Global Expertise
Trusted Standards
Improved Health

U.S. Pharmacopeial Convention

The USP Excipients Stakeholder Forum
Meeting #1
June 7, 2013

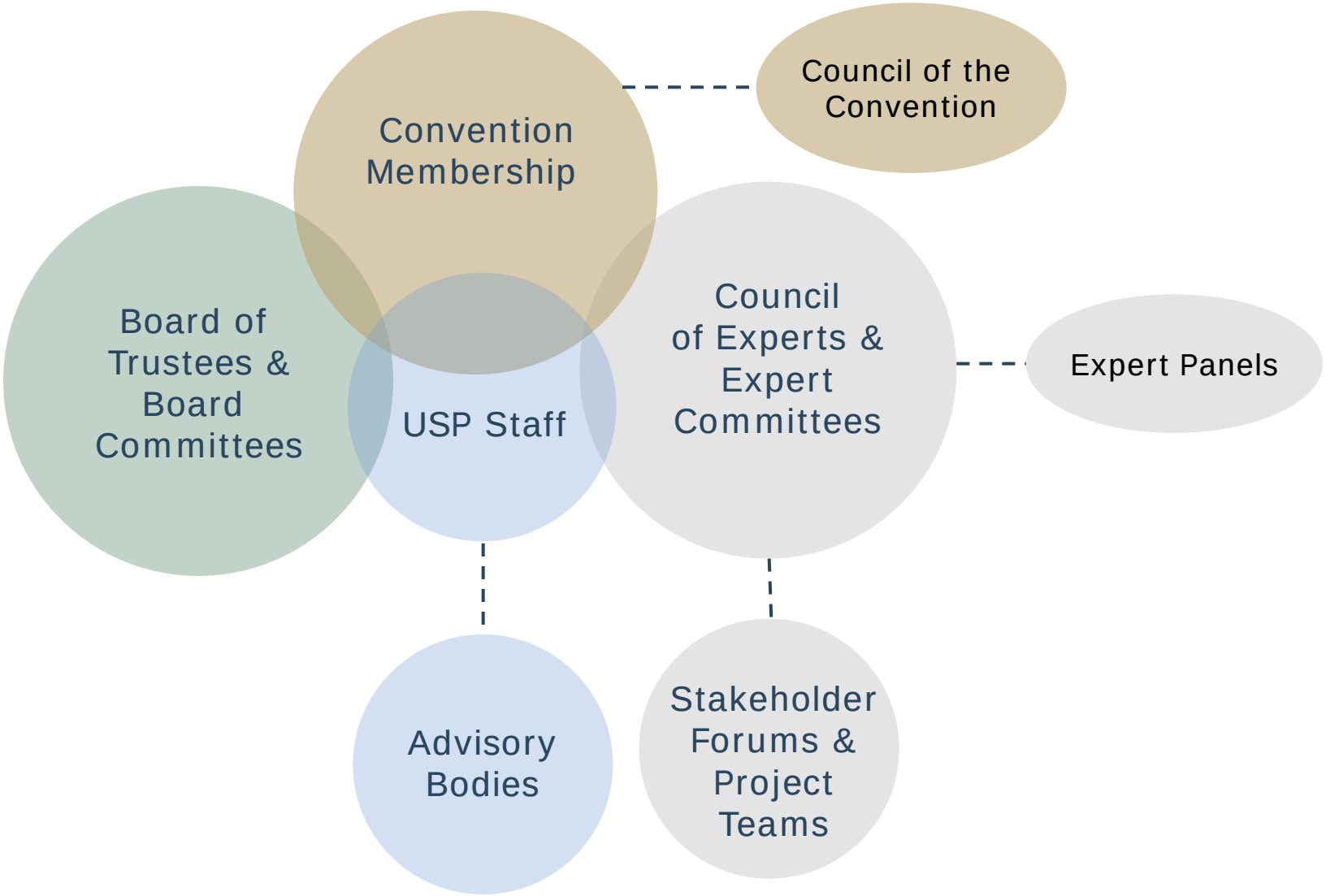
USP's Global Science and Standards Division

