Pharmacopeial Collaboration and Harmonization: PDG from the USP Perspective

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Tokyo, Japan
October 3, 2019

Presentation Outline

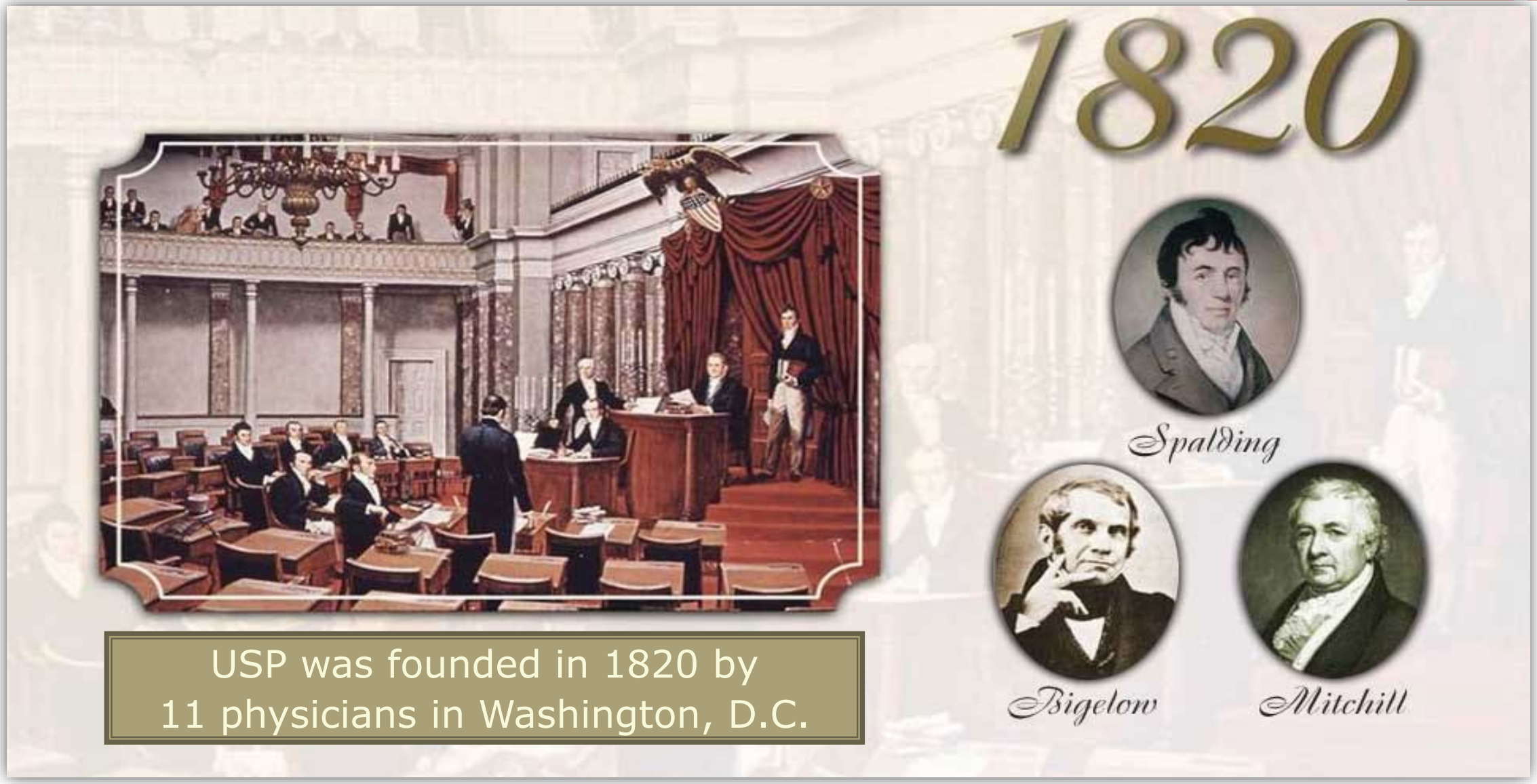
- USP Overview and Strategy
- Benefits of Pharmacopeial Collaboration and PDG History from the USP Perspective
- Future Vision for PDG and the Pharmacopeial Collaboration Model

