Global Expertise
Trusted Standards
Improved Health

U.S. Pharmacopeial Convention

Latest Trends And Future Efforts Of USP In The Progress Of Globalization

130th Anniversary of the Japanese Pharmacopeia

Jaap Venema, Ph.D.

Chief Science Officer & Chair, Council of Experts

創立記念日おめでとうございます！

日本薬局方

Presentation Outline

- Overview of the U.S. Pharmacopeial Convention (USP)
- How USP Standards are Established
- *USP-NF* Up-to-Date Initiative
- Research & Innovation - Continuous Manufacturing
- Global Health Standards Program

MISSION

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

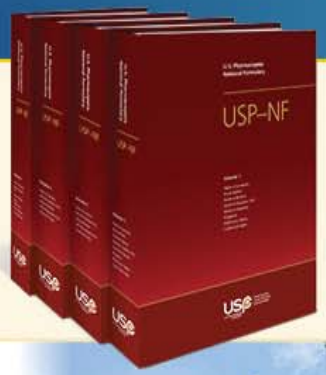
About USP

- Founded in 1820, nonprofit, private, independent, and self-funded
- Values-driven, scientific organization focused on empowering its staff and volunteers

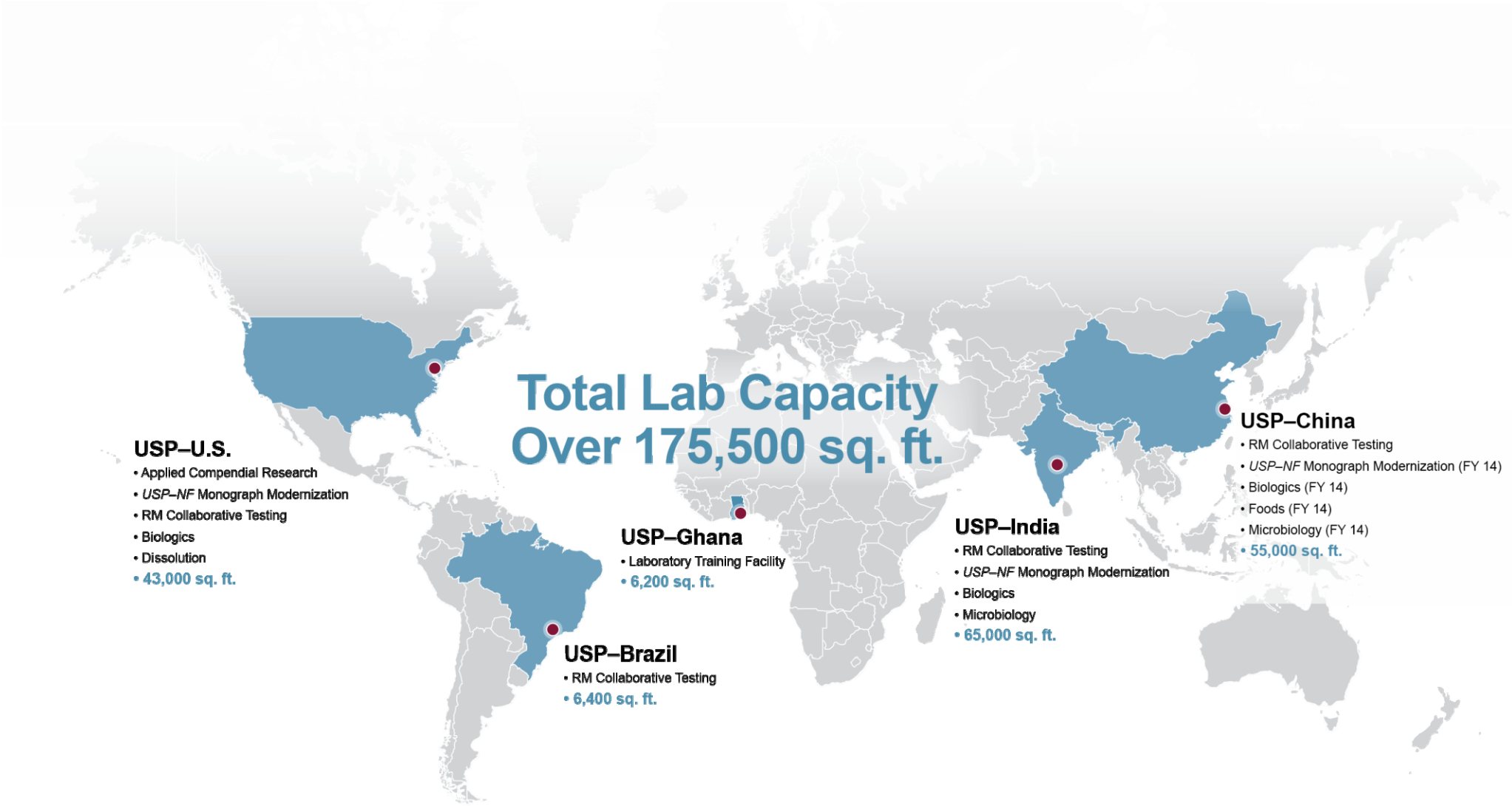
- More than 1,000 employees worldwide
- Laboratory facilities in U.S., India, China, Brazil, and Ghana
- Offices in Switzerland, Ethiopia, Indonesia, the Philippines, and Nigeria

- Works with more than 900 scientists, practitioners, and regulators to revise standards that help protect public health
- Internationally recognized and globally focused

Almost 200 Years of Building and Advancing the Founders' Vision

1820		Today
217 medicines covered		**Over 5,900 monographs**, covering pharmaceuticals, food ingredients, herbal medicines, dietary supplements
No formal legal recognition		Standards used in more than 140 countries— **legally recognized in 39**
The Pharmacopeia		**Expanded offerings:** • > 3,300 Reference Standards • > 6,000 Professionals Trained • Verification Program • Global Health Impact Programs 
U.S. focused		**Global presence:** facilities in India, China, Brazil, Switzerland, Ghana, Ethiopia, and Indonesia—with continued commitment as Pharmacopeia of the United States