V. Srini Srinivasan, Ph.D.
Executive Vice President and CSO

USP's Mission

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



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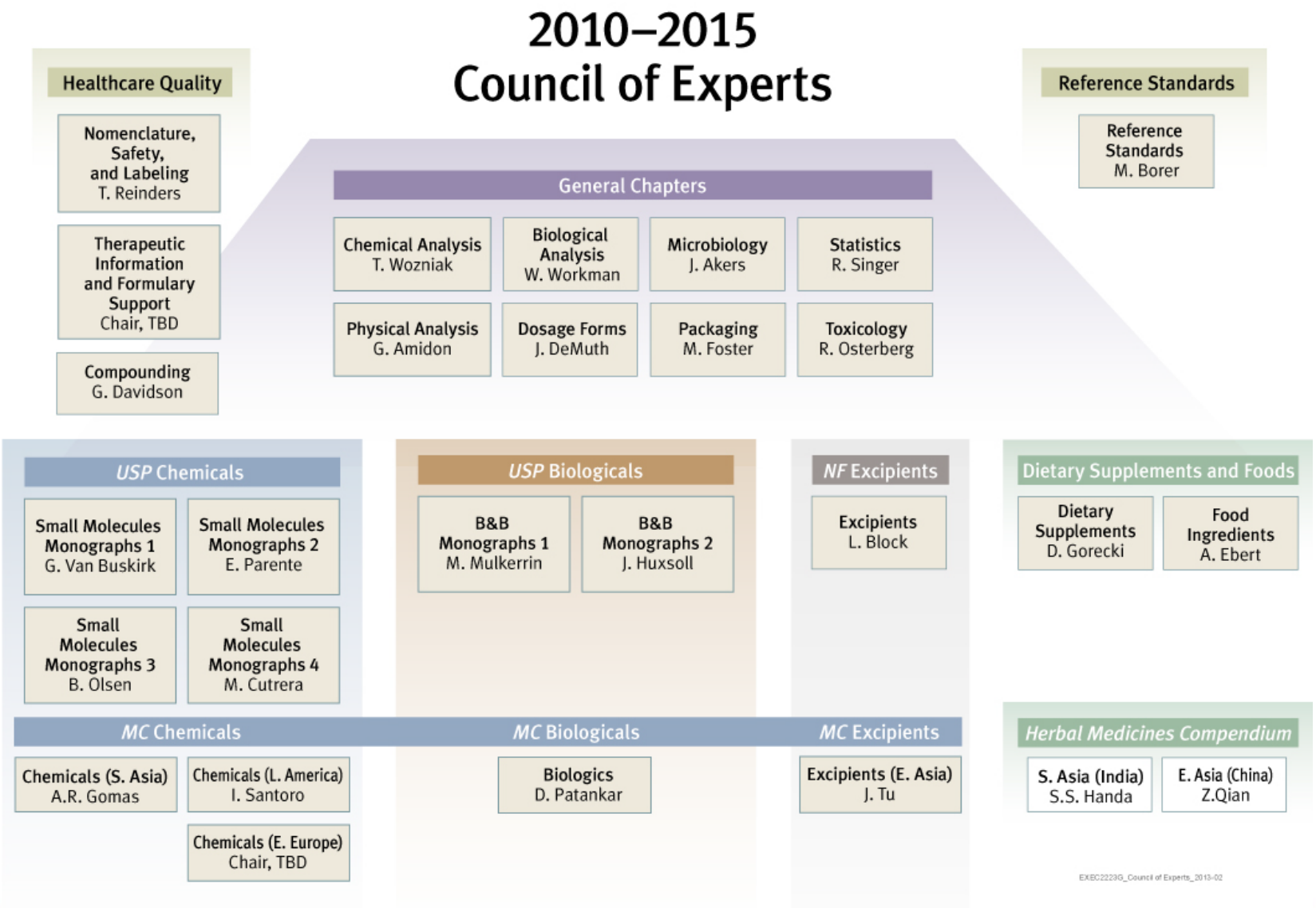
2010-2015 Council of Experts



2010-2015 Council of Experts - Demographics

- 861 expert volunteers from 34 countries serving on 24 Expert Committees and 65 Expert Panels
- 366 Expert Committee members
- 372 Expert Panel members*
- 123 Government Liaisons
  - 111 FDA Liaisons
    - CDER: 76
    - CFSAN: 13
    - CBER: 12
    - CVM: 6
    - ORA: 3
    - CDRH: 1
  - 3 Chinese Pharmacopoeial Commission Representatives
  - 1 European Food Safety Authority Representative
  - 2 Health Canada Representatives
  - 1 Indian Pharmacopoeia Commission Representative
  - 1 NIST Representative
  - 3 Brazil (ANVISA, Brazilian Pharmacopoeia, INCQS)
  - 1 CCAYAC/COFEPRIS (Mexico)

* This number does not include Expert Committee members also serving on Expert Panels.

