The United States Pharmacopeia (USP)

Overview of Pharmacopeial Convergence and Harmonization: Pilot for USP- JP Prospective Harmonization

Kevin Moore; Sr. Manager, Pharmacopeial Collaboration
Behnaz Almasi; Principal Scientist, Small Molecules
Andrea Carney; Senior Manager, Small Molecules

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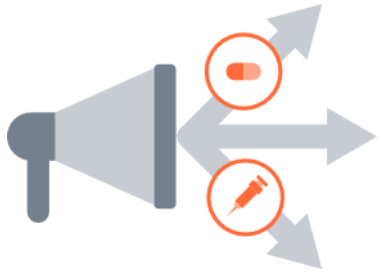
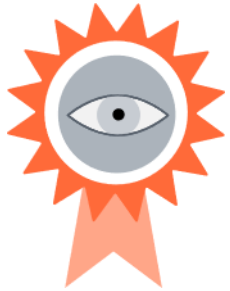
The Value of Effective Pharmacopeial Collaboration



PROMOTE

Access to Quality medicines leveraging global expertise



INCREASE

Value of public quality standards

FACILITATE

Global access to state of the industry technology

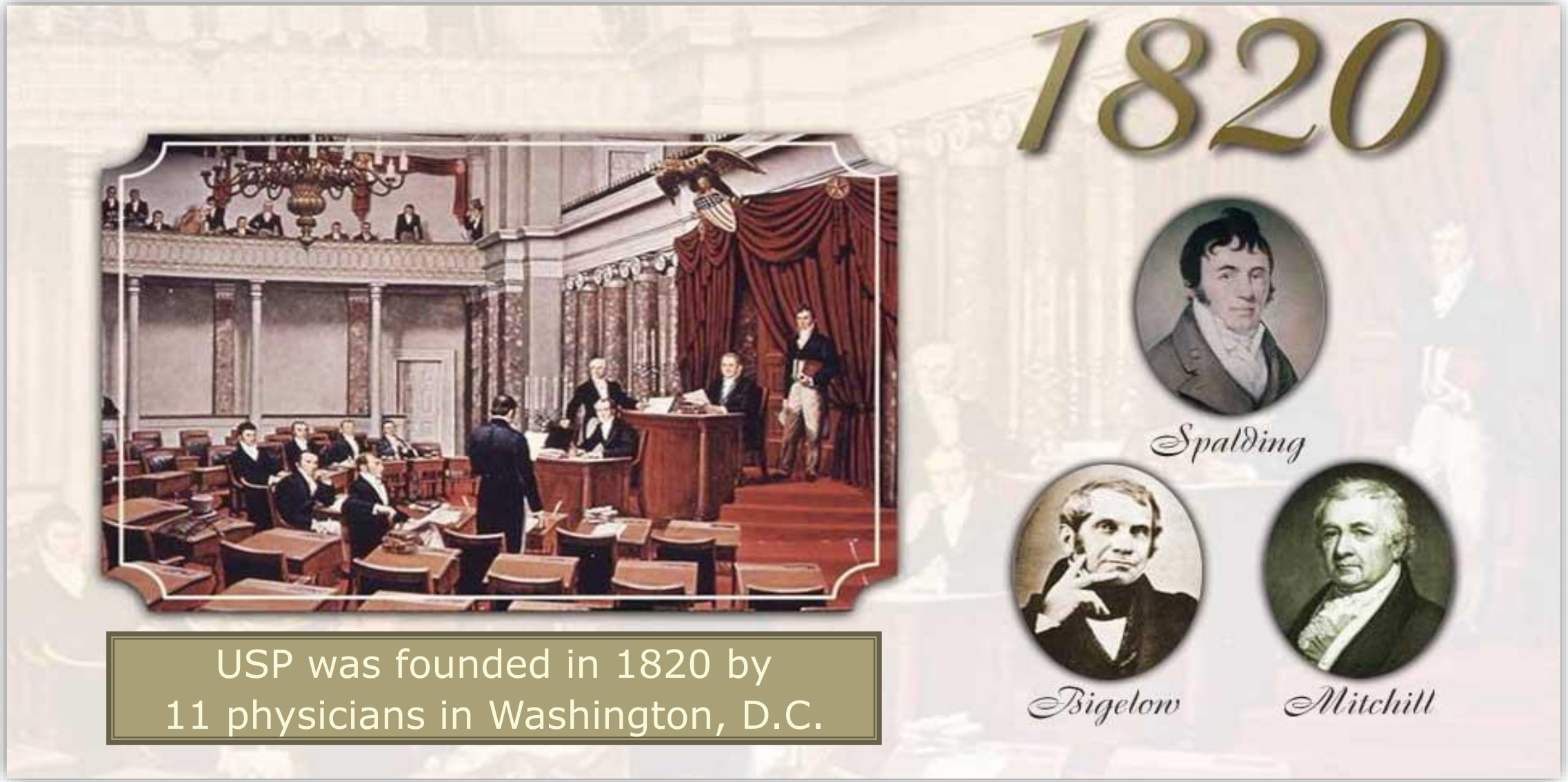
PRIORITIZE

Balance current paradigms and future trends

ENABLE

Global pharmaceutical trade

USP's Original "Pharmacopeial Convergence" Team



USP was founded in 1820 by
11 physicians in Washington, D.C.

Why Do We Need Harmonization?

If each country/region has own pharmaceutical regulation without harmonization….

- Pharmaceutical products approved in one country/region that are sold in other countries/regions must meet the quality standards recognized in those countries/regions
- Must conduct similar redundant tests in each country/region, adding no value to the patient or public health

Pharmacopoeial Harmonization

→ can align test methods and specifications to a common quality standard

Shifting Landscape & Learnings

- Changing landscape:
  - Rising importance of new regions in pharma quality as supply chains continue to globalize
  - Rising tide of nationalism that runs counter to collaboration