PDG Delegation, Rockville 2017

Mission

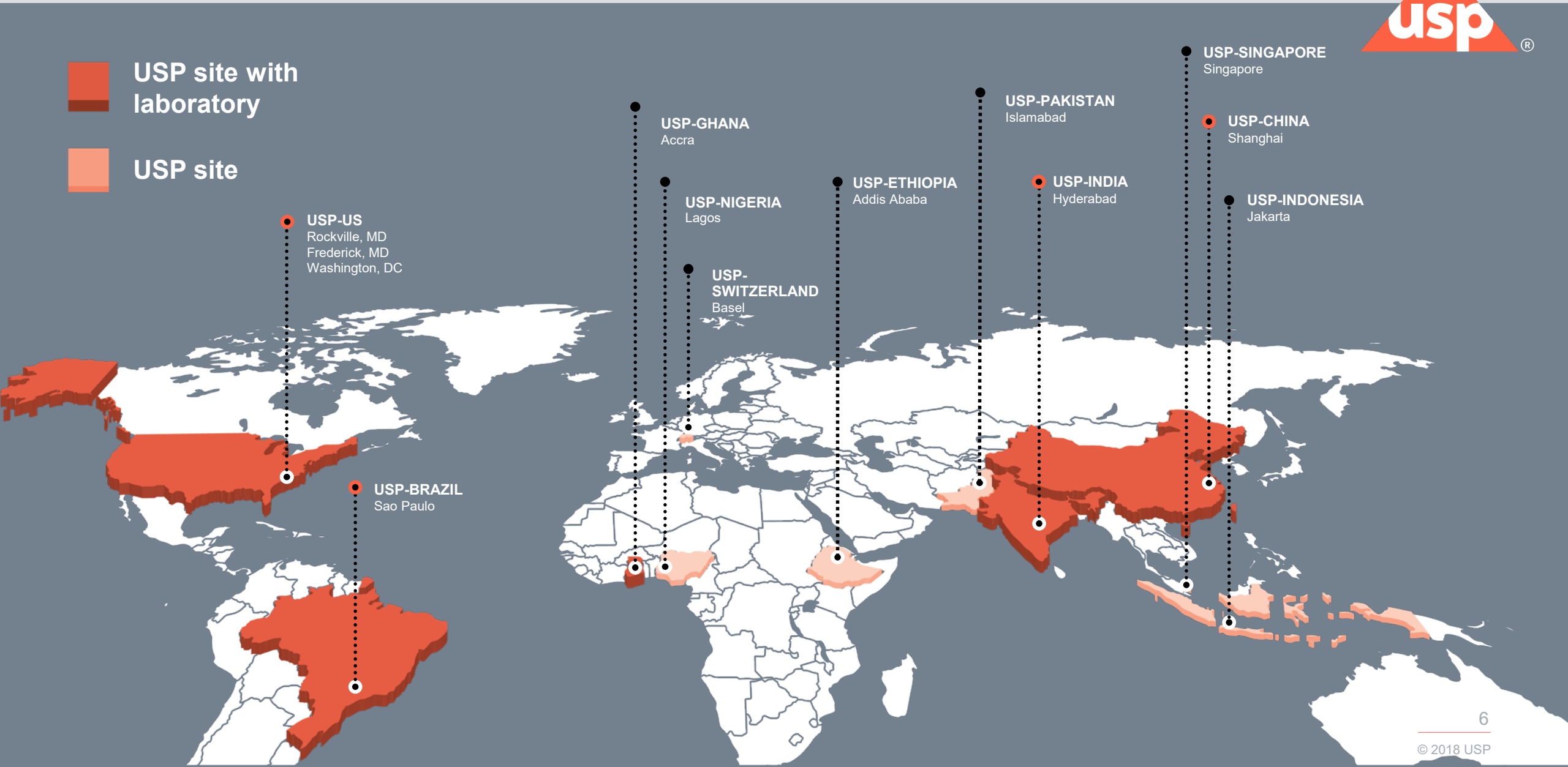
To improve global health through public standards and related programs that help ensure the quality, safety and benefit of medicines and foods