USP's Laboratories Has Built Significant Global Laboratory Capacity



USP – PMDA: A Rich History of Bilateral Cooperation

- PMDA International Liaison Officers: USP has proudly hosted the following officers from PMDA
  - Mr. Nobuo Uemura: Feb-2010 to Jul-2011
  - Dr. Tetsuya Kusakabe: Jul-2011 to Aug-2012
  - Dr. Eriko Fukuda: Sep-2012 to Sep-2013
  - Dr. Chie Mizumaru-Sato: Mar-2015 to Mar-2016
  - Dr. Yujiro Kameyama: Aug-2016 – Feb 2018 (planned)
- Development of opportunities for prospective harmonization between USP and JP.
  - Pilot program for five new excipient monographs (Isostearyl alcohol, Myristyl Myristate, Polysorbate 65, Sodium Cetyl Sulfate, Calcium Silicate)
  - Working protocol to ensure more efficient development of harmonized monographs, using existing framework of standard setting in both USP and PMDA and aligning timing
  - Expand project to additional prioritized monographs, including excipients, drug substances, drug products, and APIs (Dr. Kameyama)
- Personnel exchange for PMDA (JP) and USP training programs
- Establishment of regular bi-monthly meeting for the purposes of information exchange and updates on bilateral harmonization progress

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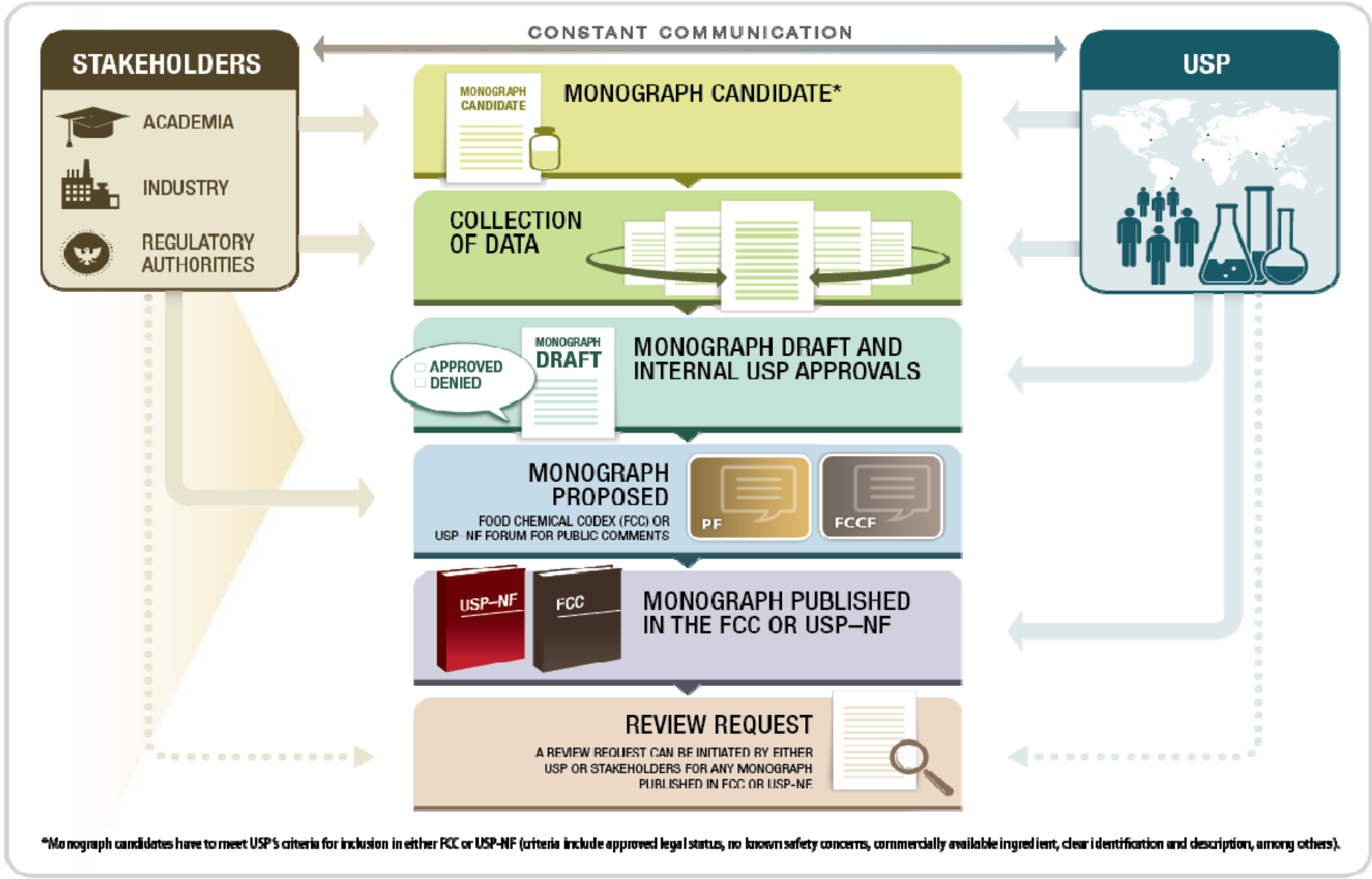
Science is the Base of USP Standard Setting