  - More complex medicines and emerging quality paradigms

- 30 years of learnings on barriers to harmonization from PDG and ICH

Resource & time Intensive

Misaligned Priorities & Incentives

Technical and regulatory hurdles

Revision Hesitance

Overview of USP-JP Prospective Harmonization

- Memorandum of Cooperation (MOC) was signed in September 2016
- JP and USP short listed potential monographs for harmonization and identified potential candidate, May 2023
- Dapagliflozin Tablets monograph was chosen for the pilot, June 2023
- New strategy; Proactively approached innovator to discuss interest in prospective harmonization with JP
  - Dapagliflozin Propanediol API was developed in collaboration with EP last year and it will be official on USP 2023 Issue 3, December 1, 2023.
  - JP agreed to adopt USPs monograph for API
- Meetings held between JP, USP, and the sponsor, August 2023
- The press release for the pilot was announced in Oct 2023

Comparison with PDG Harmonization

	PDG Harmonization	JP and USP Prospective Harmonization
Goal	Align test procedures and limits to a common quality standard Texts do not have to be identical	
Launched	1989	2023
Participating pharmacopoeias	Ph. Eur., USP, JP, WHO (joined as observer in 2001), IPC (joined in 2023)	JP and USP
Focus	Revisions to existing excipient monographs and general chapters	New active substance and medicinal product monographs for products still under patent
Process	Official procedure	Respective internal processes for monograph elaboration
Work initiation	Determined by the PDG	Collaboration with Sponsor (subject to the agreement of the JP and USP)

