

**2020-2025 Council of the Convention (CoC)
Meeting #7
Wednesday, July 20, 2022**

Minutes – Final

Goals and Anticipated Outcomes

- Discuss outcomes of Supply Chain Exchange Series and a recent meeting of the APAC Regional Chapter
- Review innovation concepts and ongoing USP work related to Resolutions 5 Innovation and 6 Digital Transformation of Standards through presentations and CoC discussions

Attendees: See addendum for a list of CoC and USP staff attendees.

1. Welcome, Opening Remarks, Confirmation of Quorum and Agenda Approval

Welcome

Dr. Dennis E. Doherty, Chair, Council of the Convention (CoC), welcomed everyone to the seventh meeting of the CoC for the 2020–2025 cycle and opened the meeting at 7:00 a.m. ET. The Chair thanked CoC Members for completing the survey for the Volunteer Leadership Meeting that is planned for October 11–13, 2022.

Mr. Mario Sindaco confirmed that a quorum was present.

Overview of Agenda and Meeting Goals

The Chair reviewed the meeting agenda, asked CoC Members if there were any corrections, and called on the CoC to approve the meeting's agenda.

Motion to Approve Agenda

Motion: Mr. Stephen Mullenix moved to approve the agenda, and the motion was seconded. The motion carried by unanimous consent, and the agenda was approved.

2. Approval of Minutes from Previous Meeting

The Chair asked attendees if there were any corrections to the minutes of the April 20, 2022, CoC Meeting.

Motion: Dr. Emmanuel Akala moved to approve the minutes from the previous meeting, and the motion was seconded. The motion carried by unanimous consent, and the minutes were approved.

3. Asia Pacific Regional Chapter Meeting Update

Dr. John Lim provided a summary of the key takeaways of the Asia Pacific Regional Chapter's June 8–9, 2022, meeting. Dr. Lim emphasized that the sense of community revolving around USP across the Asia Pacific region is currently strong and can be fostered by continued engagement of the Chapter. Supply chain resiliency, impurities, and advanced therapies were highly relevant topics for the Asia Pacific region.

Dr. Lim shared the following key takeaways from the meeting:

- Trust and transparency were recurrent themes and are critical to efficient and resilient supply chains. Using data and new technologies can help build trust, transparency, and resilience.
- The regulatory landscape in the region is evolving quickly. Regulatory agility is a key to responding to the pandemic, drug shortages, and disruptions.
- USP standards are critical to help ensure patient access to quality medicines. USP's nitrosamines knowledge hub is an important resource for the Asia Pacific region, where the nitrosamines landscape is rapidly evolving.
- The Regional Chapter provides a key platform to continue building a multi-stakeholder community, enhancing trust, and facilitating exchange of information and expertise.

4. Innovation at USP

Mr. Anthony Lakavage provided context for the innovation work happening across USP. Mr. Lakavage summarized the 2015–2020 Resolution related to research and innovation and the 2020–2025 Resolutions related to innovations and digital transformation of standards that followed. Mr. Lakavage emphasized USP's commitment to keeping pace with and leading transformative innovation in ways that ensure our impact through standards, capability building, and advocacy.

a. Background and Current USP Work on Innovation

i. USP's Approach to Innovation

Mr. Michael Levy provided an overview of the Digital & Innovation (D&I) division's two main pillars of activity that relate to 2020–2025 Convention Resolution 5, Innovations, and Resolution 6, Digital Transformation of Standards. Mr. Levy noted that the D&I division's goal is to advance USP's public health mission by exploring emerging science and technologies, maturing promising innovations, and delivering digital solutions that address stakeholder needs.

Mr. Levy summarized the disruptors that have shaped USP's evolution and the key functional areas across D&I that address these disruptors and explore emerging trends and technologies. Mr. Levy also summarized the metrics D&I uses to qualitatively prioritize topics to pursue. He noted that innovation happens across USP, not only in the D&I division, and that innovation generally falls into the following three buckets: keeping pace with scientific developments, fostering innovation, and innovating ourselves.

ii. Enabling Access to Biologic Therapies

Dr. John Kokai-Kun provided an overview of USP Biologics' approach to standards development and focus on performance standards. Key areas where USP is keeping pace with innovation include advanced therapies, monoclonal antibodies, vaccines, and biomarkers.

