

**2020–2025 Council of the Convention
Meeting #12
Wednesday, October 11, 2023**

Webex

Minutes – Final

Goals and Anticipated Outcomes

- Hear updates from recent Convention meetings and events.
- Hear highlights from USP's Year-3 progress report on Resolutions.
- Hear a discussion from Regional Chairs on the role of regional chapter meetings.
- Participate in a team collaboration activity.

Attendees: See addendum for a list of Council of the Convention (CoC) and USP staff attendees.

1. Opening Remarks, Confirmation of Quorum, and Approval of Agenda and Previous Meeting's Minutes

USP staff noted that a quorum was present.

The CoC Chair welcomed everyone to the twelfth meeting of the CoC for the 2020–2025 cycle and convened the meeting at 2:05 p.m.

a. Overview of Agenda

The Chair reviewed the meeting agenda. CoC Members provided no edits.

Motion: Hanan Sbouh moved to approve the meeting agenda. The motion was seconded and there was no discussion.

Vote: The motion carried by unanimous consent.

b. Approval of Minutes from Previous Meeting

The Chair asked attendees if there were any corrections to the minutes of the July 19, 2023, CoC Meeting. CoC Members provided no edits.

Motion: David Gaugh moved to approve the minutes of the July 19, 2023, CoC meeting. The motion was seconded and there was no discussion.

Vote: The motion carried by unanimous consent.

2. CEO Welcome

USP's CEO, Ron Piervincenzi, welcomed attendees to the CoC meeting.

3. Convention Activities Updates

Convention Sector Chairs provided the following updates:

Joint Sector and Chapter Meeting on Nitrosamines

The Chair of the Excipients Sector noted that the meeting topics included nitrosamines risk mitigation, exploring guidance and the importance of patient safety, and how that guidance interacts within the nitrosamines exchange. The Chair highlighted discussion points around how a potential tool for industry to collaborate on is the carcinogenic



potency and categorization approach of nitrosamines, and how global pharmaceutical challenges can be met when everyone actively engages and collaborates on this topic.

GRx + Biosims Conference

The Chair of the Generics Sector noted that this collaborative effort is between the Association for Accessible Medicines (AAM), USP, and the FDA. He highlighted USP's presence on the GRx panels. He discussed the following key themes from the USP Forum:

- Quality standards help to alleviate some of the unknowns for industry.
- USP and industry must collaborate on emerging science and innovation.
- Industry is committed to partnering with USP to drive the quality narrative.

Cancer Drug Shortage Summit

Staff provided an update on the Cancer Drug Shortages Summit. One of the key issues highlighted was mitigating cancer drug shortages, which included a description of the collaboration with American Cancer Society to find solutions. During this virtual summit, a panel of experts was invited to showcase data, discuss the challenges and drivers of shortages, and explore possible solutions.

As a next step, USP and the American Cancer Society Cancer Action Network (ACS CAN) will collaborate to bring relevant parties to the table to determine high-level recommendations for congressional consideration.

Upstream Supply Chain Policy

The Convention Secretary noted that while creating USP's Medicine Supply Map, USP learned that the early warning capabilities that are available to governments and healthcare providers are inadequate. The Secretary suggested that USP establish a "vulnerable medicines list." This would enable USP to consider where additional coordination is needed to strengthen the manufacturing base for drug products and promoting sustainable prices for generic medicines.

Discussion

The CEO noted that for a standard to be valuable, it starts with information, which mostly comes from generic studies.

A CoC member asked about the call to action for the Cancer Summit. Staff noted that USP is considering advocacy in two parallel tracks, the USP public policy position and convening experts for collaboration.

Action Item

- Staff will send the call for action regarding the collaboration between USP and ACS CAN to CoC Members.

4. Regional Chair Panel Discussion

The Secretary introduced the following panelists:

a. John Lim, Asia Pacific Regional Chapter Chair

The Chair highlighted the Asia Pacific Regional Chapter's segmentation into developed markets, maturing countries, and emerging countries, noting diverse priorities. He noted that developing countries emphasize supply chain resilience, while developed countries prioritize innovation, digitalization, and advanced therapies; additionally, the USP's APAC office is actively promoting information exchange, priority discussions, collaboration, and leveraging the Convention Cember community.

