USP Second Annual Workshop
Evolution and Advances in Compounding
Final Agenda ~ August 5, 2019

DAY ONE: Aug 6, 2019

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, HQS, USP*

9:00 – 10:00 am **Keynote speaker**
Dr. Daniel Kraft (The Future of Health and Medicine: Where Can Technology Take US?)

Session I: USP Updates

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

Time	Topic	
10:00 – 10:15 am	Updates on USP <795>, <797> and <800>	Tiffany Chan, USP
10:15 – 10:30 am	CPMs and Other Updates	Brian Serumaga, USP
10:30 – 10:40 am	Session I Discussion and Q&A	

10:50 – 11:00 am **Morning Break**

Session II: The Era of Precision Medicine – Implications For Compounders

Moderator: Connie Sullivan, Member USP Compounding Expert Committee

Objective: Panelists will discuss how scientific innovations and new technologies could impact traditional compounding.

Time	Topic	
11:00 – 11:25 am	Evolution of Pharmaceutical Dosage Forms – What Is On The Horizon For Compounders?	Bob Shrewsbury, USP Compounding Expert Committee
11:25 – 11:50 am	Pharmacogenomics: Precision Pharmacy In 503a Compounding	Tom Kupiec, ARL BioPharma
11:50 – 12:10 pm	Session I Discussion and Q&A	

12:10 – 1:00 pm **Lunch**

Session III: New and Emerging Technologies in Compounding

Moderator: Gus Bassani, Member USP Compounding Expert Committee

Objective: This session will focus on the following:

- What are the current ways in which compounders use USP standards in compounding?
- What are the new and emerging technologies being developed by various players in the compounding industry? What role do these technologies play in enhancing the ability of compounders to consistently and reliably meet compendia standards and regulatory requirements?
- What are the gaps in the existing standards that need to be filled in order to enhance the development and adoption of compounding technologies?

Time	Topic	
1:00 – 1:20 pm	The Practical Use of USP As A Primary Reference Resource for Compounded Formulations	Kim Kiefer, Empower Pharmacy
1:20 – 1:40 pm	Gravimetrics – Application in Compounding	Dennis Tribble, BD
1:40 – 2:00 pm	Using Automation and Process Workflow To Improve Accuracy In Compounding	John Barickman, Omnicell
2:00 – 2:20 pm	Panel Discussion	
2:20 – 2:30 pm	**Afternoon break**	

Session IV: Advancing Quality Compounding: Perspectives from Adopting Bodies

Moderator: Alissa Jijon, JD; USP Senior Counsel

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

- 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?
- What can we do to build practitioner awareness of appropriate circumstances and settings for compounding, including consistent procedures that promote patient safety?
- What is the appropriate role of standards of quality in helping to assure quality compounded preparations?
- 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?

Time	Topic	
2:30 – 3:00 pm	FDA Perspective	Sara Rothman, FDA/CDER
3:00 – 3:30 pm	State Perspective	Anthony Rubinaccio, NJ State Board of Pharmacy
3:30 – 4:00 pm	Perspectives from Accreditation Organizations	Robert Campbell, The Joint Commission
4:00 – 4:30 pm	Session IV Discussion And Q&A Challenges, Opportunities for Advancing Quality, Identifying Gaps, Takeaway Messages and Next Steps	
4:30 – 4:45 pm	**Day 1 wrap up**	

4:45 – 5:30 pm Reception

Agenda

DAY TWO: Aug 7, 2019

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: Innovative Approaches to Implementing USP Compounding Standards: Practitioner Perspectives

Moderator: Gigi Davidson, Chair – USP Compounding Expert Committee

Objective: This session will provide a platform for practitioners from various setting to share their experiences with preparing for the implementation of USP <795>, <797> and <800>.

Key question 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 to 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?

Time	Topic	
9:00 – 9:30 am	Practitioner from A Community Pharmacy	Rick Rhoads, University Compounding Pharmacy
9:30 – 10:00 am	Practitioner from A Hospital/Health System Setting	Kevin Hansen, Moses H. Cone Memorial Hospital
10:00 – 10:20 am	Session V Discussion and Q&A Challenges, Conflicts, Opportunities for Alignment, Take Away Messages and Next Steps	

10:20 – 10:35 am **Morning Break**

Session VI: Innovative Approaches to Facility Design of Compounding Areas

Moderator: James Wagner, Member USP Compounding Expert Committee

Objective: This session will provide a platform for builders, engineers, architects and support staff to share experiences on how to create a workspace to meet the requirements of USP compounding standards.

a) What innovative approaches have been taken to implement the requirements in USP compounding standards in their settings?
b) What challenges did they face in this process and how did they go about trying to overcome these challenges?
c) What are the lessons learned they would like to share and what recommendations can they make to 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?

Time	Topic	
10:35 – 10:55 am	Considerations for the Construction of The Compounding Room	Danny Barnes, Triangle Compounding Pharmacy
10:55 – 11:05 am	Perspectives from an architect	Carol Fuller, Architect, Chartwell
11:05 – 11:15 am	Perspectives from an engineer	Matthew Olson, AMC Engineers
11:15 – 11:35 am	Facilitated panel discussion	All panelists
11:35 – 12:00 pm	Session VI Discussion and Q&A	
12:00 – 1:00 pm	**Lunch**	

Session VII: Panel - Building Quality into The Compounding Process: Perspectives From Compounders

Moderator: Abby Roth, Member USP Compounding Expert Committee

Objective: Panelists will discuss quality issues for sterile and non-sterile 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?

Time	Topic	
1:00 – 2:00 pm	Before and After the Inspection: Perspectives From A Compounder	Gene Decaminada, Option Care Debbie Barrow, Baptist Health
2:30 – 2:30 pm	Panel Discussion: Selecting and Managing Vendors in The Compounding Operation (Certifiers, Component Suppliers, Microbiology Labs)	All Panelists
2:30 – 3:00 pm	Session VII Discussion and Q&A	

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 – 3:30 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 • Topic suggestions for the next workshop
3:30 pm	**End of Workshop/Adjourn**