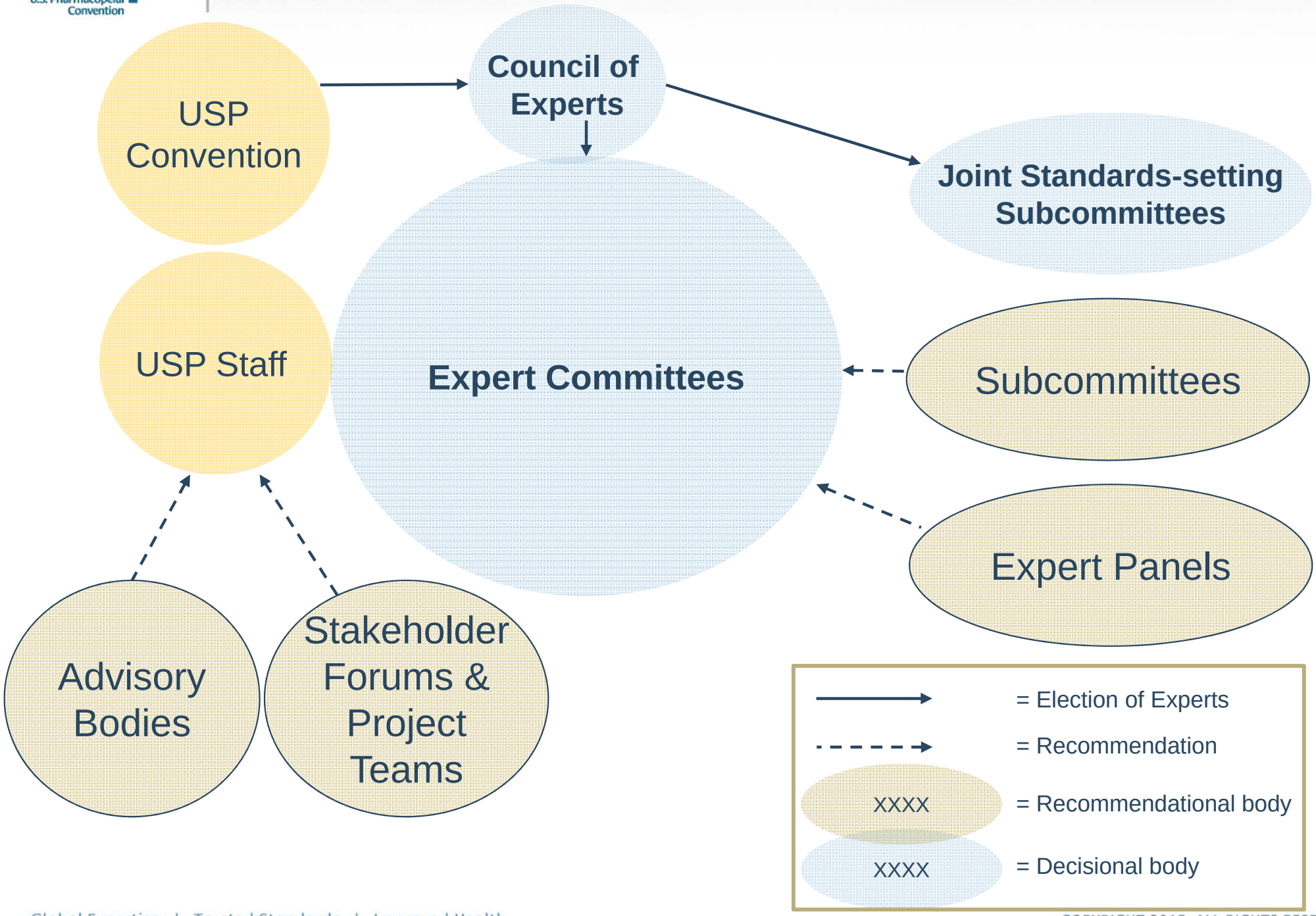
USP Documentary and Reference Standards

The reference materials relate directly to methods in the USP publications:

