concentrations for pediatric compounded medicines in Michigan	Scott Ciarkowski *University of Michigan School of Pharmacy*
12:00 – 12:30 pm	Session II Discussion and Q&A Challenges, conflicts, opportunities for alignment, take away messages and next steps	

12:30 – 1:30 pm **Lunch**

Session III: What are the emerging trends in compounding for special populations?

Moderator: Lisa Ashworth, *Member: USP Compounding Expert Committee*

Objective: This session will focus on current and planned activities to improve the quality of compounding in specialty areas.

Time	Topic	
1:30 – 2:00 pm	Current trends and emerging priorities in compounded preparations for pediatric use	Richard Parrish *St. Christopher's Hospital for Children*
2:00 – 2:30 pm	Current trends and emerging priorities in compounded preparations for veterinary use	Gigi Davidson *Chair: USP Compounding Expert Committee*
2:30 – 3:00 pm	Current trends in geriatrics, women's health, and home health	Dana Simonson *Fairview Pharmacy Services*
3:00 – 3:15 pm	Survey to pediatric pharmacists to prioritize monographs for USP development	Jessica Biggs *University of Maryland Medical Center*
3:15 – 3:30 pm	Session III Discussion and Q&A	Moderator: Lisa Ashworth

3:30 – 3:45 pm **Afternoon break**

Session IV: Panel – How are compounding support organizations approaching quality challenges for APIs and excipients?

Moderator: Dr. Tom Kupiec, *ARL*

Panelists: Compounding member support organization

Objective: Panelists from compounding support organizations will discuss initiatives they are implementing to enhance quality and safety in traditional compounding.

Time	Topic	
3:45 - 3:50 pm	Introductions	Aaron Lopez, *Medisca* AJ Day, *PCCA* Erik Tosh, *LETCO*
3:50 - 4:30 pm	Panel Discussion	

4:30 – 4:45 pm **Day 1 wrap up**

Agenda

DAY TWO: May 22, 2018

8:00 – 8:45 am **Registration and Coffee**

8:45 – 9:00 am **Welcome, announcements and recap from Day 1**
Brian Serumaga, *USP*

Session V: What are the implications of the changing regulatory environment? Perspectives from the state and federal level

Moderators: Ben Firschein, *USP*

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

Time	Topic	
9:00 – 9:45 am	Advancing quality compounding: FDA perspective	Sara Rothman *FDA*
9:45 – 10:15 am	Advancing quality compounding: State perspective	Virginia Herold *California State Board of Pharmacy*
10:15 – 10:45 am	The evolution of the accreditation process in response to changes in regulation of compounding – Perspectives from the Joint Commission	Robert Campbell *The Joint Commission*
10:45 – 11:00 am	Session V Discussion and Q&A Challenges, opportunities for advancing quality, identifying gaps, takeaway messages and next steps	

11:00 – 11:15 am **Morning Break**

Session VI: Exploring opportunities for the exchange of information on compounded drug preparation in health IT systems

Moderator: Donna Bohannon, *USP*

Objective: To obtain stakeholder feedback and discuss challenges with electronic representation of compounded preparations in computer systems.

Time	Topic	
11:15 – 11:45 am	Electronic Indexing of Compounded Preparations	Steve Emrick *USP*
11:45 – 12:15 pm	ePrescribing needs: Express Scripts electronic transmissions of CPMs	Nicole Russell, *NCPDP*
12:15 – 12:30 pm	Session VI Discussion and Q&A	

12:30 – 1:30 pm **Lunch**

Session VII: Developing criteria for the prioritization of compounded preparation monographs

Moderator: Dr. Gus Bassani, *Member: USP Compounding Expert Committee*

Panelists: Cutis Pharma, Center for Personalized Medicine, USP Compounding Expert Committee Member

Objective: This session will begin by presenting the criteria used by USP Compounding Expert Committee to prioritize formulas for development of compounded preparation monographs. The session will invite comments from key stakeholders about how these criteria can be enhanced to increase access to medicines.

Time	Topic	
1:30 – 2:30 pm	Criteria developed by the USP CEC	Brian Serumaga, *USP*
	Comments from stakeholders: Cutis Pharma	Weiyan Feng, *Cutis Pharm*a
	Comments from Stakeholders: Center for Personalized Medicine	Pamela Smith
	Comments from USP Compounding Expert Committee Member	Alan Parr
2:30 – 3:00 pm	Panel Discussion	

Session VIII: Debrief and Next steps (workshop plenary session)

Moderator: Brian Serumaga, *USP*

Objective: Developing an agenda of critical actions to enhance the creation, dissemination, and use of compounding standards.

Time	Topic
3:00 – 3:45 pm	Workshop participants will be invited to suggest: • Actions to be implemented in the next 12 months • Action to be implemented beyond the next 12 months • Topics suggestions for the next workshop
4:00 pm	**End of Workshop/Adjourn**