Advantages of Prospective Harmonization

Same documents / samples requested

Co-ordinated work

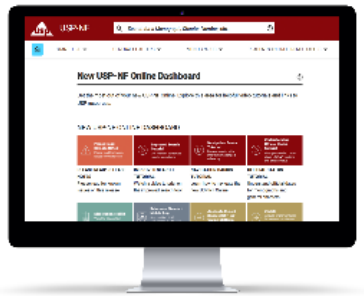
Regular updates, full transparency

Sharing of experience & knowledge

Joint communication between the manufacturer, JP & USP

Cost and time saving for manufacturers

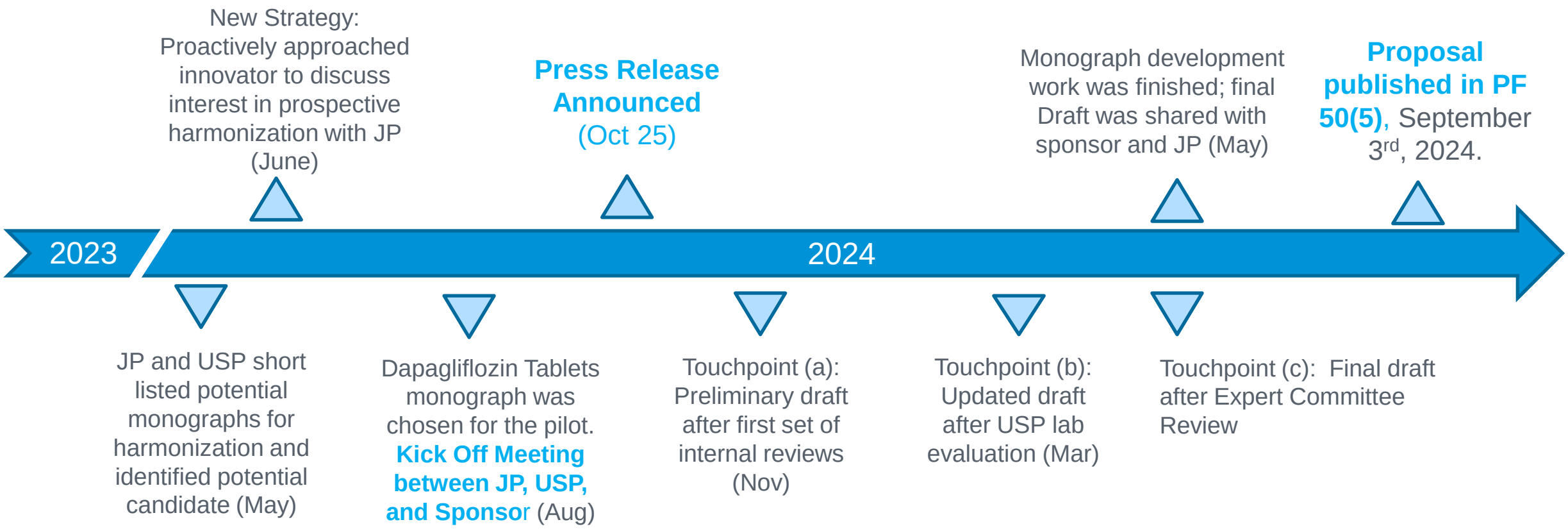
← Similar Standards →



Monograph Elaboration Touchpoints

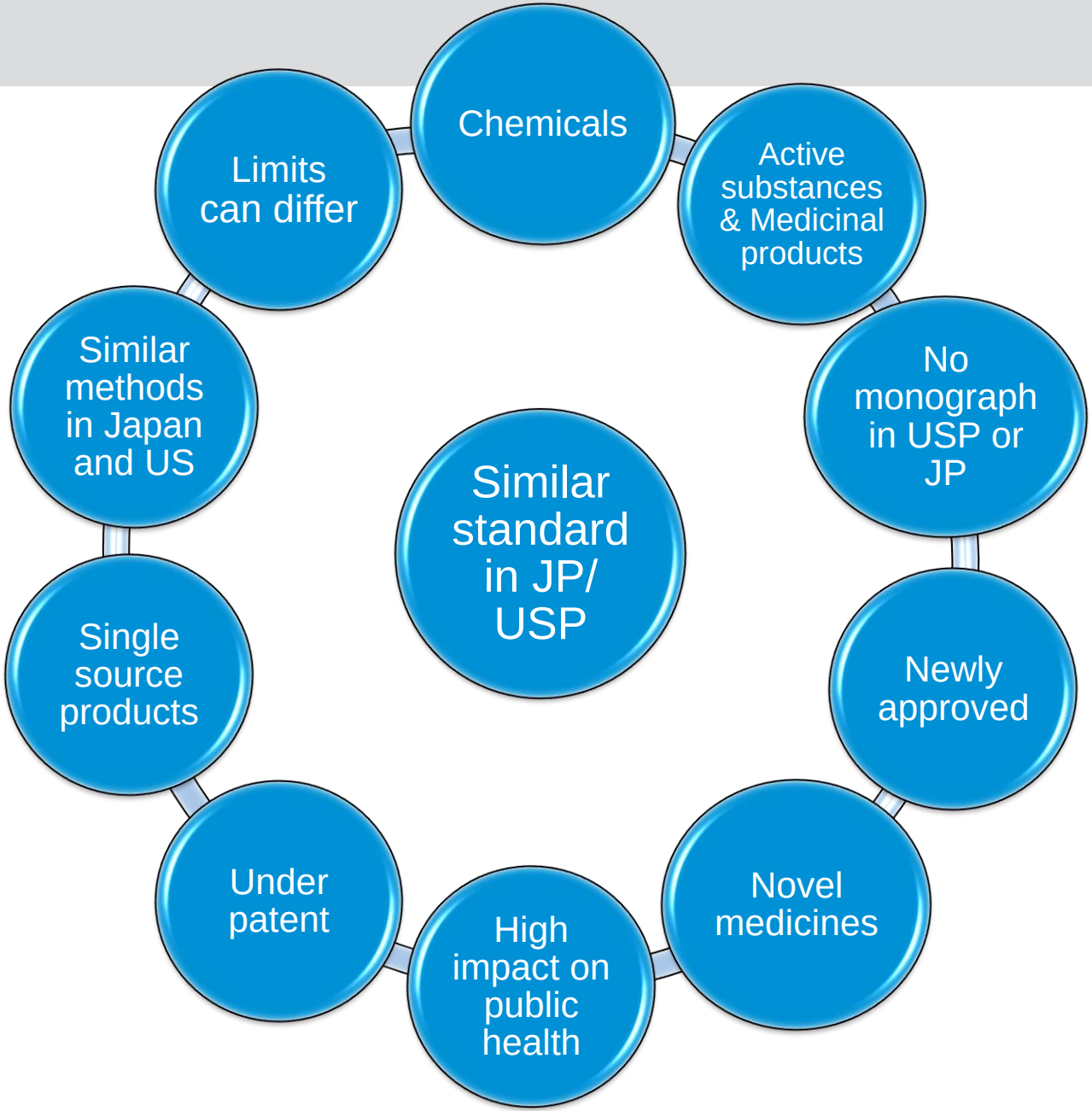
- After the monograph proposal is drafted:
  - Technical review will be performed - Touchpoint (a)
  - Internal lab assessments of the methods - Touchpoint (b)
  - Managerial scientific review
  - The draft will be shared with the sponsor
  - EC scientific review, final draft before publishing for public comments - Touchpoint (c)
- Proposal will be published for 90-day public comment period.
- Public comments will be reviewed and if deemed impactful, they will be shared - Touchpoint (d)
- Expert committee reviews comments received
- Expert committee will ballot on proposal
- Monograph will be published in compendia

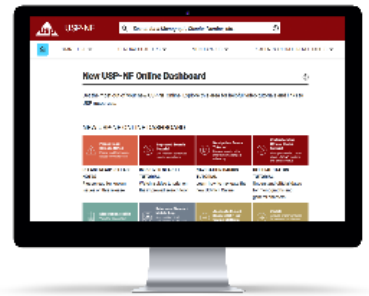
Timeline of USP-JP Prospective Harmonization



During monograph development, many scientific communications took place, and the draft was shared in 3 different stages between USP-JP.