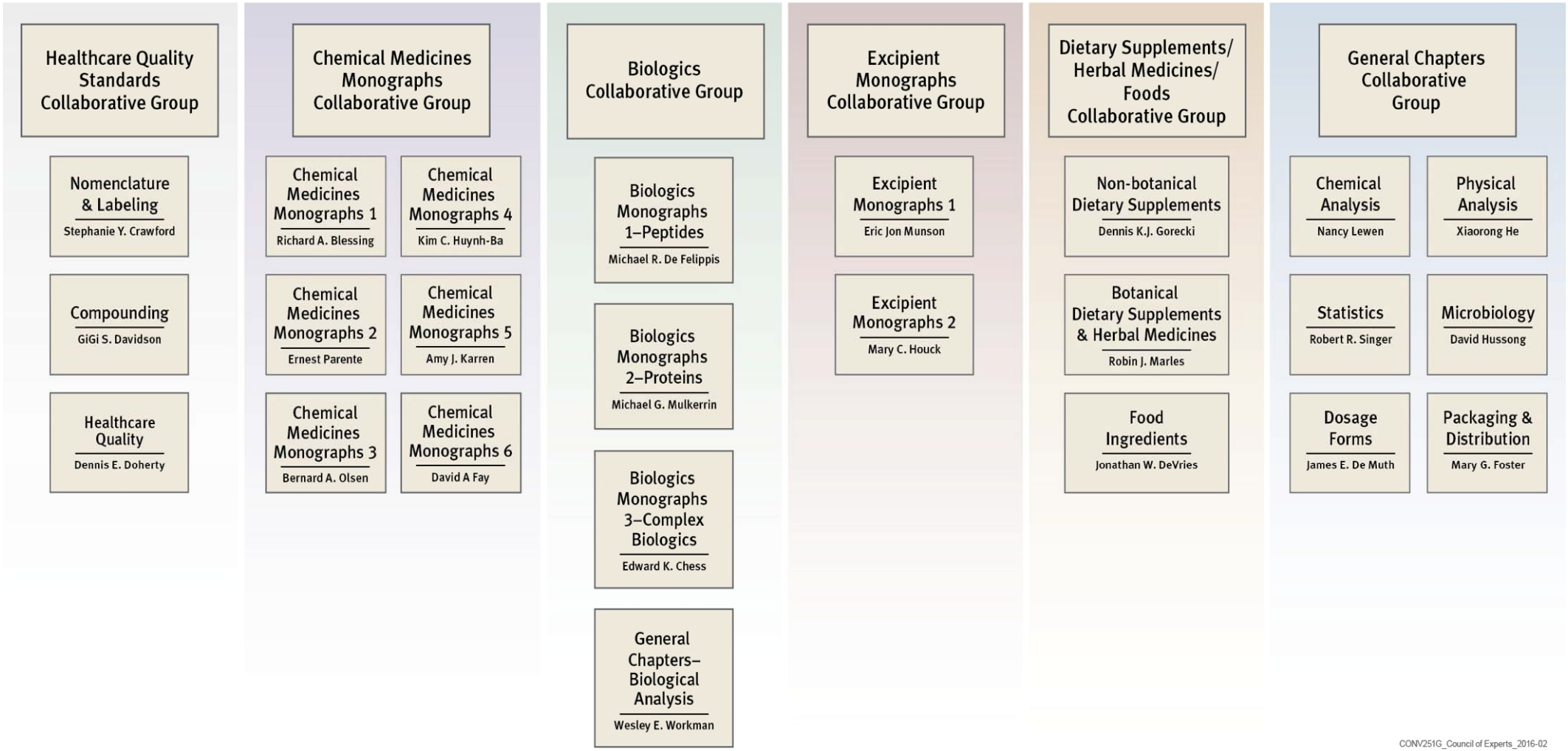
USP Standards

- General Notices
  - Key information supporting use of standards
  - Required unless noted otherwise in monograph
- Monographs
  - Specifications for pharmaceutical articles in commerce (from release through product shelf life), linked through name
  - Specifications – Tests, assays and acceptance criteria needed to demonstrate the article meets required quality standards
- General Chapters
  - Required when monograph cites them (numbered <1000)
