USP Today: Standards for Biopharmaceutical Innovation

Ronald T. Piervincenzi, Ph.D.
Chief Executive Officer

Biologics Stakeholders Forum
January 10, 2020
Overview

- Celebrating 200 years of USP
- Engagement with regulators worldwide
- Accelerating adoption of new innovations in cell and gene therapy
Celebrating 200 years of USP
Celebrating 200 years since our founding in 1820

“The value of the Pharmacopoeia depends upon the fidelity with which it conforms to the best state of medical knowledge of the day.”

- Jacob Bigelow, MD, 1808
Mission

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

1200+ Staff

- Laboratory/Science: 53%
- Development, Mrkt & Program Ops: 4%
- Administration: 15%
- External Affairs: 10%
- Global Public Health: 10%
- Global Information Services: 9%

- United States: 58%
- Brazil: 4%
- India: 6%
- Other global sites: Ethiopia, Europe, Ghana, Indonesia, Nigeria, Singapore: 4%
Public quality standards benefit public health

**Industry**
Reduce risk to manufacturers in entering the marketplace

**Practitioner/Patient**
Uphold practitioner and patient confidence in medication therapy

**Government**
Regulators ensure quality medicines reach patients
The breadth of USP’s work can be seen through the scope of our expert committees.
Global usage of USP reference standards

USP Standards were shipped to over 22,000 manufacturers in FY19

Units of USP Reference Standards shipped globally (Top 10 countries labeled; 2015-present)
Export markets for manufacturers that use USP’s reference standards
2 Engagement with regulators worldwide
Engaging with regulators to ensure quality of medicines worldwide

- Usage of USP standards in over 150 countries
- Our partnership with U.S. FDA
  - Dating back to 1906 Pure Food and Drug Act
- Meeting with regulators through direct engagement and regional platforms
Regulatory partners around the world

BRAZIL
National Health Surveillance Agency (ANVISA) Signed June 2016

INDIA
Indian Pharmacopoeia Commission (IPC) Renewed March 2017
National Institute of Pharmaceutical Education and Research – Hyderabad (NIPER) Signed October 2016

JAPAN

LATIN AMERICA & CARIBBEAN
Pan American Health Organization (PAHO) Renewed June 2017

MEXICO
Permanent Commission of the Pharmacopeia of the United Mexican States, Fed. Commission for the Protection Against Sanitary Risks (FEUM/COFEPRIS) Renewing March 2018

RUSSIA
Federal Service on Surveillance in Healthcare (ROSZDRAVNADZOR) Renewed June 2015

SAUDI ARABIA
Saudi Food & Drug Authority (SFDA) Signed September 2015
National Institute of Food & Drug Safety Evaluation (NIFDS) Renewed April 2015

CHINA
Chinese Pharmacopoeia Commission (ChP) Renewed October 2016

INDIA
Indian Pharmacopoeia Commission (IPC) Renewed March 2017

JAPAN

LATIN AMERICA & CARIBBEAN
Pan American Health Organization (PAHO) Renewed June 2017

MEXICO
Permanent Commission of the Pharmacopeia of the United Mexican States, Fed. Commission for the Protection Against Sanitary Risks (FEUM/COFEPRIS) Renewing March 2018

RUSSIA
Federal Service on Surveillance in Healthcare (ROSZDRAVNADZOR) Renewed June 2015

SAUDI ARABIA
Saudi Food & Drug Authority (SFDA) Signed September 2015
National Institute of Food & Drug Safety Evaluation (NIFDS) Renewed April 2015

WHO WORLD MEETING OF PHARMACOPEIAS
Global & regional platforms driving harmonization

- **World Health Organization**: Official Relations Framework for Engagement of Non-State Actors (FENSA)
- **ECOSOC United Nations**: NGO Consultative Status United Nations Economic & Social Council
- **ICH**: Observer Status International Council for Harmonisation
- **APEC Life Sciences Innovation Forum**: Board Member; Center of Regulatory Excellence
- **African Medicines Quality Forum**: Reference Center of Regulatory Excellence (RefCORE)
- **Pan American Health Organization**: Official Observer Status Non-State Actor

Advocate for medicines quality issues in global policies
Consultations at different levels of governments
Regional platform: APEC

