



Global Expertise
Trusted Standards
Improved Health

The USP Excipients Stakeholder Forum
Meeting # 2
June 18, 2014

USP Overview

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United States Pharmacopeial Convention

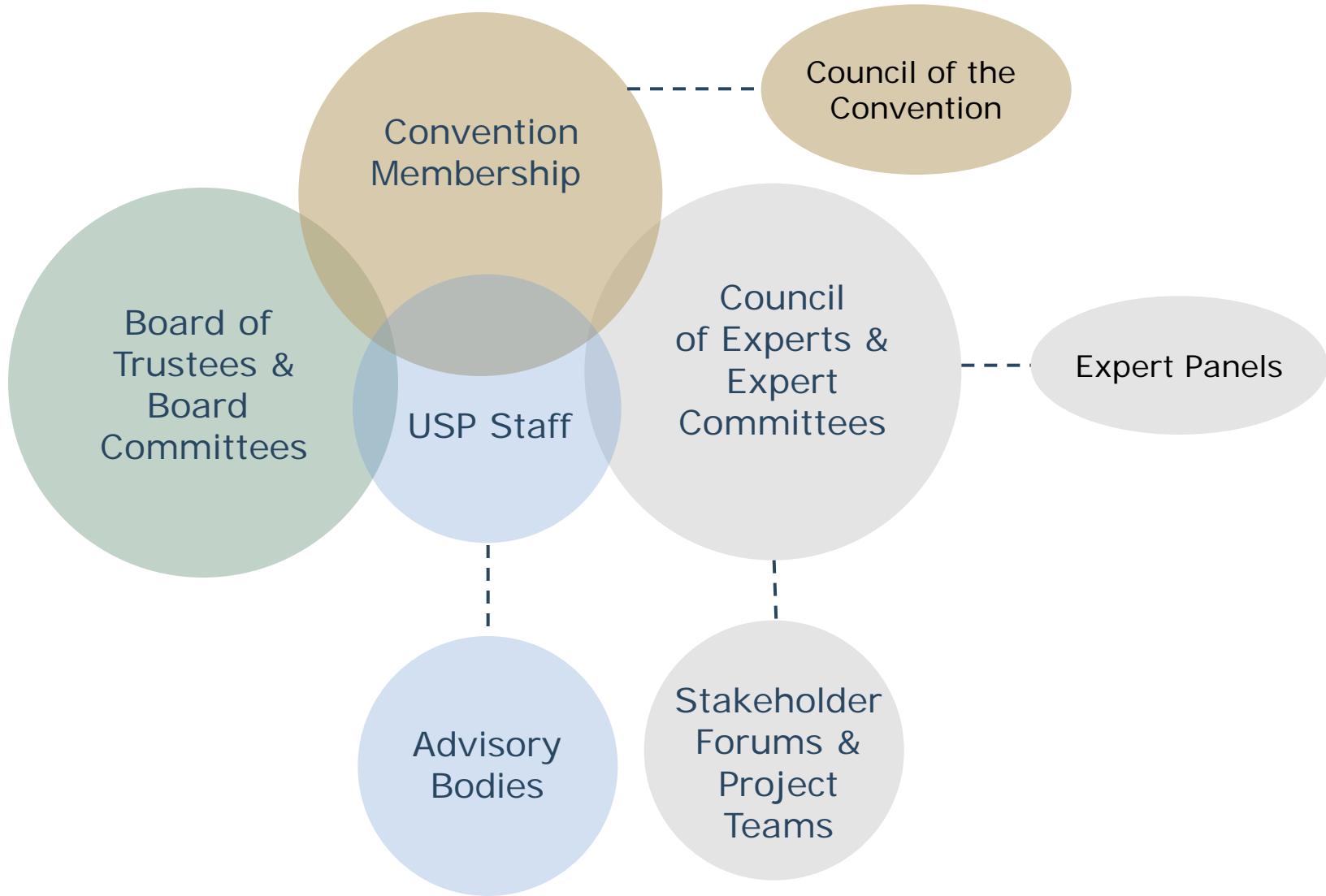
US Pharmacopeial Convention (USP) founded in 1820. USP is a scientific, nonprofit, nongovernmental, private, independent, and self-funded organization



Headquartered in Rockville, MD; 700 employees; facilities in India, China, Switzerland, Brazil

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

USP Governing and Advisory Bodies



Resolutions provide stakeholders an opportunity to influence USP's strategic direction at the beginning of each five-year cycle.

Resolution 2

Strengthen Focus on Core Compendial Activities

USP resolves to strengthen its focus on core compendial activities, working collaboratively with academia, industry, regulators and other stakeholders, and utilizing a robust quality management system within USP and its Council of Experts, to ensure relevant, timely and accurate public standards

Resolution 3

Strengthen USP's Relationship with the U.S. Food and Drug Administration

USP resolves to strengthen its relationship with the Food and Drug Administration (FDA), and work with FDA and other public and private stakeholders to explore mechanisms to enable USP to provide and maintain up-to-date national standards for legally marketed drugs and excipients in the United States.