  - Some are informational ONLY (numbered 1000-1999)
  - Support monographs by centralizing methods and procedures
- Physical Reference Materials
  - Provide traceable standards to demonstrate broad-based acceptability of procedures

USP Standards-Setting Bodies



2015–2020 Council of Experts
Expert Committees and Collaborative Groups



CONV251G_Council of Experts_2016-02

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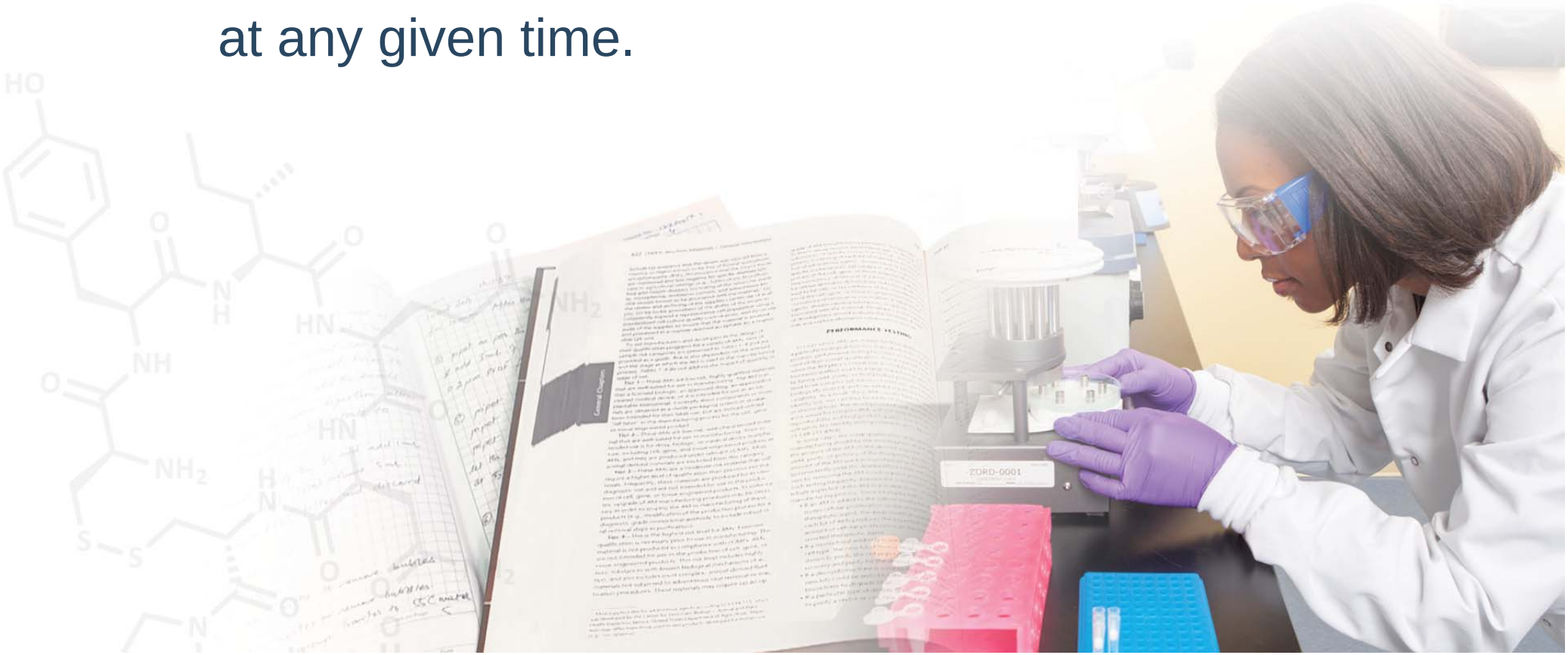
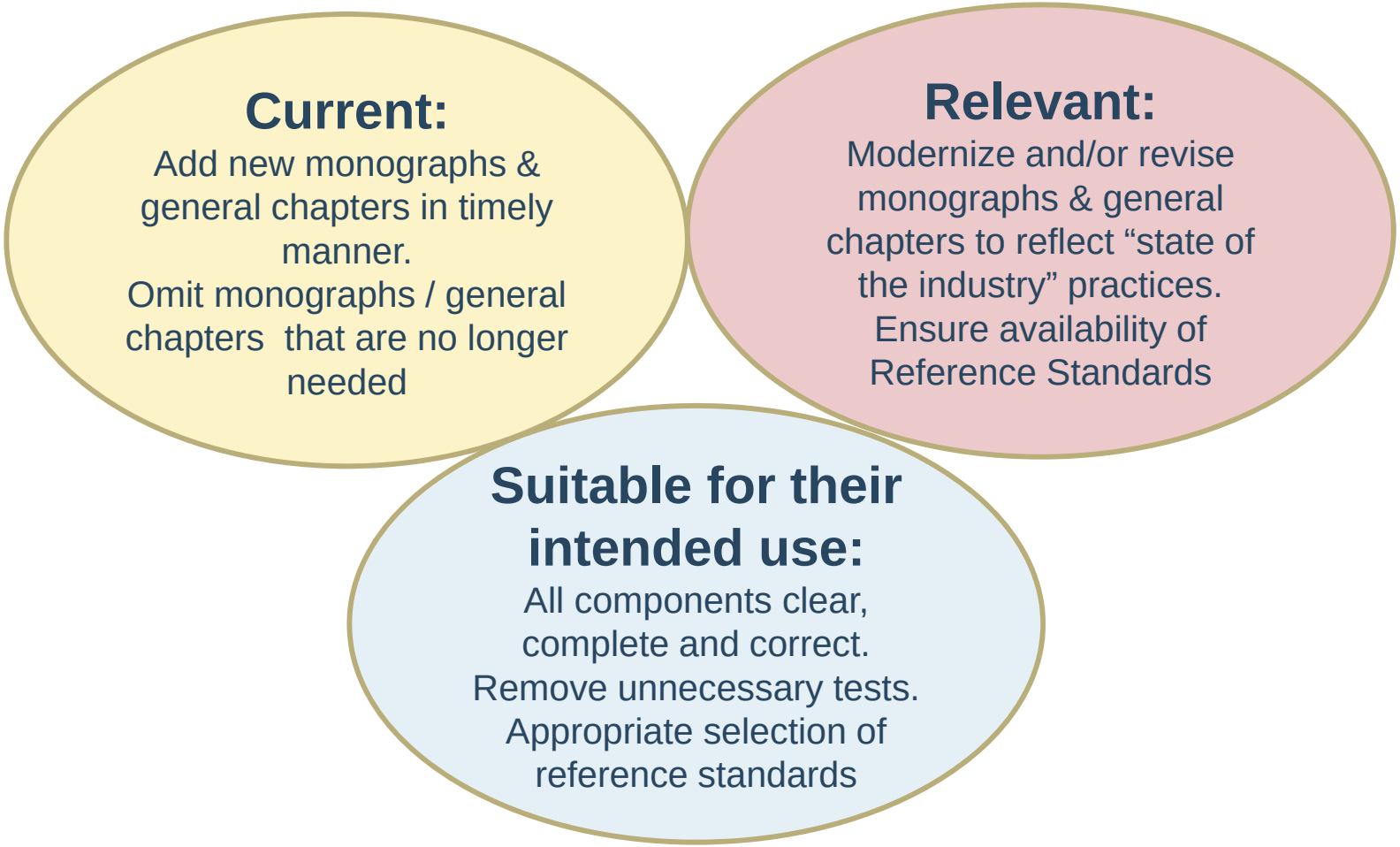
USP–NF Up-To-Date

