

USP Overview and Global Impact USP

USP-PMDA Meeting

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USP's enduring mission



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



USP Today



- ▶ Global non-profit organization founded in 1820
- ▶ 1,300+ global staff
- ▶ Offices in seven countries
- ▶ 2 hubs: Maryland, USA and Hyderabad, India
- ▶ Governed by:
 - Convention of 460+ organizations with 40+ countries represented
 - Council of Experts
 - 800+ expert volunteers
 - 250+ FDA liaisons
 - Board of Trustees



USP Convention Sectors & Chapters



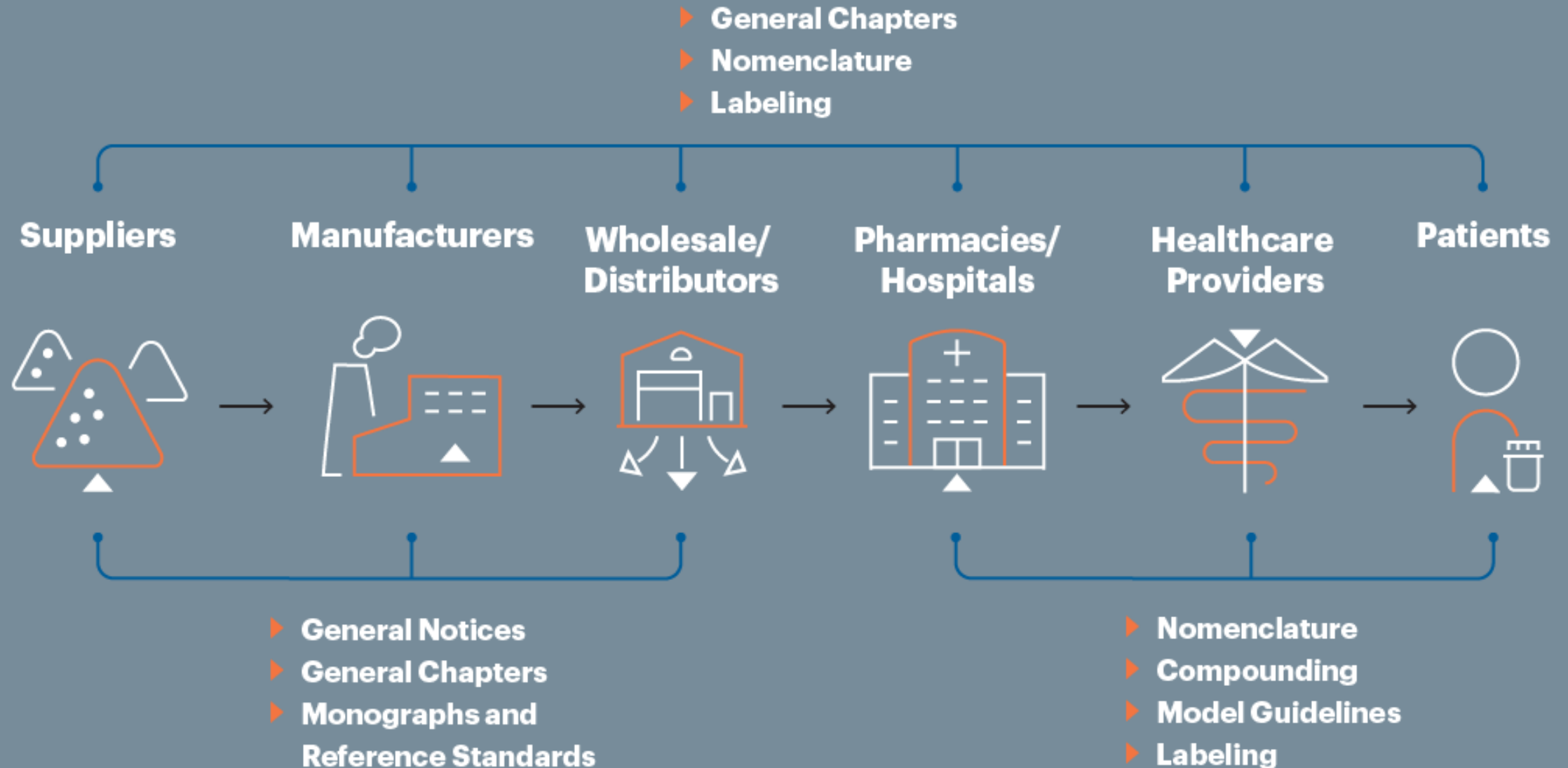
Convention



- ▶ Share information
- ▶ Learn from each other
- ▶ Provide insight to USP
- ▶ Sectors: Collaborate on priority topics
- ▶ Chapters: Engage with Regional Chapter members and address shared Regional interests