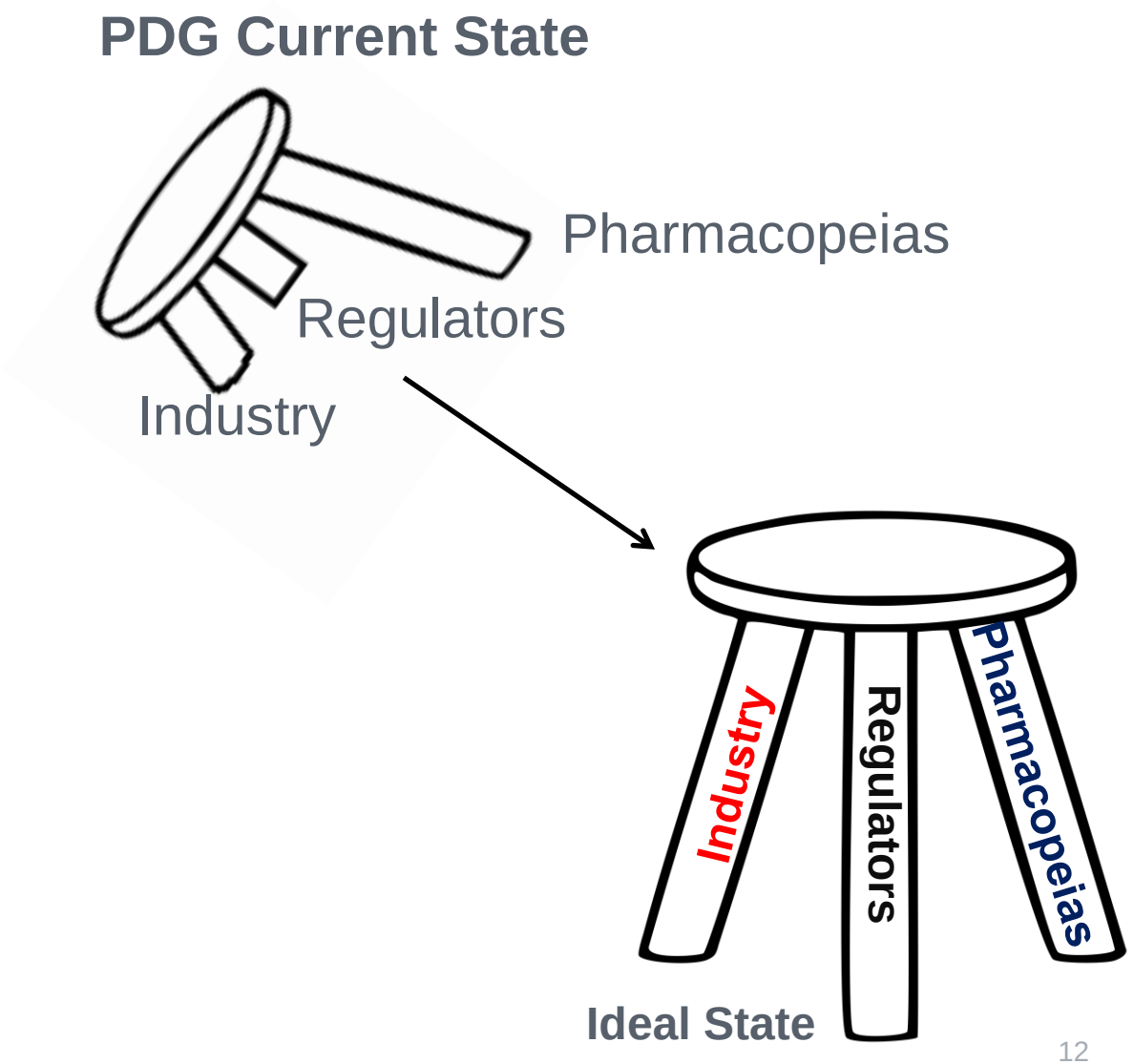
Next Steps: Identify Future Eligible products





“Three-Legged Stool” for a Convergence Model

- Currently, most formal harmonization efforts constitute a “one-legged stool” with heavy lifting done by the Pharmacopeias
- Improved model requires early engagement of industry and regulators to provide aligned or harmonized standards



A Vision for Convergence

- Drive global convergence of pharmaceutical quality standards through collaboration to increase patient access to quality medicines
- Take advantage of changing stakeholder landscape and implications
- Use our unique resources and capabilities

Stay Connected

ktm@usp.org; afc@usp.org; ba@usp.org

The standard of trust

Expert Volunteers help power USP's impact on global public health

Serving on Expert Committees, Panels and Sub-Committees, they collaborate to develop quality standards and other solutions that help build a more resilient supply of quality medicines.

Apply and amplify your impact

Thank You

The standard of trust