Resolution 5

Strengthen and Expand Harmonization Efforts

USP resolves to strengthen and expand its efforts to work with pharmacopeias, industry, academia, regulators, international organizations and other stakeholders around the world to develop harmonized global standards.

<http://www.usp.org/about-usp/our-vision/2010-2015-resolutions>

2010–2015 Council of Experts

Healthcare Quality

**Nomenclature,
Safety,
and Labeling**
T. Reinders

**Therapeutic
Information
and Formulary
Support**
J. Braden

Compounding
G. Davidson

Reference Standards

**Reference
Standards**
M. Borer

General Chapters

Chemical Analysis
T. Wozniak

**Biological
Analysis**
W. Workman

Microbiology
J. Akers

Statistics
R. Singer

Physical Analysis
G. Amidon

Dosage Forms
J. DeMuth

Packaging
M. Foster

Toxicology
R. Osterberg

USP Chemicals

**Small Molecules
Monographs 1**
G. Van Buskirk

**Small Molecules
Monographs 2**
E. Parente

**Small
Molecules
Monographs 3**
B. Olsen

**Small
Molecules
Monographs 4**
E. McGonigle

USP Biologicals

**B&B
Monographs 1**
M. Mulkerrin

**B&B
Monographs 2**
J. Huxsoll

NF Excipients

Excipients
L. Block

Dietary Supplements and Foods

**Dietary
Supplements**
D. Gorecki

**Food
Ingredients**
A. Ebert

MC Chemicals

Chemicals (S. Asia)
A.R. Gomas

Chemicals (L. America)
I. Santoro

Chemicals (NIS)
A. Mikhaylova

MC Biologicals

Biologics
D. Patankar

MC Excipients

Excipients (E. Asia)
J. Tu

Herbal Medicines Compendium

S. Asia (India)
S.S. Handa

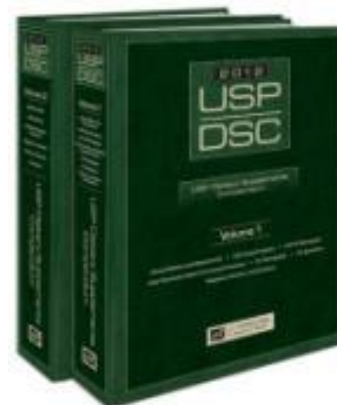
E. Asia (China)
Z.Qian

- 1010 experts serving on 26 Expert Committees, 72 Expert Panels and 1 Advisory Group
- 412 Expert Committee members
- 440 Expert Panel members*
- 28 Advisory Group members*
- 130 Government Liaisons
 - 116 FDA Liaisons

– CDER: 75	– ORA: 4
– CFSAN: 15	– OC/ONDQA: 2
– CBER: 10	– CDRH: 2
– CVM: 8	
 - 3 Brazil (ANVISA, Brazilian Pharmacopoeia, INCQS)
 - 1 CCAYAC/COFEPRIS (Mexico)
 - 2 Centers for Disease Control and Prevention
 - 1 Centers for Medicare and Medicaid Services
 - 2 Chinese Pharmacopoeial Commission Representatives
 - 2 Health Canada Representatives
 - 1 NIST Representative
 - 1 Saudi Food and Drug Authority
 - 1 U.S. Public Health Service