Quality standards for drugs must undergo continuous revision, or modernization in order to reflect “state-of-the-industry” practices at any given time.

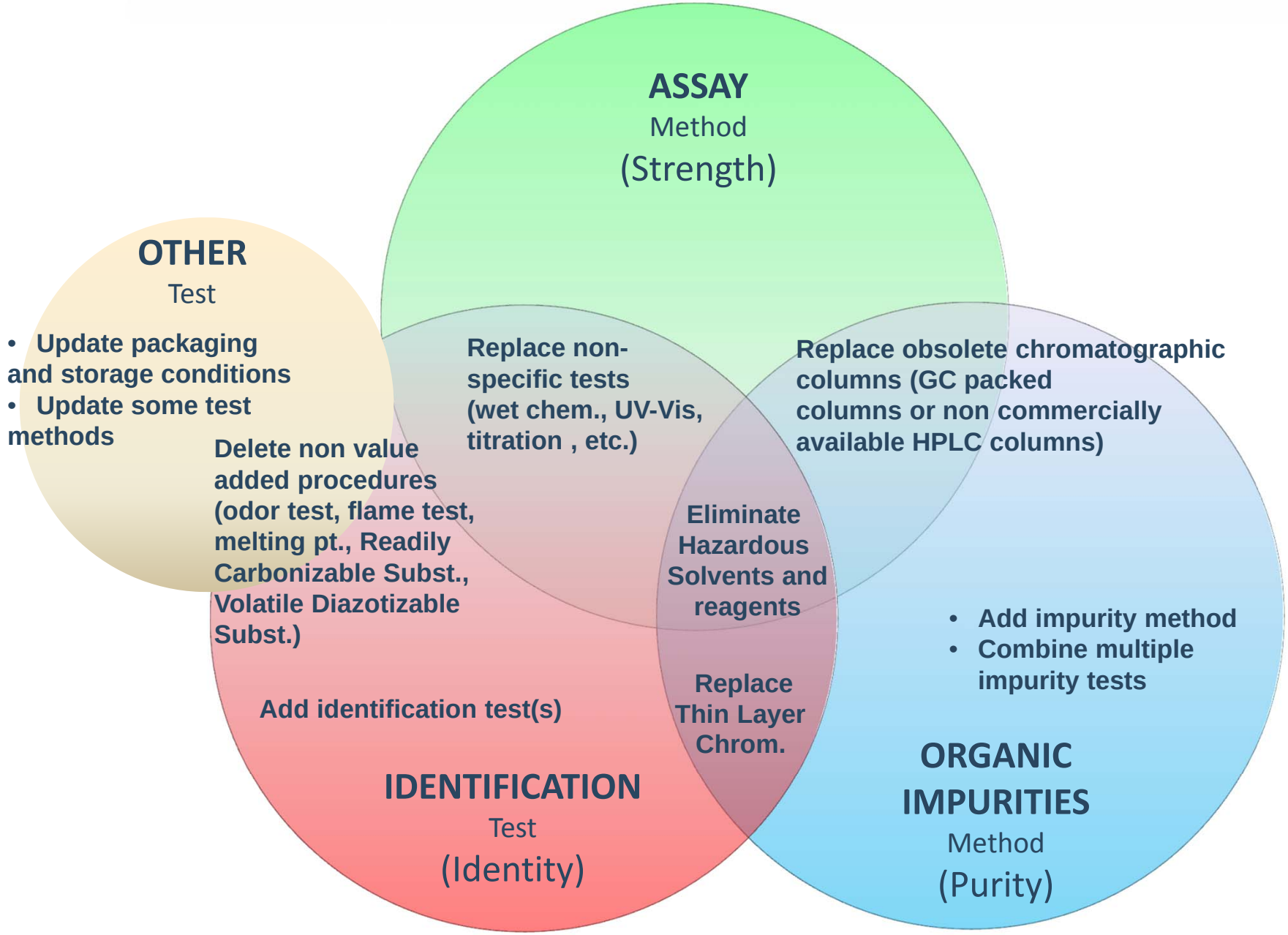


USP-NF Up to Date

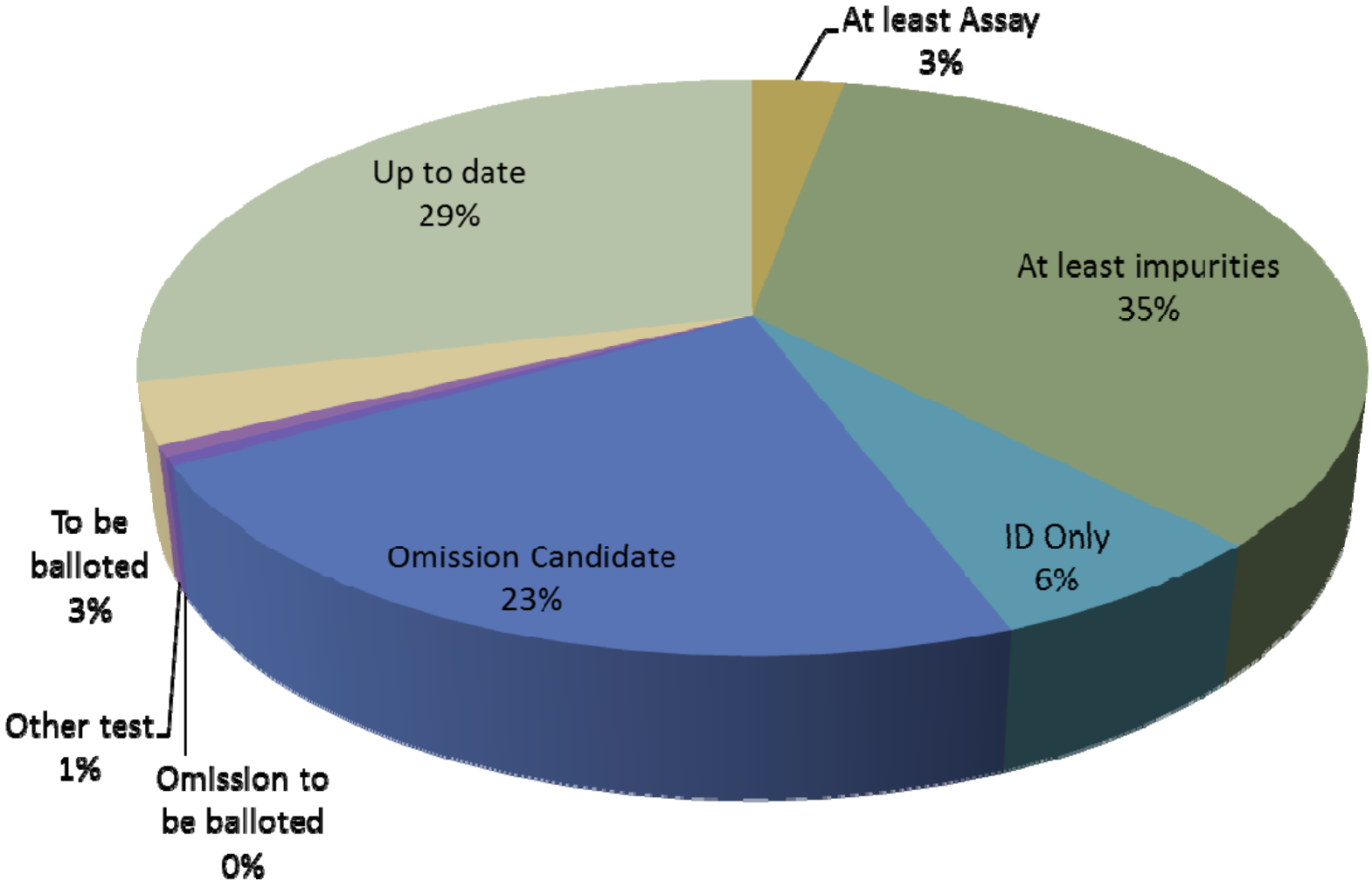
What does "*USP-NF* Up to Date" mean?



USP-NF Up to Date Prioritization Scheme



Distribution of Procedures Needed



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R&I Strategy

R&I Vision
To drive USP standard setting activities and related programs and services, responding to the needs of USP's stakeholders and customers.

R&I Strategy

- Develop a global Research & Innovation Function to support and sustain USP's long-term mission
- Mobilize a culture of innovation across the organization
- Identify and support new technologies and capabilities relevant to USP standard-setting processes and allied programs
- Recognize, evaluate and develop new opportunities that respond to the needs of USP's stakeholders and enhance its vision and mission

R&I will help drive USP's mission by:

- ❑ Enabling USP's role in the "Quality of the Future"
- ❑ Exploring critical enabling technology to advance standard setting
- ❑ Implementing a sustainable all-employee indigenous idea system
- ❑ Leveraging new business opportunities and technology applications

Continuous Manufacturing—consistent and broad access to better quality medicines at reduced costs

Manufacturing process:

- Smaller manufacturing footprint, equipment, labor engagement
- Faster development with less raw materials and minimal to no scale up
- Rapid startup and manufacture times (no “stockpiling”)
- Adjustable production with flexible batch size and no hand-offs

Quality:

- Quality built into process and formulation design directly
- Uniform processing and consistent manufacturing
- Sound control strategies to ensure product quality
- Amenable to process analytical technology (PAT) and real-time measurement
- Lower cost of quality assurance

