USP Views on the Future of Pharmacopeial Collaboration

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Meet the World Pharmacopoeias Symposium
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Overview

- USP introduction
- The future
  - USP 2020-25 and beyond
  - USP visions for the future of pharmacopeial collaboration & harmonization
- Ideas for strengthening IMWP
Mission

To improve global health through public standards and related programs that help ensure the quality, safety and benefit of medicines and foods

The Breadth of USP’s Work Can Be Seen through the Scope of Our Expert Committees

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<th>Chemical Medicines</th>
<th>Biologics</th>
<th>Excipients</th>
<th>Dietary Supplements &amp; Herbal Medicines, Food Ingredients</th>
<th>Healthcare Quality &amp; Safety</th>
<th>General Chapters</th>
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- Antibiotics, antimicrobial, & antiparasitic
- Cardiovascular, renal, endocrine & diabetes
- Gastrointestinal, oral, respiratory, allergy & oral hygiene
- Neuronal & neurologic agents, neurodegenerative, psychiatric, & psychoactive
- Pulmonary & asthma
- Over-the-counter (OTC) methods & approaches

- Peptide & insulin
- Therapeutic proteins
- Advanced therapies & cell, gene, & gene-modifying
- Antibiotics using microbial assays
- Complex products & vaccines

- Simple: Carbohydrates, minerals & solute
- Complex: Polymers, albumins, fats, tissues, plants & drugs
- Excipient test methods

- Food ingredients
- Non-biological dietary supplements
- Botanical dietary supplements & herbal medicines
- Administration, evaluation & labeling

- Medicines & labeling
- Healthcare quality
- Compounding
- Healthcare information & technology

- Packaging & distribution
- Microbiology
- Dosage forms
- Chemical analysis
- Physical analysis
- Statistics
- Measurement and data quality

2020-2025 Council of Experts-Expert Committees
USP by the Numbers: FY19 Snapshot

- **234 donations** of methods and materials
- **1200+ USP staff** globally
- **125,000 hours** volunteered to USP by **800+ volunteer experts**
- **3800+ lab projects** from USP’s in 5 countries with **185,000+ ft²**
- **439 new/revised documentary standards**
- **108 released RS**
- **7500+ attendees** to USP Education courses and workshops
- **140 scientific publications and presentations**
- **6 quality control laboratories** in Africa and Asia achieved ISO accreditation via technical assistance from USP’s PQM
- **2 billion people** with access to quality medicines and foods because of USP
- **140+ countries** using USP standards

The Future: Disruptors on the horizon

- Digitalization, Data Analytics, Informatics
- Explosion of new medicine modalities
- Complex, globalized supply chain
- New quality paradigms and analytical technologies
- Increasingly difficult for USP to connect to scientific community
- New ways of disseminating knowledge
USP 2020-2025 Strategy

USP WILL BE A DEFINITIVE SOURCE OF MEDICINE AND FOOD QUALITY STANDARDS

ADVOCACY

STANDARDS

MISSION IMPACT

CAPABILITY BUILDING

People | Quality | Digital | Investment and Sustainability

Advancing Science @ USP: Focus Areas

APPROACHES TO QUALITY: Identify and facilitative standardization of new scientific approaches for ensuring quality of current and new medicines and modalities throughout their lifecycles
- Flexible, performance-based, risk-based, predictive
- New medicine modalities
- Article performance

TECHNOLOGIES: Facilitate adoption of analytical and manufacturing technologies with the most potential to improve quality without increasing cost
- Next HPLC
- Digital and informatics
- PCM

SCIENCE CONNECTIVITY

SHAPE OF STANDARDIZATION TO COME
Advancing Science @ USP: Focus Areas

**SCIENCE CONNECTIVITY:** Proactively build a scientific community around USP
- New model for convening volunteer experts
- Young scientist engagement

**SHAPE OF STANDARDIZATION:**
- Faster and more iterative information and knowledge dissemination
- Evolution of RS
- Interoperability of standards
- Ph. Collaboration

USP’s Harmonization Learnings from PDG

Analysis of PDG’s 74 Outputs to Date

- 14% "Harmonized"
- 28% Mostly harmonized
- 58% Significant local differences

Vs
Opportunity Cost to Pharmacopeias

- Resource & time Intensive
- Misaligned Priorities & Incentives
- Technical and regulatory hurdles
- Revision Hesitance
Global Situation

- Globalization of supply chains and manufacturing will continue
- Increasing tide of “nationalism” runs against international and multilateral harmonization and collaboration
- Recognition that we need to evolve existing and strengthen emerging pharmacopeias and their regulatory & quality systems, particularly in LMIC
  - BUT, right it is happening in a way unlikely to lead to convergence and will result in redundant standards and guidances

How to Move Forward?

USP visions for the future of pharmacopeial harmonization and collaboration

1. Do more to increase chances of future global convergence
2. Align priorities with resources to drive “harmonization”
3. Reduce stakeholder barriers for dealing with dis-harmonization
How to achieve vision #1?

Vision: Do more to increase chances of future global convergence

a) Early pharmacopeial information and knowledge exchange, and collaboration

b) Develop standards that are easier to converge

c) Evolve existing and strengthen emerging pharmacopeias with convergence as a goal
How to achieve vision #1?

**Vision:** Do more to increase chances of future global convergence

a) Early pharmacopeial information and knowledge exchange, and collaboration

b) Develop standards that are easier to converge

c) Evolve existing and strengthen emerging pharmacopeias with convergence as a goal

How to achieve vision #2

**Vision:** Align priorities with their resources to drive “harmonization”

- In other words develop a new model that brings industry to the table with pharmacopeias and lets the one(s) with priority resource and drive through the process
How to achieve vision #3

**Vision:** Reduce stakeholder barriers for dealing with dis-harmonization

- Leveraging modern information technology to help users identify differences between pharmacopeial standards

Opportunities to Strengthen IMWP

1. Information and knowledge exchange across global pharmacopeias:
   - Platform for early pharmacopeial knowledge exchange (e.g. symposia)
   - Early warning and coordination of pharmacopeias for emerging issues (e.g. nitrosamines in 2018)

2. Focusing technical outputs of IMWP on advocating value of pharmacopeias and public standards, and not technical standards elaboration
Central to USP’s achievements are the contributions of countless professionals, who volunteer their time and knowledge in USP’s Council of Experts and Expert Committees and Panels.

Our Call for Candidates is now open.

Join other motivated colleagues to help us set the standards that make it possible for 2 billion people around the world to have access to quality medicines, foods and dietary supplements.

Contact us at USPVolunteers@usp.org