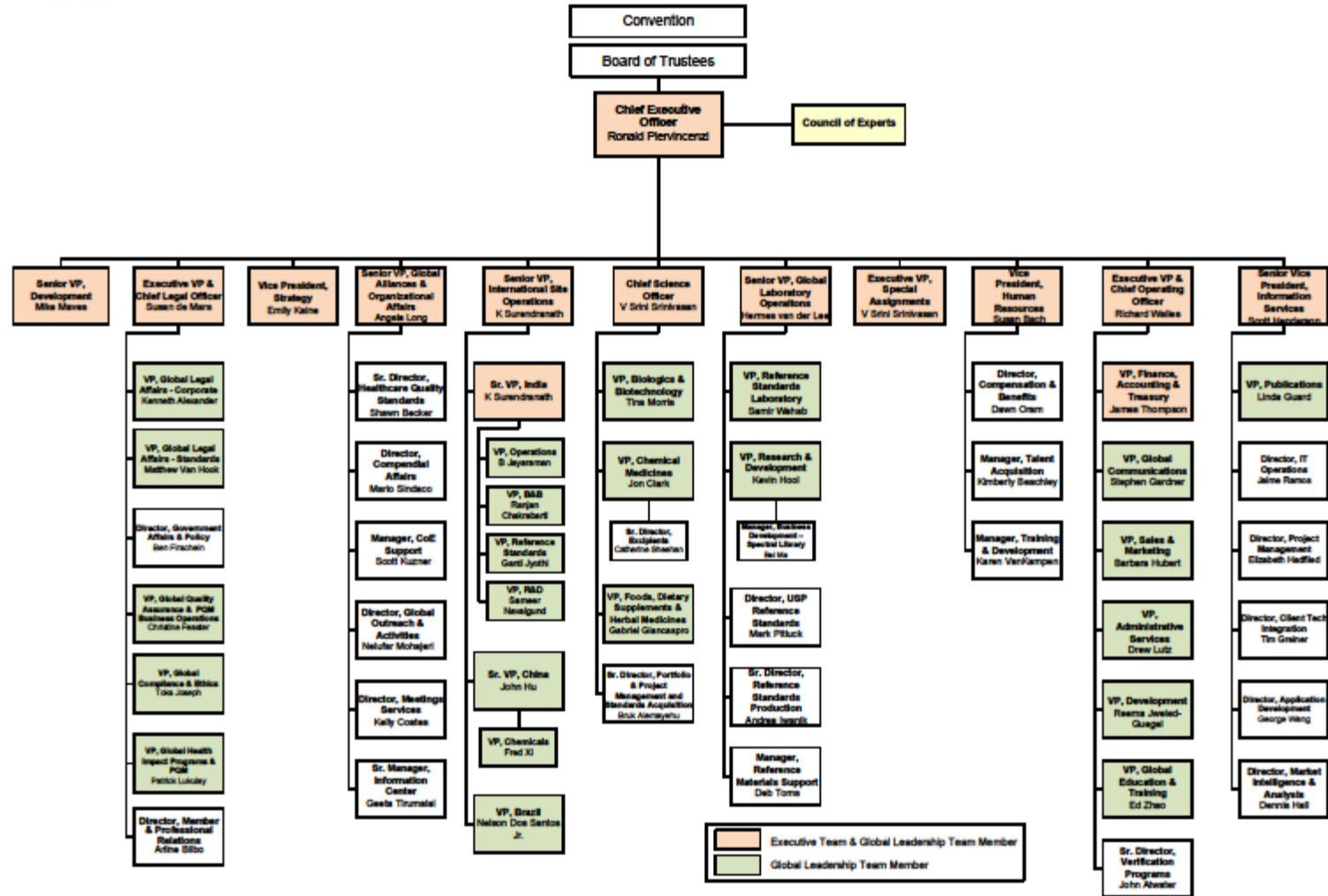
* Does not include Expert Committee members also serving on Expert Panels or Advisory Groups

1. *The United States Pharmacopeia*
 2. *National Formulary (USP–NF)*
 3. *Food Chemicals Codex (FCC)*
 4. *USP Dietary Supplements Compendium (DSC)*
 5. *USP Medicines Compendium (MC)*
 6. *USP on Compounding*
 7. *Herbal Medicines Compendium (HMC)*
- ▶ **Other Resources**
- *Pharmacopeial Forum (PF)*
 - *FCC Forum (FCCF)*
 - *USP Dictionary*
 - *Chromatographic Columns*



COMPOUNDING

U.S. Pharmacopeial Convention New Organization Structure Effective Tuesday, June 3, 2014



- ▶ Engagement of key stakeholders in
 - Updating/modernizing existing monographs and general chapters
 - Developing new monographs and general chapters and allied reference materials
 - Harmonization of excipient monographs and related general chapters through the Pharmacopeial Discussion Group

FDA Monograph Modernization Task Group (MMTG)

The FDA MMTG was established within the FDA Pharmaceutical Quality Standards Working Group, whose purpose it is to :

- ▶ Identify USP-NF monographs in need of modernization and is especially focused on monographs with outdated or inadequate ID tests or analytical methods that may make the drug or excipient vulnerable to economically-motivated adulteration (EMA).
- ▶ Facilitate monograph modernization and monograph prioritization activities of FDA.
- ▶ This is in keeping with resolutions adopted by USP at its April 2010 Convention to work to modernize its monographs as a priority in its work plan for the next five years.
- ▶ Develop a science- and risk-based approach for ongoing prioritization and oversight of USP monograph modernization efforts.
- ▶ Focus ongoing efforts for USP monograph modernization on those monographs and general chapters whose improvement would most greatly benefit public health by reducing potential risks.

Global Laboratory Capacity	Square Footage
USP US	43,000 sq. ft.
USP India	65,000 sq. ft.
USP China	Jan '14: 55,000 sq. ft.
USP Brazil	6,400 sq. ft.

USA Laboratory Capacity	Square Footage
Research & Development	15,500 sq. ft.
Biologics and Biotechnology	4,500 sq. ft.
Reference Standards Laboratory	19,000 sq. ft.
Dosage Form Performance	4,000 sq. ft.



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Thank You