Ensuring the supply of quality medicines

An Overview of USP

January 2023

Overview

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

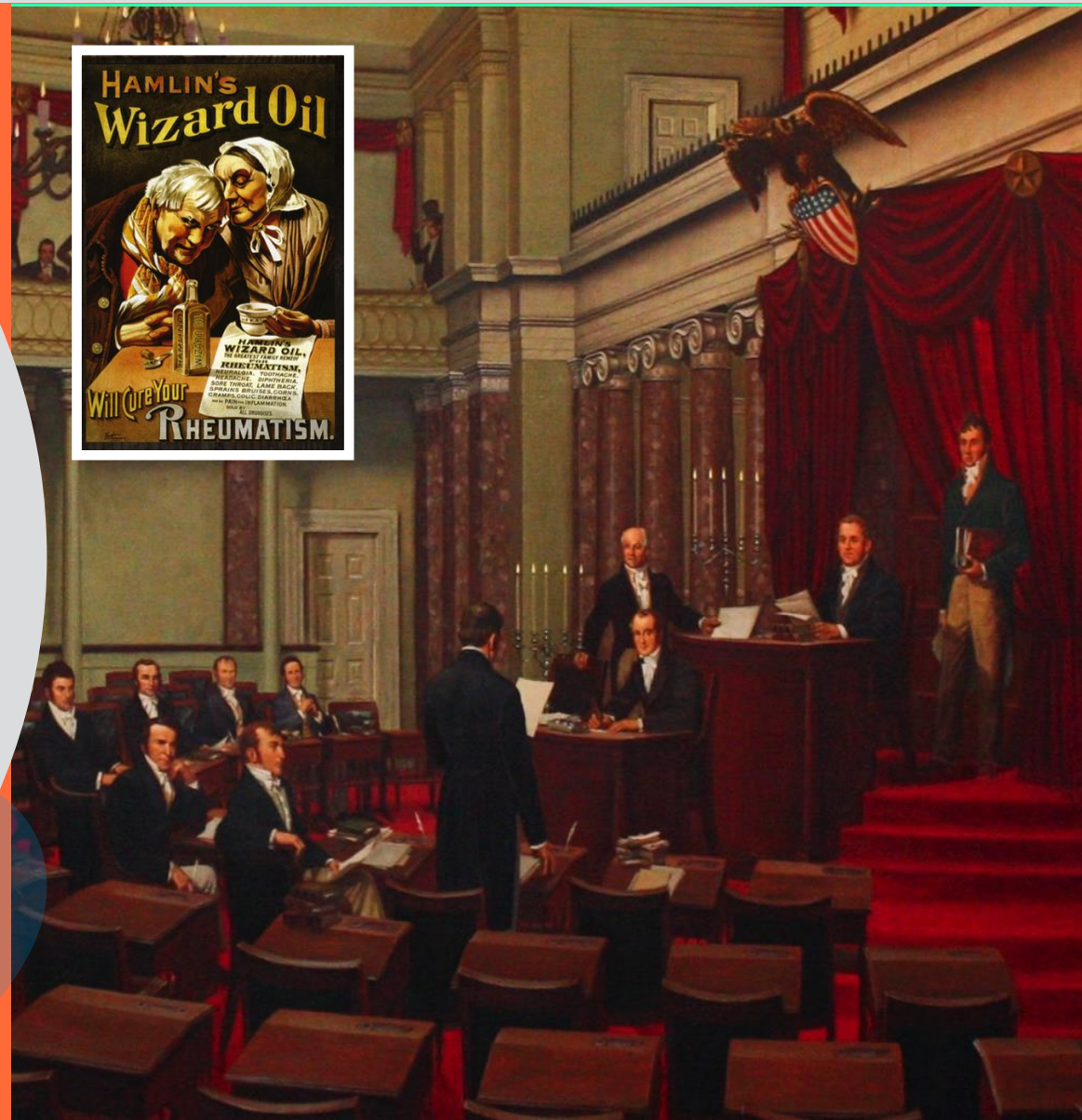
© 2019 USP

1 USP’s third century

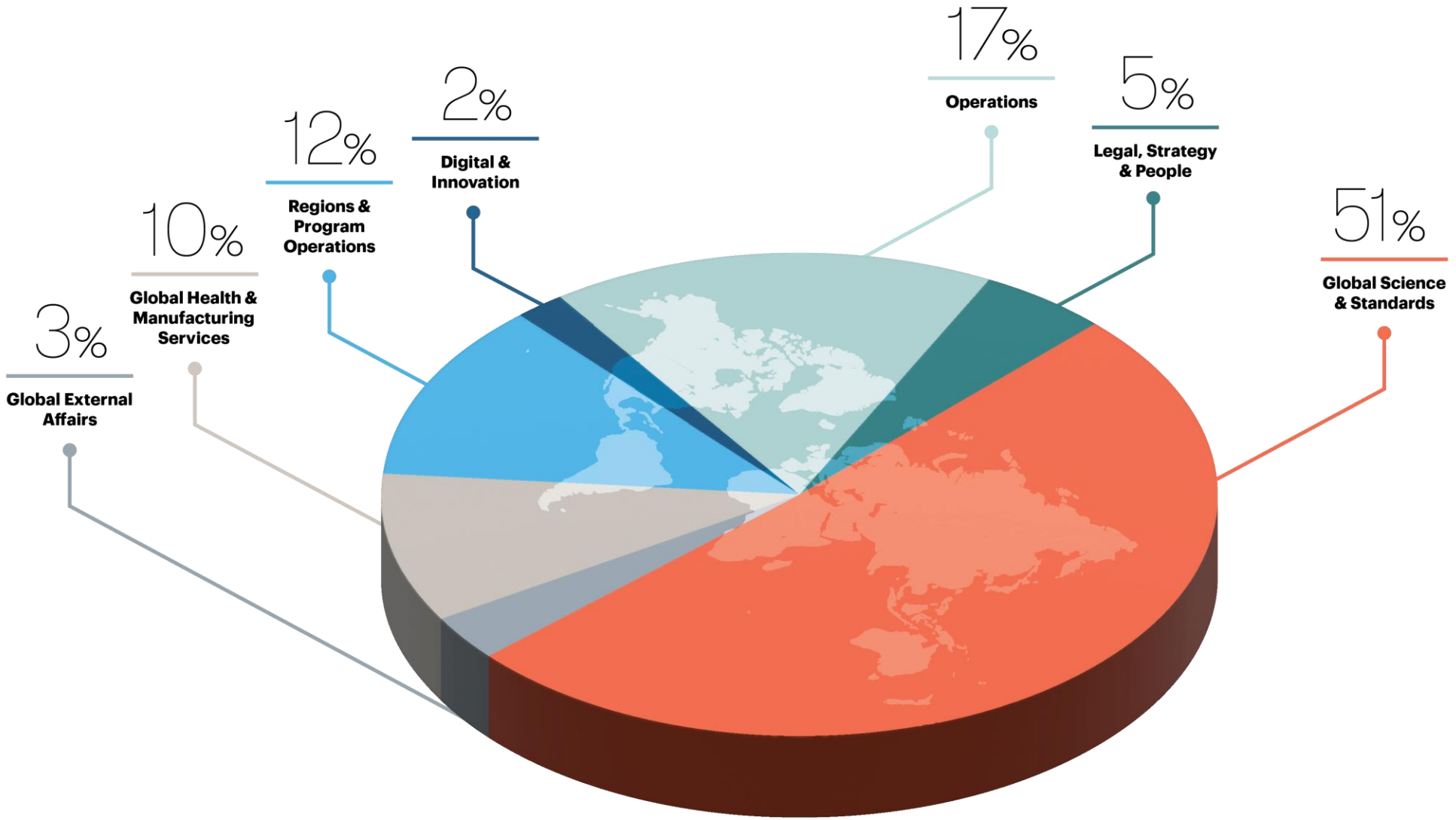
© 2018 USP

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



© 2023 USP

USP staff are located where medicines are made

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

:1 USP

USP convention – regional and sector engagement

Sectors

Chapters

To be developed

Europe

Sub-Saharan Africa

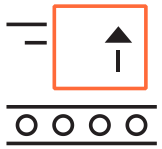
© 2022 USP

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

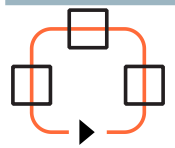
Administration

- 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

© 2021 USP

Factors shaping our evolution

Digitalization, Data Analytics, Informatics

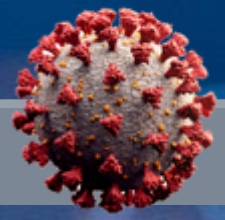
Explosion of new medicine modalities

Complex, globalized supply chain

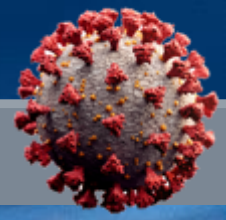
New quality paradigms and analytical technologies