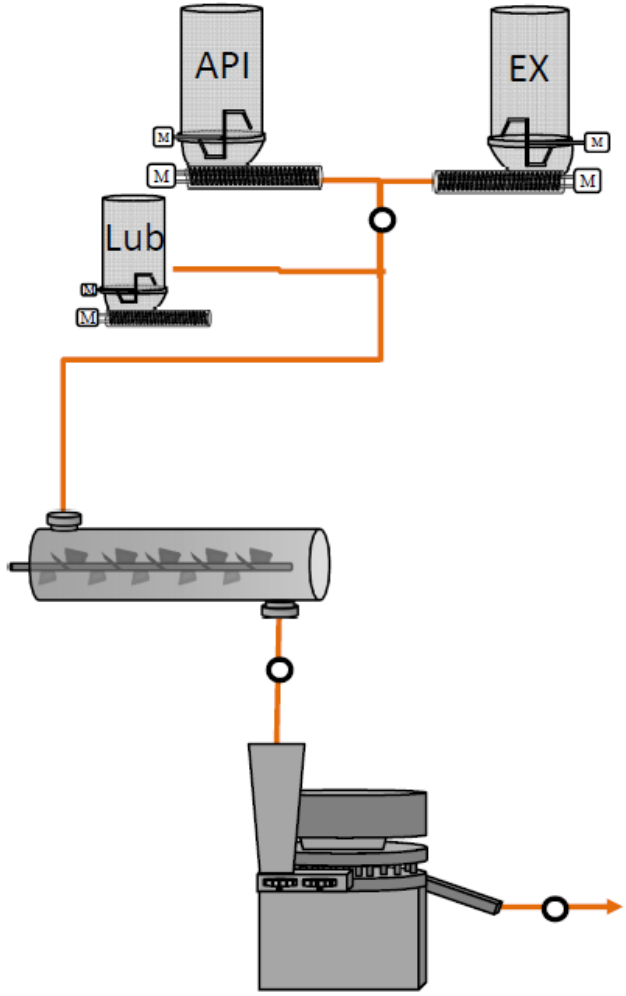
Current Landscape and Outlook

- Nearly all Big Pharma have entered the CM arena
- For drug products, many companies seem to be in R&D mode, and are assessing which products to commercialize
- Some companies have a platform focus (high investment without specific product in mind) others have a product focussed deployment strategy
- Most companies see the need for collaboration and want to participate in sharing information
- Guidelines, boundaries and strategies are being explored and shaped today, which especially includes the need for compendial standards

> *" Right now, manufacturing experts from the 1950s would easily recognize the pharmaceutical manufacturing processes of today. It is predicted that manufacturing will change in the next 25 years as current manufacturing practices are abandoned in favor of cleaner, flexible, more efficient* ***continuous manufacturing****."*
>
> Dr. Janet Woodcock, AAPS Annual meeting October 2011

Opportunities for Compendial Standards

- Standardizing terms
- Material characterization
- System Validation/Qualification
- In-process control using statistical methods
- Real Time Release Testing standardized approaches
- A material attributes library inclusive of predictive modeling approach
- Standardization of equipment



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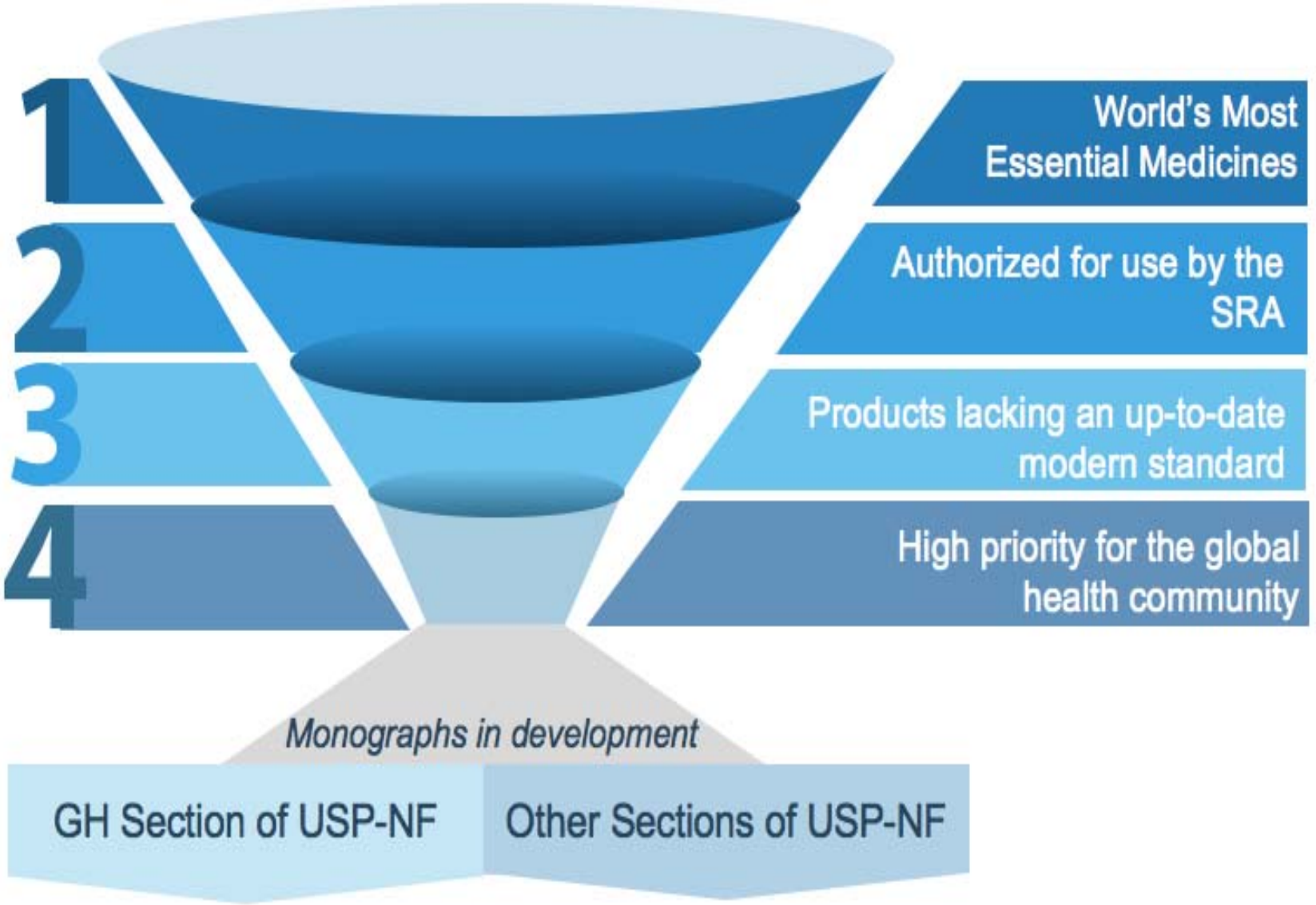
The Global Health Standards Program