USP's Original "Harmonization" Team



200 Years of Building Trust

We Work Globally



USP 2020-2025 Strategy

Impact Ambitions

USP's work is a powerful tool in solving today's public health challenges by:

- Being a voice for medicine quality
- Building capabilities around the world to advance medicine quality, and
- Developing quality public standards for today's evolving public health needs

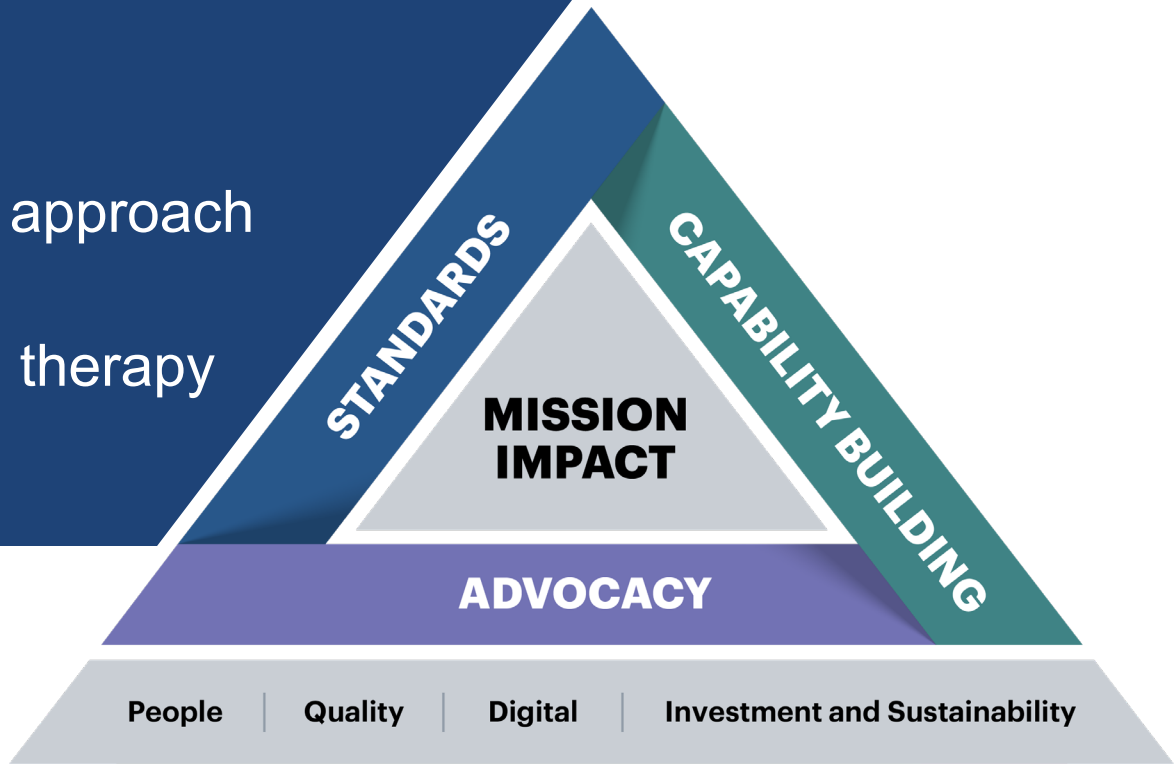
Enabling Ambitions

Our Enabling Ambitions are critical success factors that must be cultivated in order for us to fulfill our mission and deliver the greatest impact.