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

2 Our impact

© 2018 USP

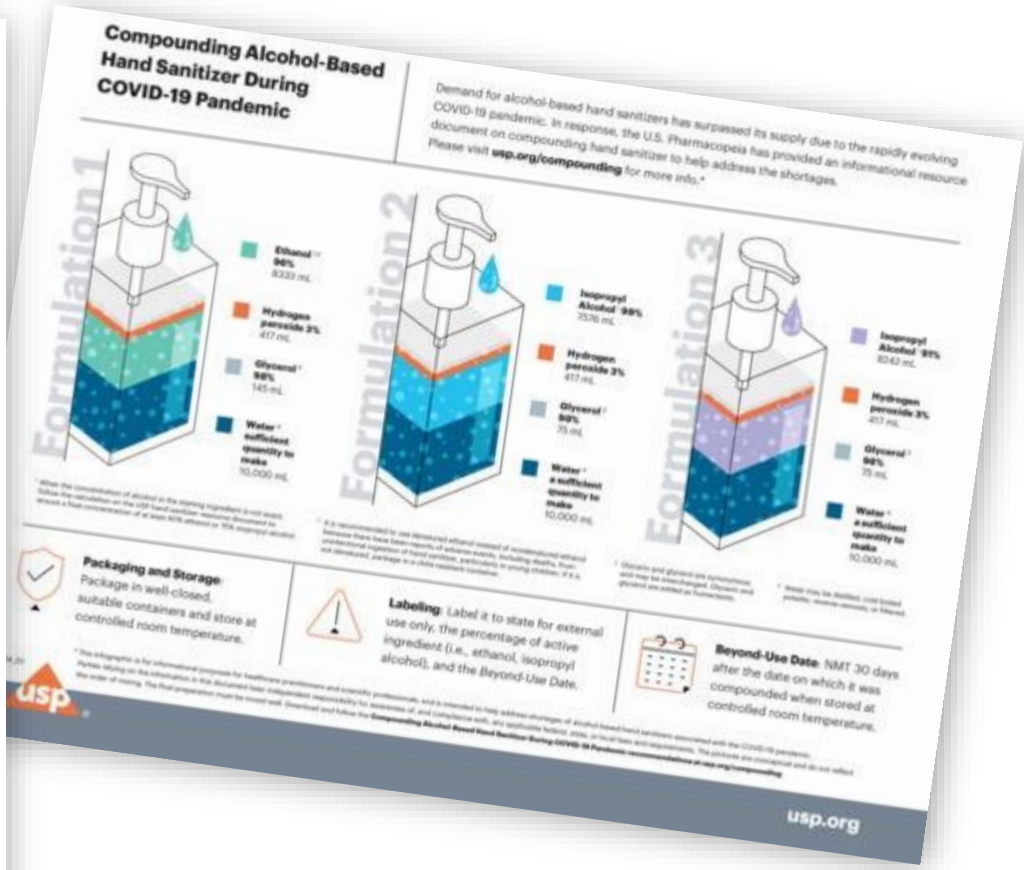
Public health priorities we are helping to address