b. Caroline Weinstein, Latin America Regional Chapter Chair

The Chair discussed shared priorities in the region and recent meetings covering regulatory harmonization, medical cannabis, nitrosamines, and an upcoming post-market surveillance meeting involving regulators, academia, and associations. The Chair emphasized the diverse regulatory maturity in the region, and highlighted key points, including the need for standards in the emerging cannabis market, diverse regional regulatory frameworks, the importance of pharmacovigilance, ongoing development in quality control, and the associated risk of adulterations.

c. Hanan Sboul, MENA Regional Chapter Chair

The Chair noted that there have been three meetings where they discussed priorities including strengthening regulatory systems, nitrosamine, and biosimilars. Within this context, she highlighted the importance of interactive discussion. She reviewed the Chapter's engagement with USP's Resolutions, engaging volunteers for the call for candidates, and the focus on priorities, such as regulatory systems strengthening.

d. Chaitanya Koduri, Director, International Government and Regulatory Engagement, USP

The USP Staff member reviewed the history of USP's work to address upstream supply chain resilience since 2020, with a focus on nitrosamines. He noted that currently, one main issue is drug shortages and should be addressed via collaboration with regulators and industry to develop a vulnerable list. Investing in quality continues to be a priority.

5. Year-3 Resolution Progress Report

CoC Members agreed to table this topic for a future meeting due to time constraints.

6. Collaborating and Communicating

CoC Members were grouped into teams for an exercise on collaboration and communication.

7. What's Next

Staff recapped the action items from the meeting and noted next steps.

Action Items

- Staff will send the call for collective action regarding drug shortages.

8. Adjourn and Closing Remarks

The Chair congratulated CoC Members for their accomplishments. The Chair adjourned the meeting at 4:30 p.m.

Addendum

CoC Members in Attendance

1. Dennis E. Doherty, M.D., Convention President and CoC Chair
2. Lynette Bradley-Baker, Ph.D., R.Ph., CoC Vice Chair, Membership Committee Vice Chair, American Association of Colleges of Pharmacy

USP Convention Sector Chairs

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

USP Convention Regional Chapter Chairs

7. 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
8. Latin America Region Chapter Chair: Caroline Weinstein, Ph.D., Chilean Pharmacopeia
9. Asia-Pacific Region Chapter Chair: John Chien-Wei Lim, M.D., M.S., Centre of Regulatory Excellence, Duke-NUS Medical School
10. South Asia Region Chapter Chair: Bhojraj Suresh, M.Pharm., Ph.D., D.Sc. Indian Association of Colleges of Pharmacy (IACP)

At-Large Members

11. Emmanuel Akala, R. Ph., Ph.D., DIM, Howard University College of Pharmacy
12. Barbara Exum, Pharm.D., Virginia Commonwealth University/Medical College of Virginia School of Pharmacy
13. Stephen Mullenix, BS Pharm., R.Ph., National Council for Prescription Drug Programs
14. Pallavi Nithyanandan, Ph.D., FDA Center for Drug Evaluation and Research
15. Sue Peschin, M.H.S., Alliance for Aging Research

Council of Experts Representatives

16. Martin Coffey, Ph.D., USP General Chapters—Dosage Forms Expert Committee
17. Stephanie Crawford, M.P.H., Ph.D., USP Nomenclature and Labeling Expert Committee
18. Kim Huynh-Ba, M.S., B.Sc., USP Small Molecules 4 Expert Committee
19. Otilia Koo, Ph.D., USP Complex Excipients Expert Committee

Unable to Attend

Mingzhe Xu, Greater China Region Chapter Chair, National Institutes for Food and Drug Control
Pam Traxel, American Cancer Society/Cancer Action Network

Jay Sirois, Dietary Supplements Sector Chair, Consumer Healthcare Products Association
Catherine Duggan, Europe Region Chapter Chair, Ph.D., FRPharmS, Honorary Professor

USP Staff

Ronald Piervincenzi, PhD., CEO

Anthony Lakavage, J.D., Convention and Board Secretary and Senior Vice President, Global External Affairs

Shelley Whiddon, M.A., Vice President, Global Stakeholder and Convention Engagement

Darcy Gentleman, Ph.D., Senior Stakeholder Engagement Manager

Carrie Harney, Vice President, US Government and Regulatory Affairs

Chaitanya Kumar Koduri, International Government & Regulatory Engagement Director

Max Saffell, MBA, Senior Manager, Stakeholder Engagement

Diego Salazar, M.S., Senior Board & Convention Operations Manager, Global Stakeholder Engagement

Amy Sonderman, Director, Convention and Stakeholder Engagement

Katie Daud, Technical Writer II, Publications