2025 Strategy: Diving Into Standards

USP WILL BE A DEFINITIVE SOURCE OF MEDICINE AND FOOD QUALITY STANDARDS

- Remain Up-to-Date
- Adopt a more flexible, agile, and iterative approach to standards development and delivery
- Address new and emerging products and therapy classes



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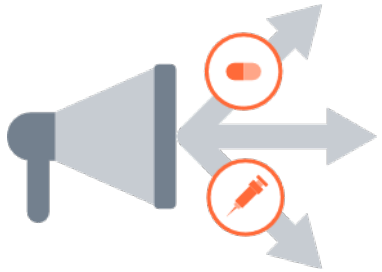
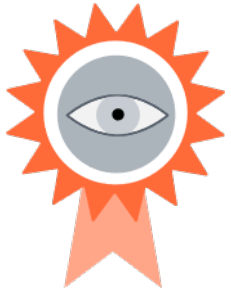
Value of Effective Pharmacopeial Collaboration



PROMOTE

Access to Quality medicines leveraging global expertise



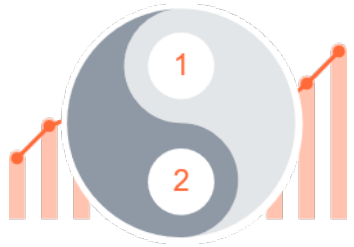
INCREASE

Visibility Importance of pharmacopeias

Value of public quality standards

FACILITATE

Global access to state of the industry technology



PRIORITIZE

Balance current paradigms and future trends

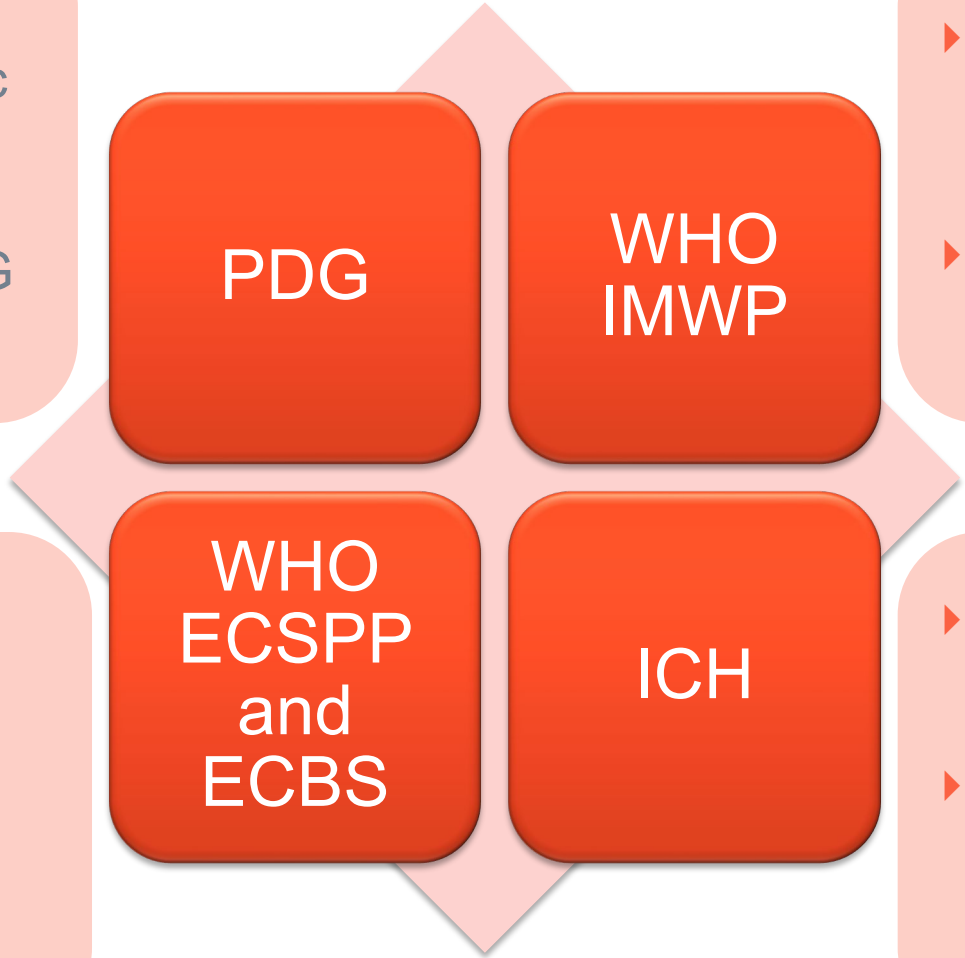
ENABLE

Global pharmaceutical trade

The Global Landscape is Ever Changing

- Current work program is chapter and excipient-centric
- Processes currently undergoing overhaul by PDG partners (USP, EP, JP)