Global Health Standards Program Objectives:

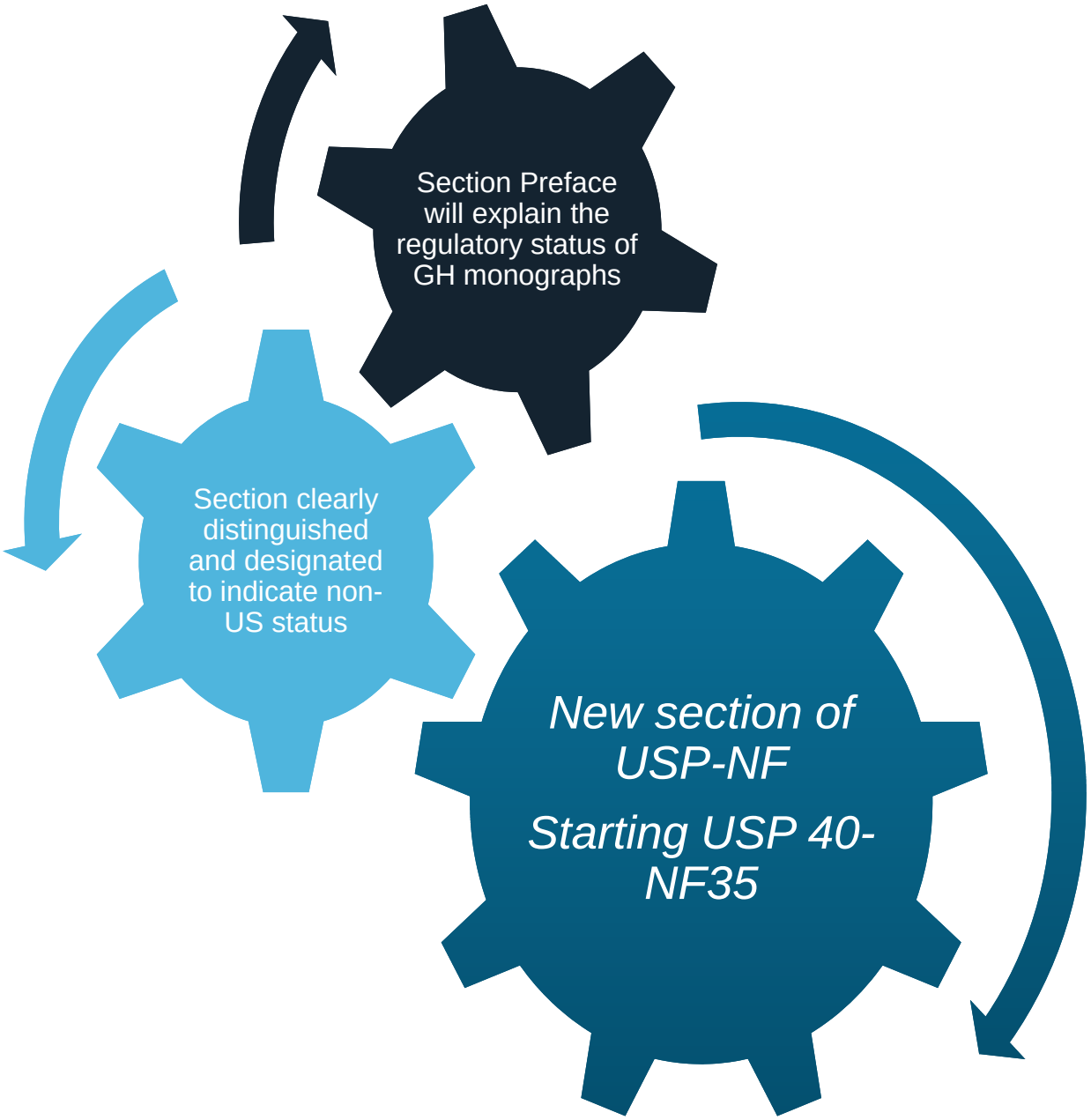
- Ensure availability of relevant, modern standards for the world's most essential medicines;
- Enable accessibility of these standards in non-US settings;
- Engage stakeholders for development, adoption, and implementation of these standards for improved public health outcomes

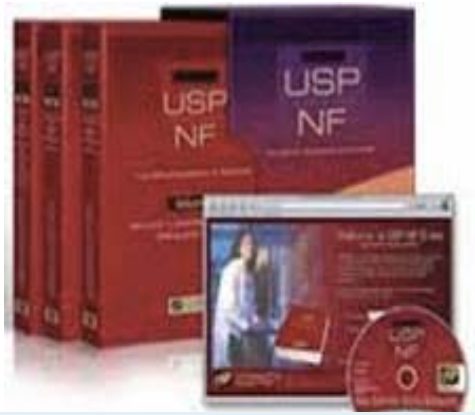
GHS Program: Medicines of Global Health Importance Marketed Outside the US



Prepared by Gaurvika Nayyar

The Global Health Monographs will have a New Section in the USP-NF





Preface

"This section contains monographs for articles which are not currently legally marketed in the United States, but which have been approved by a stringent regulatory authority as defined by the World Health Organization and are used for essential purposes in other parts of the world. Selection and prioritization of new entries to this section will be accomplished in close collaboration with stakeholders throughout the global health community. These monographs are not applicable to articles marketed for use in the United States."

GHS Program's Implementation Strategy Includes 4 Key Activities

COLLABORATE & PRIORITIZE MONOGRAPHS FOR DEVELOPMENT

Collaborate with global stakeholders select new medicines for monograph development

DEVELOP MONOGRAPHS

Develop standards utilizing existing standards-setting capabilities, including USP Expert Committees

DISSEMINATE

Disseminate the standard to key quality assurance entities

ENABLE STAKEHOLDERS

Enable communities to protect the quality of medicines

Global Expertise
Trusted Standards
Improved Health

U.S. Pharmacopeial Convention

ご清聴有難うございました

Thank You