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

© 2022 USP

COVID-19 response

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

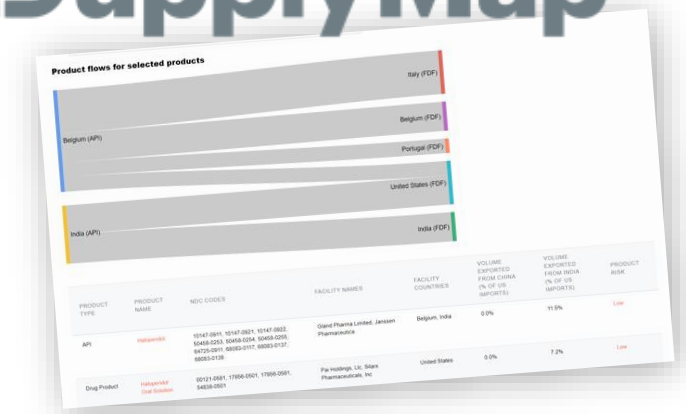


© 2022 USP

Supply chain resiliency

Delivering insights to inform decision making

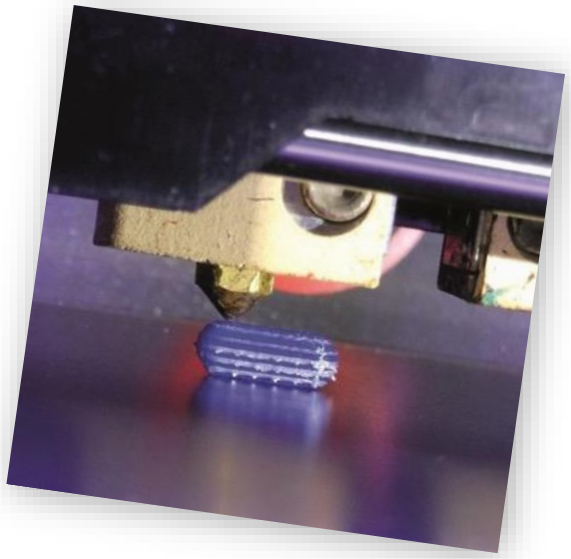
Medicine SupplyMap



- 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



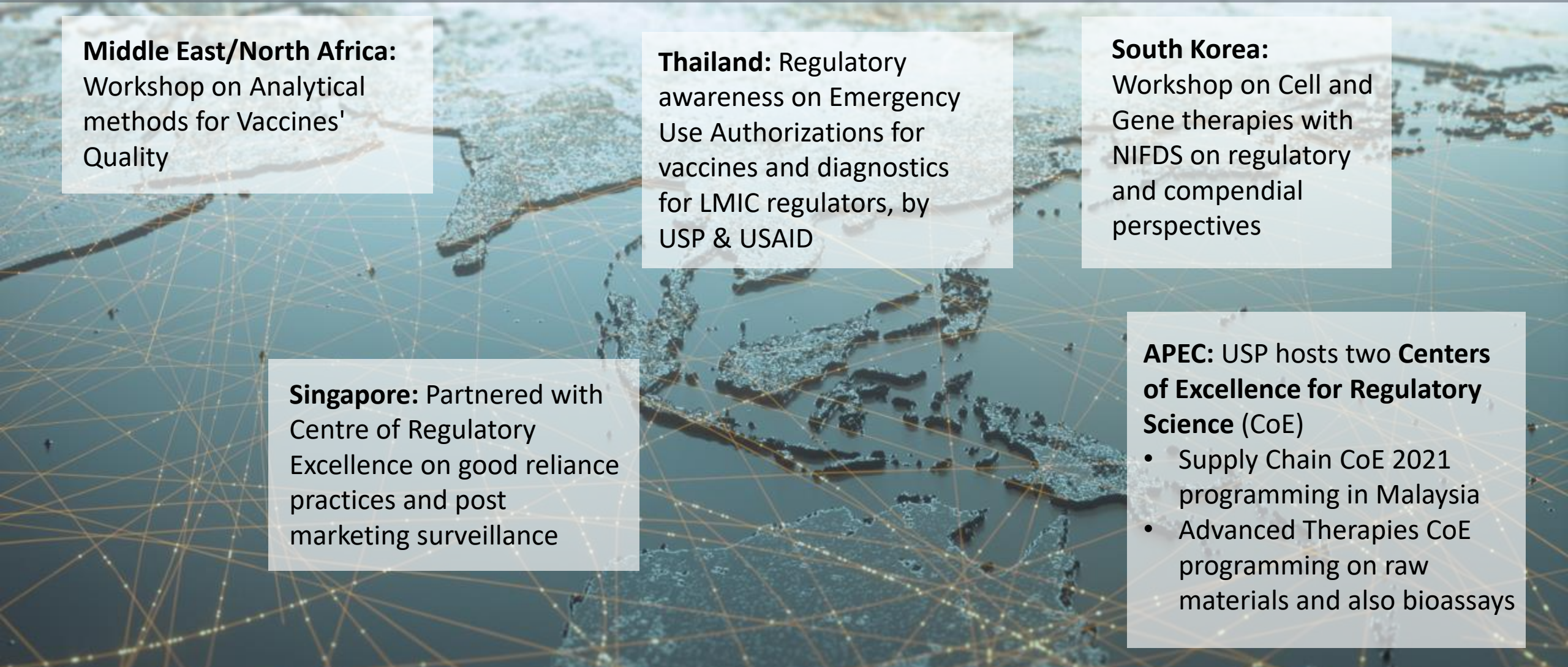
Harnessing biomedical innovation

Standards that help accelerate innovative drug development

Industry challenge	USP performance standard solutions
Ensure accuracy and consistency	**CD34+ cell counting**
Assess quality attributes across lots and manufacturers	**mRNA vaccine general chapter**
Confidence in analytical testing and quality control of new modalities	**Monoclonal antibodies work**

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

Future commitments

© 2018 USP

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

USP Convention Resolution

Environmental Concerns (1995)

The USP is encouraged to initiate a program to protect the environment by adopting standards and analytical methods for pharmaceuticals, containers, and other articles that reduce the amount of reagents and materials used in pharmaceutical tests and assays that have the potential to cause harm to human health and the environment.

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

- 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)

Jane Sheridan, chairman of the USP Subcommittee on Chemical Purity.

Methods specific for the solvent residues that may be present should be used, and the limits for toxic solvents such as methylene chloride and methanol should differ from those for compounds like ethanol.

© 2021 USP

Thank You

Empowering a healthy tomorrow