Mr. Levy provided information about advanced manufacturing technologies (AMT), another important area where USP is keeping pace with innovation. AMT includes such technologies as continuous manufacturing and additive manufacturing with 3D printing. Mr. Levy emphasized that USP is working to

advance the supply of quality medicines by being a leading provider of services, standards, and other solutions to industry and regulators seeking to use AMT in their processes and approvals.

iii. Awareness, Engagement, and Action

Dr. Darcy Gentleman provided a summary of the first in the USP Convention's Innovation Series. Dr. Gentleman summarized the approaches to innovation shared in the Series meeting by the Personalized Medicine Coalition, the Allotrope Foundation, and Research!America.

Mr. Levy described efforts to develop digital standards that will integrate with laboratory information systems and enable more seamless evaluation of quality. He also provided a summary of D&I's early research pipeline and incubation areas of exploration. CoC Members will receive an email with a link to a miro board, open until August 15, 2022, that CoC Members can use to submit ideas about emerging trends and technologies that USP staff should consider processing through its prioritization metrics.

b. Small Group Discussions

Ms. Shelley Whiddon noted that CoC Members will meet in small groups to discuss the following related questions and then share their insights:

- In what ways can standards foster innovation?
- What challenges arise from medicine/therapy innovations? How can USP help to address these challenges?
- What can be done to help bring innovations to patients, such as advocacy, education, partnerships?

c. Breakout Insights

Ms. Whiddon introduced the following breakout group representatives who provided summaries of their group's key themes and insights.

Dr. Ilisa Bernstein provided the following breakout summary:

- USP's work on 3D printing has the potential to improve utilization of the technology through application of standards.
- Transparency in the process helps foster the acceptance of standards.
- Innovation in digital standards was appreciated by breakout participants. USP could consider looking at how to incorporate patient data into digital standards.
- Breakout discussion emphasized the following:
 - USP standards could help close the lag time between innovation and acceptance.
 - USP could include more people who understand new technologies when developing monographs.
 - There are challenges related to cost and access to new technologies.
 - Standards can help level the playing field in preparation for new technologies and products entering the marketplace.

Ms. Susan Cantrell provided the following breakout summary:

- Discussion emphasized the drug development and regulatory review processes as well as challenging situations between sponsors and contract research organizations.
- USP can play an important role in developing standardization for T-cell assays specific to SARS-CoV-2. NIH and FDA have a keen interest in T-cell assays; however, sufficient standards do not currently exist, and this is an area USP should consider exploring.
- USP performance standards play an important role in innovation.
- USP can help fill the gap between innovation and regulation, especially in some areas of the world that lack sophisticated regulatory infrastructures.
- USP could play an important role providing information and intelligence on COVID-19 vaccines to countries throughout the world, especially to developing nations.

Ms. Sue Peschin provided the following breakout summary:

- Ms. Peschin encouraged USP to repeat this breakout exercise and ask the single question, “What are ideas or areas where USP could get involved?”
- Discussion emphasized important areas of USP work, including over-the-counter standards vs. different modalities, advanced therapies, developing standards around mRNA vaccines, cells, microbiology, pediatric dosages, and formulations.
- USP could explore universalizing standards developed by the private sector groups into a single standard.
- USP could undertake occasional landscape analyses for areas in which standards have not yet been developed and explore developing standards to fill the gap before a problem arises.
- USP could explore whether some excipients are active and affect quality.
- USP could explore a consumer education role on how supplements may negatively interact with prescription drugs.
- USP could explore standards and education on CBD and THC products.
- USP could explore the importance of standards fostering both innovation and competition.
 - Standards are important for scaling for competition in industry.
 - USP could serve as a credible educator on how intellectual property fits into the ecosystem with innovation and competition.

Ms. Whiddon commented that she hoped these insights will continue through the Miro board as well as at the Volunteer Leadership Meeting.

The Chair thanked participants for an engaging presentation and discussion.

The Chair introduced two new members of the CoC: Dr. Ilisa Bernstein of the American Pharmacists Association and Dr. Erik Burns of the American Association of Pharmaceutical Scientists.

Action Item

- USP staff will email a Miro board link to CoC Members.

5. Supply Chain Exchange Series

Ms. Amy Sonderman provided an overview of the Supply Chain Exchange Series held on February 25, April 1, and May 24, 2022, that explored multi-stakeholder approaches to building a resilient supply of quality medicines. Ms. Sonderman emphasized the following key insights:

- Public-private partnerships need sustained investment and are strengthened by interdisciplinary collaboration in order to accelerate their response and continuously help scale innovations in biopharmaceuticals.
- Diverse challenges include: regulatory, financial, and legal barriers; limited expansion of antibiotic stewardship programs; and lack of focus on supply chain management.
- Multi-stakeholder collaboration is key to: future workforce training in AMT; the conservation and stewardship of antimicrobials in order to prevent resistance; sharing real-world data and evidence; and establishing a continuous cycle of preparedness.