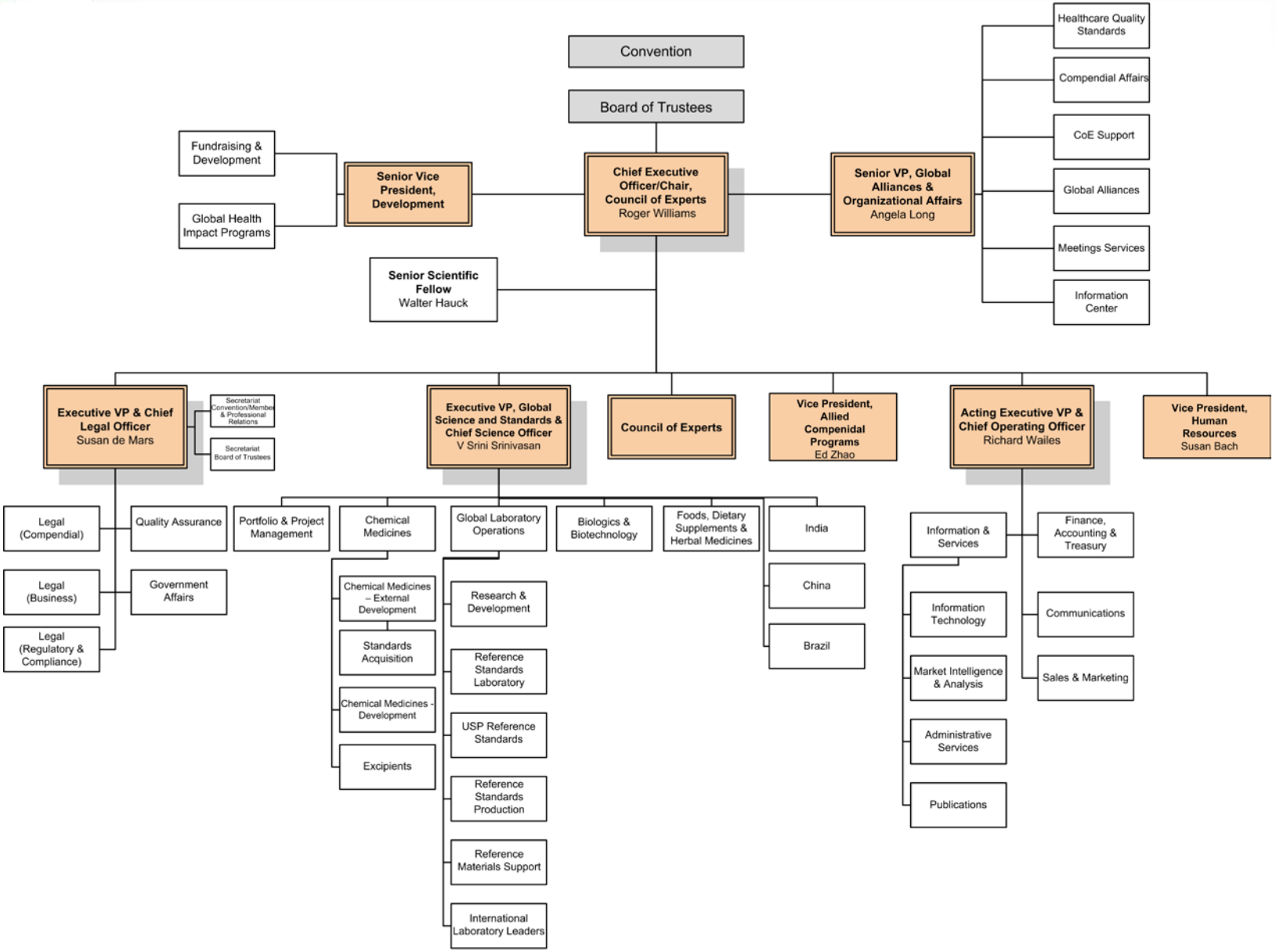
USP Compendia

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)*

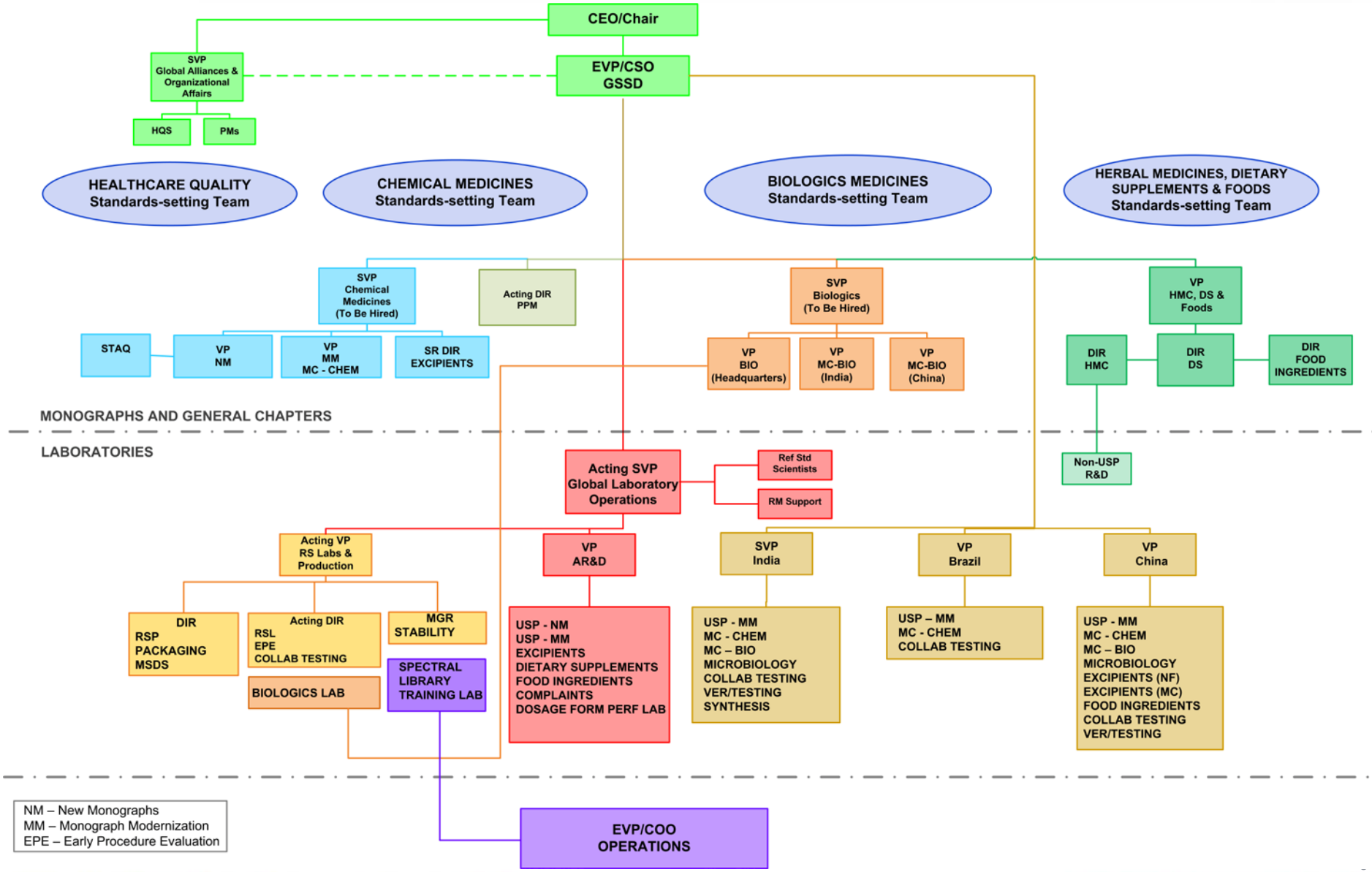
- Other Resources
  - *Pharmacopeial Forum (PF)*
  - *FCC Forum (FCCF)*
  - *USP Dictionary*
  - *Chromatographic Columns*

COMPOUNDING

USP Organizational Organization Chart



GSSD Functional Organizational Chart



Global USP Laboratory Capacity

Global Laboratory Capacity	Square Footage
USP US	43,000 sq. ft.
USP India	65,000 sq. ft.
USP China	Current: 3,000 sq. ft. 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.

USP US Laboratory Facility

- Research and Development Laboratories
  - Monograph Development and Modernization
    - Chemical Medicines, Excipients, Foods, Dietary Supplements, Biologics
      - Isolation and Characterization of Impurities
      - Complex Materials Characterization/Authentication
  - Dosage Form Performance Lab
- Reference Standards Laboratory
  - Testing of Candidate Reference Standards
    - Identification; Structure Verification, Purity determination
  - Investigations / Complaints
  - Continued Suitability for Use testing
    - New to USP Technology Program
    - Dissolution Research and PVT RS Development

Quality Systems

- ISO 9001:2008 certified (BSI)
- ISO 17025:2005 certified (ACLASS)

International Harmonization Efforts

- Pharmacopoeias
  - Pharmacopoeial Discussion Group
  - Prospective Harmonization (I, II, III)
  - Bilateral Agreements (MOUs)
  - WHO's World Meetings of International Pharmacopoeias; Good Pharmacopoeial Practices
  - Global Summit of the Pharmacopoeias
- World Health Organization
  - Expert Committee on Specifications of Pharmaceutical Preparations
  - Expert Committee on Biological Standards
  - International Nonproprietary Names
- ISO Remco
- International Congress on Harmonization
  - Q3D Elemental Impurities

Key Initiatives for Excipients

- Developing new monographs
- Updating/modernizing existing monographs
- Harmonization of Excipient Monographs
- Reformatting ('monograph redesign')
  - Completed for *USP 36-NF 31*

Thank You