Ensuring the supply of quality medicines

An Overview of USP
January 2023
Overview

- USP’s third century
- Our Impact
- Future commitments
USP’s third century
Our enduring mission

"To improve global health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods."
More than 1300 USP staff deliver our global mission
USP staff are located where medicines are made

<table>
<thead>
<tr>
<th>Region</th>
<th>Location</th>
<th>Laboratory &amp; Standard Setting</th>
<th>Engagement (scientific, customer and stakeholder)</th>
<th>Strategic support</th>
</tr>
</thead>
<tbody>
<tr>
<td>North America</td>
<td>Frederick, MD</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td></td>
<td>Rockville, MD</td>
<td>●</td>
<td>●</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Washington, D.C</td>
<td>●</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Latin America</td>
<td>Brazil</td>
<td>●</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Chile</td>
<td>●</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mexico</td>
<td>●</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Southeast Asia</td>
<td>China</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td></td>
<td>Knowledge Park, Hyderabad, India</td>
<td>●</td>
<td>●</td>
<td></td>
</tr>
<tr>
<td></td>
<td>HITEC City, Hyderabad, India</td>
<td>●</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Singapore</td>
<td>●</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>South Korea</td>
<td>●</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Middle East and Africa</td>
<td>Ghana</td>
<td>●</td>
<td>●</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Jordan</td>
<td>●</td>
<td>●</td>
<td></td>
</tr>
<tr>
<td>Europe</td>
<td>Basel, Switzerland</td>
<td>●</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Donor funded work (e.g., PQM+, World Bank, etc.)</td>
<td>Bangladesh, Ethiopia, Ghana, Indonesia, Kenya, Nepal, Nigeria, Pakistan, Uzbekistan</td>
<td>●</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td></td>
<td>Rockville, MD</td>
<td>●</td>
<td>●</td>
<td></td>
</tr>
</tbody>
</table>
USP convention – regional and sector engagement

**Sectors**

- Biologics sector
- Healthcare Practice sector
- Generic Medicines sector
- Dietary Supplements sector
- Excipients sector
- Innovation sector

**Chapters**

- South Asia Regional Chapter
- Latin America Regional Chapter
- Asia Pacific Regional Chapter
- Greater China Regional Chapter
- Middle East and North Africa Regional Chapter

To be developed

Europe

Sub-Saharan Africa

© 2022 USP
More than 7,000 USP standards support quality across the supply chain

**Manufacturing**
- Standards
  - Drug and API monographs
  - Compounding monographs
  - General chapters
  - Characterized reference materials
- Manufacturer capability building
  - Advanced Manufacturing, incl. Pharmaceutical Continuous Manufacturing
  - USAID-funded PQM+ program
  - API and excipient verification

**Distribution**
- Standards
  - Good Distribution Practices
  - Packaging and distribution

**Administration**
- Standards
  - Labeling
  - Nomenclature
  - COVID-19 Vaccine Handling Toolkit

**Collaborations**
- USAID-funded PQM+ program for regulatory capability building in low- and middle-income countries
- APEC Center of Excellence on product and supply chain quality
- Co-hosted summits with WHO to advocate for medicines quality around the world
- Collaboration towards pharmacopeial convergence within the Pharmacopeial Discussion Group (PDG)

**Supply chain diagnosis and monitoring**
- Medicine Supply Map – identifying, characterizing and quantifying risk in the upstream supply chain
Factors shaping our evolution

- Digitalization, Data Analytics, Informatics
- Explosion of new medicine modalities
- Complex, globalized supply chain
- New quality paradigms and analytical technologies
- New ways of engaging scientists
- Medical information & knowledge tsunami

COVID-19 Pandemic
Responding to today’s public health challenges through coordinated standards, advocacy, and capability building

- **Standards**: To be a definitive source of standards for the supply of quality medicines

- **Advocacy**: To be the global institutional leader advancing the supply of quality medicines

- **Capability Building**: To be a leading provider of services that advance the supply of quality medicines to improve the health and well-being of people and patients
Our impact
Public health priorities we are helping to address

- COVID-19 response
- Supply chain resiliency
- Harnessing advances in biomedical science
- Expanding regulator capacity
COVID-19 response

Helping to ensure the supply of quality vaccines, treatments and health information
Supply chain resiliency

Delivering insights to inform decision making

- Informatics to identify risks in the upstream supply chain
- 200,000 data points
- Developed to inform investments, purchasing, and policy reforms

Leveraging standards and technology to enhance production of quality medicines

- Standards to foster adoption of pharmaceutical continuous manufacturing and 3D printing
- Partnership with Phlow to provide a supply of essential medicines utilizing continuous manufacturing
**Harnessing biomedical innovation**

**Standards that help accelerate innovative drug development**

<table>
<thead>
<tr>
<th>Industry challenge</th>
<th>USP performance standard solutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ensure accuracy and consistency</td>
<td>CD34+ cell counting</td>
</tr>
<tr>
<td>Assess quality attributes across lots and manufacturers</td>
<td>mRNA vaccine general chapter</td>
</tr>
<tr>
<td>Confidence in analytical testing and quality control of new modalities</td>
<td>Monoclonal antibodies work</td>
</tr>
</tbody>
</table>
Regulator capacity

Supporting regulator capabilities around the world

**Middle East/North Africa:** Workshop on Analytical methods for Vaccines' Quality

**Thailand:** Regulatory awareness on Emergency Use Authorizations for vaccines and diagnostics for LMIC regulators, by USP & USAID

**South Korea:** Workshop on Cell and Gene therapies with NIFDS on regulatory and compendial perspectives

**Singapore:** Partnered with Centre of Regulatory Excellence on good reliance practices and post marketing surveillance

**APEC:** USP hosts two Centers of Excellence for Regulatory Science (CoE)
- Supply Chain CoE 2021 programming in Malaysia
- Advanced Therapies CoE programming on raw materials and also bioassays
3 Future commitments
Meeting the challenges of public health priorities

1. Remove barriers to the adoption of advanced manufacturing technologies to support production of quality medical products

2. Characterize supply chain vulnerabilities that enable our partners' preventative and mitigative actions

3. Expand services to individual manufacturers to enhance capacity to produce quality medical products

4. Create and modernize standards to address the most pressing issues in production of quality medical products

5. Support the quality supply of current and future COVID-19 treatments in, and entering, the market
Improving the pharmaceutical environmental footprint initiative

Furthering USP’s leadership role in improving the environmental impact of pharma manufacturing, quality testing, and across the supply chain while ensuring quality medicines

- Inventory finding over 3 decades of positive impact through USP modernization and harmonization initiatives
- Early stakeholder roundtable with key pharma and environmental associations
- US government engagement (Office of Science and Technology Policy, FDA, EPA) and international planning (Pharmacopeial Discussion Group)

- New incubation exploring over 60 opportunities for standards, advocacy and capability building
Thank You

Empowering a healthy tomorrow