More than 9,000 USP standards support quality across the supply chain



USP impact



USP standards used in
150+ COUNTRIES
around the world



Every year, **BILLIONS**
of people rely on
medicines based on
USP standards



Our scientists and
volunteers dedicate
7,000+ HOURS of time
each year to our mission

REGIONAL CHAPTER: AFRICA | ASIA-PACIFIC | CHINA | EUROPE | LATIN AMERICA | MIDDLE EAST | SOUTH ASIA

CONVENTION SECTORS: GENERICS | BIOLOGICS | HEALTHCARE PRACTICE | EXCIPIENTS | INNOVATION |
DIETARY SUPPLEMENTS

We are increasing access to quality medical products



Fostering local
manufacturing



Strengthening
regulatory and
laboratory
systems

Optimizing
resources and
financial structures
for sustainability



Strengthening
medical product
quality assurance
systems



We have partnerships across the globe – both bilateral and with multilateral organizations



- ▶ MOUs with 30+ organizations worldwide
- ▶ Our partnerships have strengthened 65+ NRAs globally



Official Relations Framework for
Engagement of Non-State Actors (FENSA)



**ICH Observer and Founding Member of the
Pharmacopoeial Discussion Group (PDG)**



**Asia-Pacific
Economic Cooperation**

**APEC Regulatory Harmonization
Steering Committee**

Center of Excellence for Supply Chain
Center of Excellence for Advanced Therapies



African Medicines Quality Forum
Reference Center of Regulatory
Excellence (RefCORE)



**Pan American
Health
Organization**



REGIONAL OFFICE FOR THE
Americas

Official Observer Status
Non-State Actor

Advocate for medicines quality issues in global policies
Consultations at different levels of governments

USP & PMDA – enduring partnership

- ▶ Pharmacopeial Discussion Group (PDG): 35 year partnership in PDG focusing on the harmonization of excipient monographs and general chapters.
- ▶ PMDA/MHLW Executive Exchange Partnership, with a total of six liaison officers visiting USP from 2012-2020.
- ▶ Prospective Harmonization Pilot started 2023; first example of a bilaterally harmonized drug product monograph between USP and JP
- ▶ Future collaboration on increasing global convergence of standards between USP and JP where possible



Amplify your impact as a USP Expert Volunteer



Share your expertise,
knowledge, and
experience with others
from around the world.
Learn more and apply.



2025 – 2030 Strategic Priorities



Convention



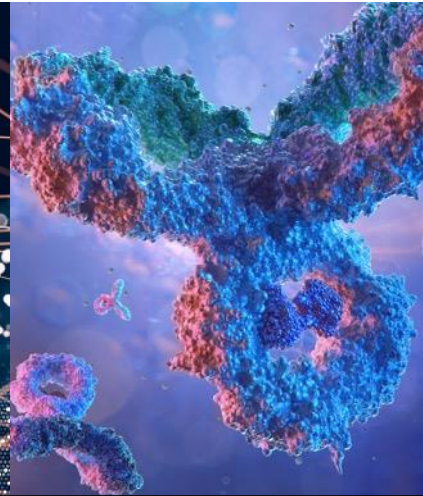
Increase the volume of the world's most relied upon quality-assured medicines



Solve cross-cutting quality challenges to improve medicines, dietary supplements, and foods



Strengthen resilience of the global pharmaceutical supply chain



Expand availability of and access to quality-assured biologics products



Accelerate adoption of digital tools for quality assurance of medicines



Enable more environmental sustainability across pharmaceutical life cycle



Thank You



The standard of trust