Ms. Sonderman invited attendees to email her for more information.

6. What's Next

Mr. Sindaco summarized the objectives and planned content and activities for the following meetings:

- South Asia Regional Chapter meeting (July 27, 2022)
- Innovation Series (August 11 & September 12, 2022)
- 2022 Volunteer Leadership Meeting, which brings together the CoC, the Board of Trustees, and Council of Experts (October 11–13, 2022)

Mr. Sindaco noted that USP staff hope that everyone who is able and willing will join the meetings in person, but a virtual option will also be available.

Mr. Sindaco noted that USP staff will email a Miro board link to attendees and invited CoC Members to provide their input by August 15, 2022.

Action Item

- USP staff will email a Miro board link to CoC Members.

7. Adjourn and Closing Remarks

The Chair thanked everyone for their time and invited CoC Members to send input for future topics to the Chair and USP staff.

The Chair **adjourned the meeting at 9:00 a.m.**

ADDENDUM

CoC Members

CoC Chair and President of the Convention

1. Dennis E. Doherty, M.D., Convention President and CoC Chair

USP Convention Sector Chairs

2. Generics Sector Chair: David Gough, R.Ph., Association for Accessible Medicines
3. Biologics Sector Chair: Susan Cantrell, BS Pharm., Academy of Managed Care Pharmacy
4. Dietary Supplements Sector Chair: Jay Sirois, Ph.D., Consumer Healthcare Products Association
5. Healthcare Practice Sector Chair: Ilisa BG Bernstein, PharmD, JD, FAPhA, American Pharmacists Association
6. Excipients Sector Chair: Erik Burns, Ed.D., M.A., MBA, American Association of Pharmaceutical Scientists

USP Convention Regional Chapter Chairs

7. Latin America Region Chapter Chair: Caroline Weinstein, Ph.D., Chilean Pharmacopeia
8. Asia Pacific Region Chapter Chair: John Chien-Wei Lim, M.D., M.S., Centre of Regulatory Excellence, Duke-NUS Medical School
9. Middle East and North Africa Region Chapter Chair and Membership Committee Chair: Hanan Sboul, M.B.A., B. Pharm, CAE, Jordanian Association of Pharmaceutical Manufacturers
10. South Asia Region Chapter Chair: Bhojraj Suresh, M.Pharm., Ph.D., D.Sc. Pharmacy Council of India
11. Greater China Region Chapter Chair: Mingzhe Xu, National Institutes for Food and Drug Control

At-Large Members

12. Emmanuel Akala, R. Ph., Ph.D., DIM, Howard University College of Pharmacy
13. Barbara Exum, Pharm.D., Virginia Commonwealth University/Medical College of Virginia School of Pharmacy
14. Stephen Mullenix, BS Pharm., R.Ph., National Council for Prescription Drug Programs
15. Pallavi Nithyanandan, Ph.D., FDA Center for Drug Evaluation and Research
16. Sue Peschin, M.H.S., Alliance for Aging Research
17. Pam Traxel, American Cancer Society/Cancer Action Network
18. Kanecia Zimmerman, M.D., American Academy of Pediatrics

Council of Experts Representatives

19. Martin Coffey, Ph.D., USP General Chapters—Dosage Forms Expert Committee
20. Stephanie Crawford, M.P.H., Ph.D., USP Nomenclature and Labeling Expert Committee
21. Kim Huynh-Ba, M.S., B.Sc., USP Small Molecules 4 Expert Committee

Unable to attend

Lynette Bradley-Baker, Ph.D., R.Ph., CoC Vice Chair, American Association of Colleges of Pharmacy

USP Staff

1. Anthony Lakavage, J.D., Convention and Board Secretary and Senior Vice President, Global External Affairs
2. Darcy Gentleman, Ph.D., Senior Stakeholder Engagement Manager
3. Amy Sonderman, Director, Convention and Stakeholder Engagement
4. Shelley Whiddon, M.A., Senior Director, Operations, Convention and Stakeholder Engagement

5. Mario Sindaco, M.S., M.B.A., Senior Board and Convention Operations Director
6. Doug Podolsky, Technical Writer III, Publications
7. Raliza De Souza, M.B.A., Project Manager, Global Stakeholder Engagement
8. Justin McNeely, M.A., Communication Systems Engineer, IT Operations
9. John Kokai-Kun, Ph.D., Director, External Scientific Collaboration
10. Michael Levy, M.Sc., M.B.A., Senior Vice President, Digital & Innovation