- Current work program is product quality centric and focused on essential medicines



- Good Pharmacopeial Practices document completed
- Dialogue on value of Pharmacopeias

- Approach to Quality topics is in transition
- ICH membership expanding, but pharmacopeial participation in strategic quality dialogue is limited

Pharmacopeial Discussion Group (PDG) – 30 Years of Collaboration

- Formed in 1989 as an informal body of representatives from
  - European Pharmacopoeia (EDQM)
  - Japanese Pharmacopoeia (MHLW/PMDA)
  - United States Pharmacopeia (USP)
  - WHO (observer since 2001)
- Linked to ICH until 2011
- Focused on harmonizing general chapters and excipient monographs
- Limited but steady progress through retrospective harmonization

PDG Definition of Harmonization

- “A pharmacopeial general chapter or other pharmacopeial document is harmonized when a pharmaceutical substance or product tested by the document’s harmonized procedure as published in EP, JP and USP yields the same results, and the same accept/reject decision is reached”

- “Key Takeaways:
  - Text does NOT have to be identical
  - Each pharmacopeia can adapt the text to local style, and take into consideration local reference standards and reagents

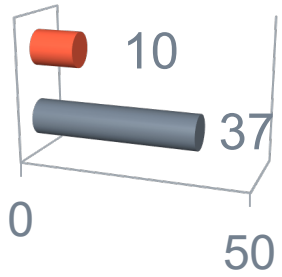
PDG: A Story of Limited But Steady Progress

Recent success stories

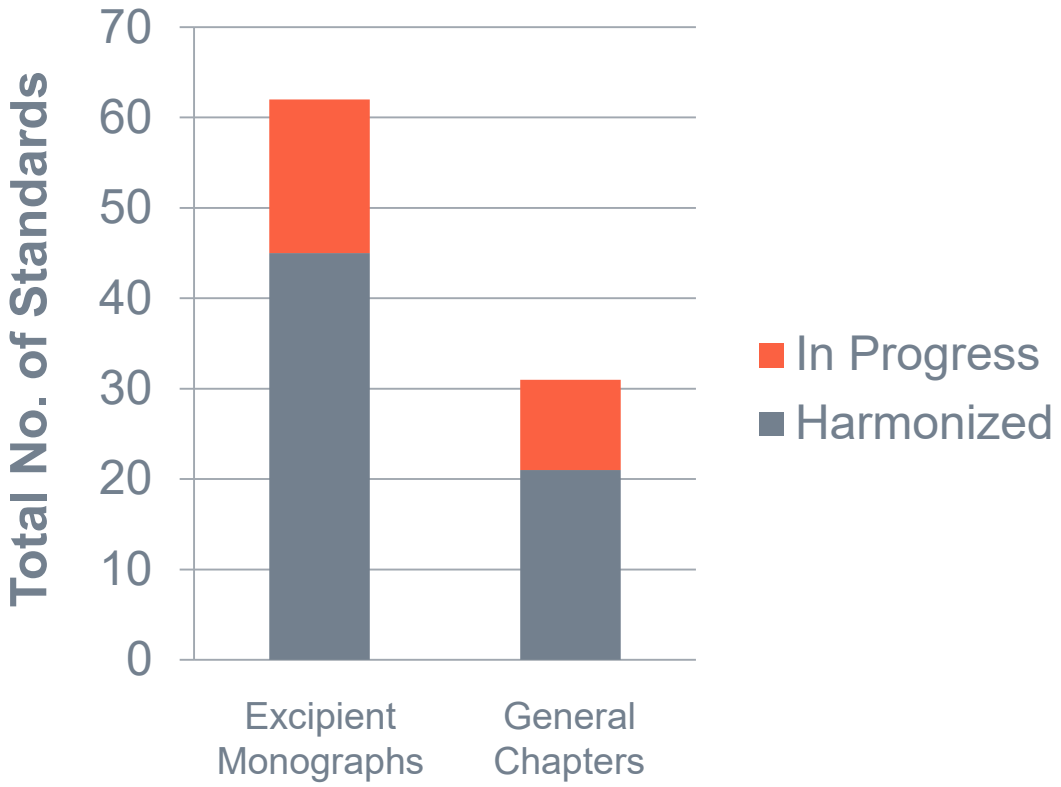
- PDG successfully resolved 11 difficult points of contention to harmonizing on the chapter on Sterility during one face-to-face meeting of the technical experts
- PDG successfully updated the monographs for six chemically modified cellulosic excipients with specific GC Assay methods