- 19 out of 21 APEC economies use USP standards
- USP-APEC Center of Excellence designation in 2017- focus on supply chain
- New Center of Excellence in 2020 with focus on advanced therapies
- Regional approach to train and implement quality standards
  - Convening US and international regulators, and industry on training to GMP, GDP, and screening technology best practices identified by APEC community
Regulatory activities in China through USP-China’s 11-year history

- Regular dialogue with senior officials from NMPA, ChP and NIFDC, and key industry stakeholders
- Advocate for strengthened global collaborations to advance medicine quality
- Held closed-door meeting with ChP, discussing future strategic collaboration direction
- Continued dialogue with ChP, NMPA
Examples of our regulatory engagement

Brazil
- Since 2016, strengthened regulatory cooperation with ANVISA under ongoing MoU
- Contributed to ANVISA’s proposal of DS regulation
- Deeper engagement with Brazilian Pharmacopoeia through roundtables, stakeholder forums, and joint education

Korea
- Renewed collaboration between USP and Korea’s drug regulator NIFDS with special focus on improving quality standards for biologic medicines for Korea and internationally
  - Joint roundtable discussions on quality of biologics
  - Scientific visitor exchange program

Mexico
- Signed an MoU with Mexico Pharmacopoeia to strengthen quality standards and patient safety
Strengthening medical product quality assurance regulatory systems in low-middle income countries

- 25+ year history with USAID
  - 10 year Promoting the Quality of Medicines (PQM) program
  - PQM+ work commenced October 2019
    - $160 Million cooperative agreement over five years

- Ensuring robust quality medicine through
  - Risk-based resource allocation
  - Information and data
  - Regional collaboration
  - Workforce development
3

Accelerating adoption of new innovations in cell and gene therapy
Two centuries of accelerating innovation

- **Reduce barriers to innovation** with Up-To-Date trusted, tested public standards and methods

- **Accelerate the uptake of innovative technologies** via partnerships and collaboration for their timely adoption

- **Facilitate the spread of innovation** by engaging internationally through programs and trainings to grow capabilities on standards, quality, and regulatory topics
  - USP’s standards are used in over 150 countries
  - Drug/medical device combinations
  - Biologics performance standards
How USP supports innovation

- **Continuous innovation**
  - Evaluating state of the industry practices to update our standards and respond to emerging needs

- **Technological innovation**
  - We assess innovative technologies for suitability and readiness for use by stakeholders, reducing risk to industry.

- **Therapeutic innovation**
  - We proactively work with the dynamic pace of healthcare by facilitating continued modernization of standards for legacy products
Pharmaceutical Continuous Manufacturing

USP’s role in promoting quality

- Helping formulate harmonized guidelines (ICH Q13)
- Developing curriculum to train workforce
- Sponsoring scientific research comparing Batch-CM routes
- Published stimuli article in *USP-NF*
- Exploring application of PCM in biologics
Convergence supporting innovation

- Efficiency and regulatory predictability in manufacturing and innovation processes
  - Standards that verify and codify processes and components of product development and manufacturing to enable innovators to focus on discovery

- Science-based expectations for medicine quality
  - A fundamental tool for regulatory oversight, and pharmaceutical manufacturing
Prioritizing public quality standards for devices that are critical to a medicine having its intended therapeutic effect

Not exhaustive
Prefilled syringe example

Sources: USP-NF Research; Chapter Chart 4b Chemical Medicines Drug Products—Specific Tests
Note that the monograph mentions prefilled syringes in context of being a container; syringes are defined as primary packaging components, being in direct contact with the article. USP does not have a monograph for the performance of the specific drug-device product. Not pictured: USP Fondaparinux Sodium for Assay RS, USP Fondaparinux Sodium System Suitability Mixture B RS
How USP drives impact in biologics

Develop new standards for biologics based on broad understanding of public health as well as regulatory and technology impact

- Modernization of standards for legacy biological products
- Prioritization of performance standards with broad applicability to classes and families of products
- Development of standards to support emerging therapies based on novel technologies
- Engagement and scientific connectivity with biologics stakeholders across industry, government, regulators, and academia
Stay Connected
@RonPiervincenzi | www.usp.org | @USPharmacopeia

Empowering a healthy tomorrow