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

Chemical Medicines

1. Antibiotic, antiviral, & antimicrobial
2. Cardiovascular, cough, cold & analgesics
3. Gastrointestinal, renal, endocrine,ophthalmic, oncology, dermatology & animal health
4. Nonradioactive imaging agents, aerosols, radiopharmaceuticals, psychiatric, & psychoactive
5. Pulmonary & steroids
6. Over-the-counter (OTC) methods & approaches

Biologics

1. Peptides & insulins
2. Therapeutic proteins
3. Advanced therapies (cell, gene, tissues, & genome-editing)*
4. Antibiotics using microbial assays
5. Complex products & vaccines

* Represents a new Expert Committee

Excipients

1. Simple: Carbohydrates, minerals & salts
2. Complex: Polymers,oils, fats, waxes, plants & clays
3. Excipient test methods*

Dietary Supplements & Herbal Medicines, Food Ingredients

1. Food ingredients
2. Non-botanical dietary supplements
3. Botanical dietary supplements & herbal medicines
4. Admission, evaluation & labeling*

Healthcare Quality & Safety

1. Nomenclature & labeling
2. Healthcare quality
3. Compounding
4. Healthcare information & technology*

General Chapters

1. Packaging & distribution
2. Microbiology
3. Dosage forms
4. Chemical analysis
5. Physical analysis
6. Statistics
7. 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

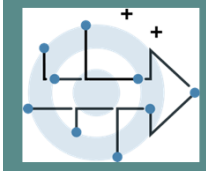
The Future: Disruptors on the horizon

- 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

Advancing Science @ USP: Focus Areas

APPROACHES TO QUALITY



TECHNOLOGIES

SCIENCE CONNECTIVITY

SHAPE OF STANDARD-(IZATION) TO COME

APPROCHES TO QUALITY: Identify and facilitative standardization of new scientific approaches for ensuring quality of current and new medicines and modalities throughout their lifecycles

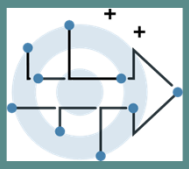
- Flexible, performance-based, risk-based, predictive
- New medicine modalities
- Article performance

TECHNOLOGIES: Facilitate adoption of analytical and manufacturing technologies with the most potential to improve quality without increasing cost

- Next HPLC
- Digital and informatics
- PCM

Advancing Science @ USP: Focus Areas

APPROACHES TO QUALITY



TECHNOLOGIES

SCIENCE CONNECTIVITY

SHAPE OF STANDARD-(IZATION) TO COME

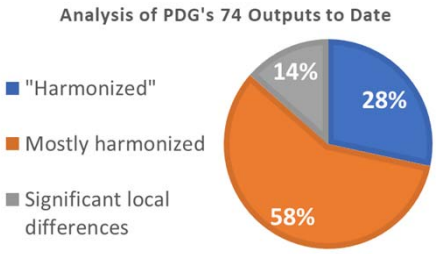
SCIENCE CONNECTIVITY: Proactively build a scientific community around USP

- New model for convening volunteer experts
- Young scientist engagement

SHAPE OF STANDARD(IZATION):

- Faster and more iterative information and knowledge dissemination
- Evolution of RS
- Interoperability of standards
- Ph. Collaboration

USP's Harmonization Learnings from PDG



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

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ASSAY

- **PROCEDURE**

Standard solution: USP Acetazolamide RS in an appropriate diluent

Sample solution: Acetazolamide in an appropriate diluent

Analytical system: Use a procedure validated as described in *MC* general chapter *and Acceptable Procedures* <10>.

System performance requirements

Precision: Meets the requirements for 98.0%–102.0%

Accuracy: Meets the requirements for 98.0%–102.0%

Specificity: Meets the requirements

Range: Meets the requirements

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of acetazolamide ($C_4H_6N_4O_3S_2$) in the *Sample solution*:

How to achieve vision #1?

Vision: Do more to increase chances of future global convergence

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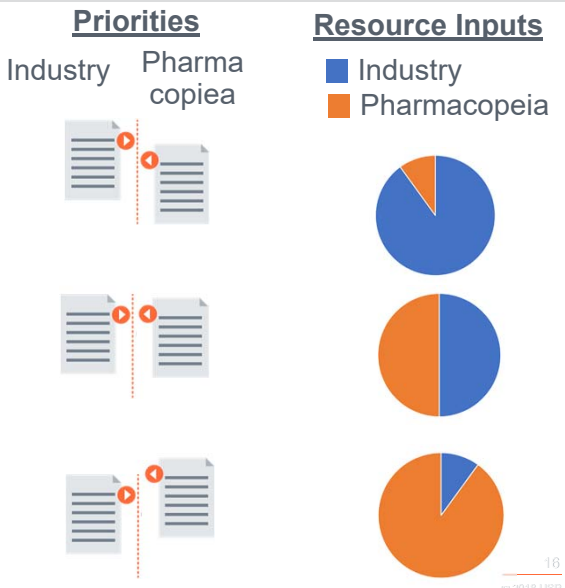
c) **Evolve existing and strengthen emerging pharmacopeias with convergence as a goal**

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

Call for Candidates

2020-2025

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

Stay Connected

jpv@usp.org | www.usp.org | @USPharmacopeia

Empowering a healthy tomorrow