Tangible benefits of harmonization:

Number of Attributes required for USP, EP, and JP compliance in the case of the **harmonized versus** non-harmonized monograph



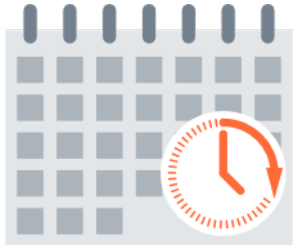
PDG Workplan Overview



Retrospective Harmonization – Challenges

Resource Intensive

- Staff
- Volunteer



Time (long process)

- Harmonization of standards to completion

Priority misalignment

- Standards and policies from pharmacopeial partners

Inefficient

Revision Hesitance

PDG Reforms – Outcomes following 2017 meeting

- Simplify PDG harmonization process steps
- Engage technical experts more directly and frequently
- Two annual meetings (one FtF) focused on strategy and prioritization
- Pilot phase for prioritization scheme for excipient monographs and general chapters

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Opportunities for PDG

- Maintain relevance in a highly globalized environment, and engage with other pharmacopeias and regulators outside of US, Europe, and Japan in new ways
  - International Meeting of World Pharmacopeias (IMWP) can view and comment at PDG text at Stage 2 and adopt PDG text at Stage 4
- Engage ICH and adapt to reforms
  - Pharmacopeias should play a critical role in the evolving ICH Quality Strategy. USP has provided leadership in shaping this overall strategy.
  - Scope of Q6 is wider than Q4, yet dependent on Q4. Other Q topics have been proposed (Q2/Q14, Q13) with USP experts participating
  - Maintenance procedures for Q4 Annexes – PDG will own content and process

PDG – Past, Present, and a Proposed Future

PAST

- Excipients and General Chapters Harmonized by Attributes
- Retrospective harmonization through formal 7 step process
- Communication between PDG pharmacopeias through written correspondence and discussions at bi-annual PDG meetings

PRESENT

- Strategic review of harmonization areas and work items
- Restructured meeting format to engage more effectively at technical level
- Streamlined working procedure and improved transparency of activities to stakeholders and other pharmacopeias

FUTURE

- Focus on Convergence – Alignment on common standards that ensure quality
- Develop globally implementable modernized standards
- Strategic partnering with critical stakeholders – linking activities to other collaborative venues (ICH, WHO)

Conclusion: A Vision for Convergence

- Convergence around **quality** standards
- Develop standards with an **innovation** focus
- Improve **global** access to quality medicines
  - 100% harmonization is aspirational, not always realistic
  - Partial harmonization feasible under a convergence model
  - Convergence on agreed sections better than a binary “not harmonized” result
- Must meet appropriate bar for quality
- In line with current best practice in regulatory harmonization

2020–2025

call for candidates

Join us on the Journey

Collaborate with highly dedicated leaders from science, medicine, healthcare practitioners, industry and academia to help us establish standards that make it possible for 2 billion people around the world to have access to quality medicines, dietary supplements and foods.

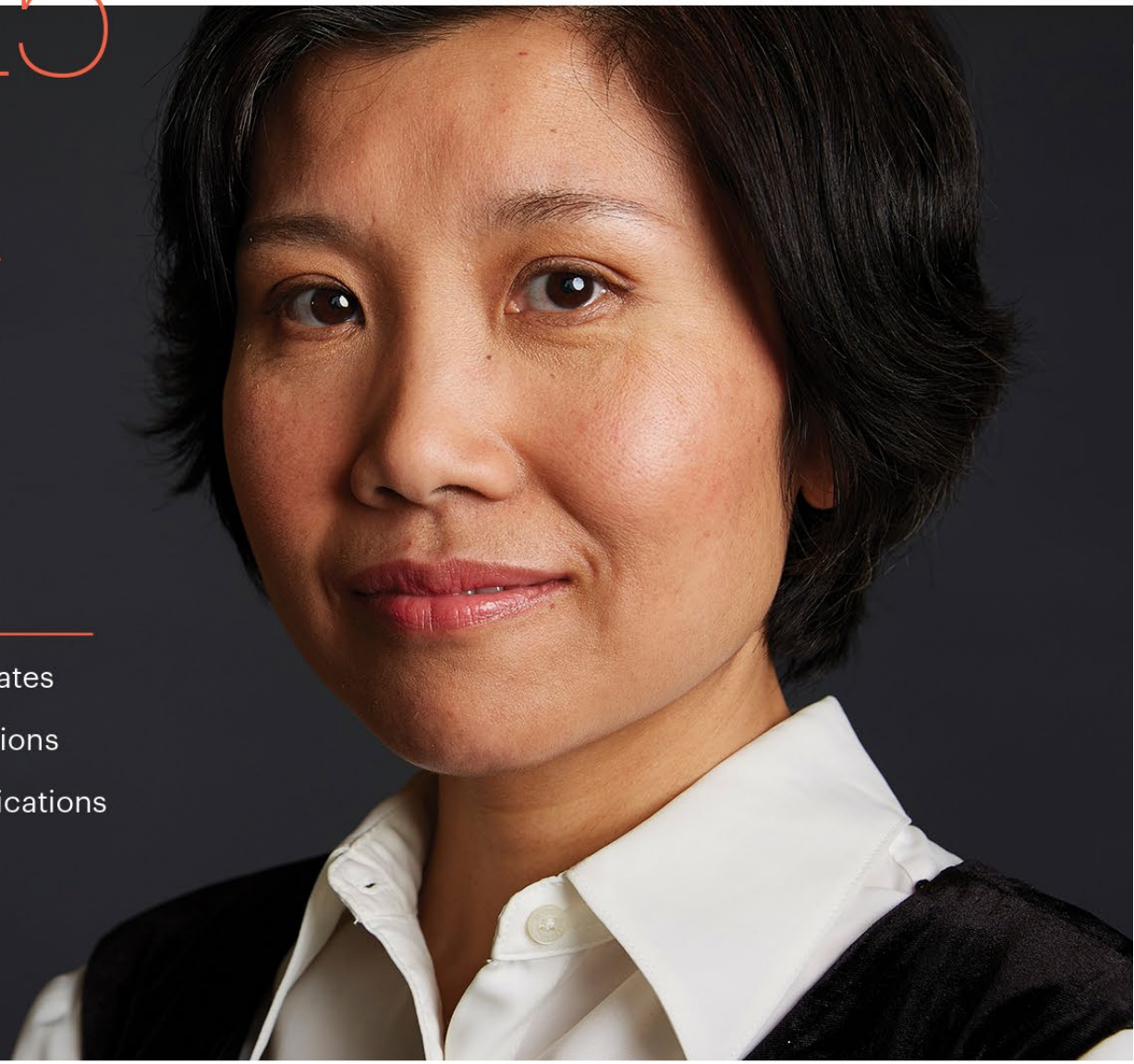
Important dates:

Jul 2018: USP launched the 2020-2025 Call for Candidates

Jan 2020: Deadline for Expert Committee chair applications

May 2020: Deadline for Expert Committee member applications

Jul 2020: 2020–2025 Council of Experts and Expert Committees begin their work



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For additional information visit **callforcandidates.usp.org** or contact **USPVolunteers@usp.org.**

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USP Harmonized Standards| jpv@usp.org

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