

Why and How to Work with USP

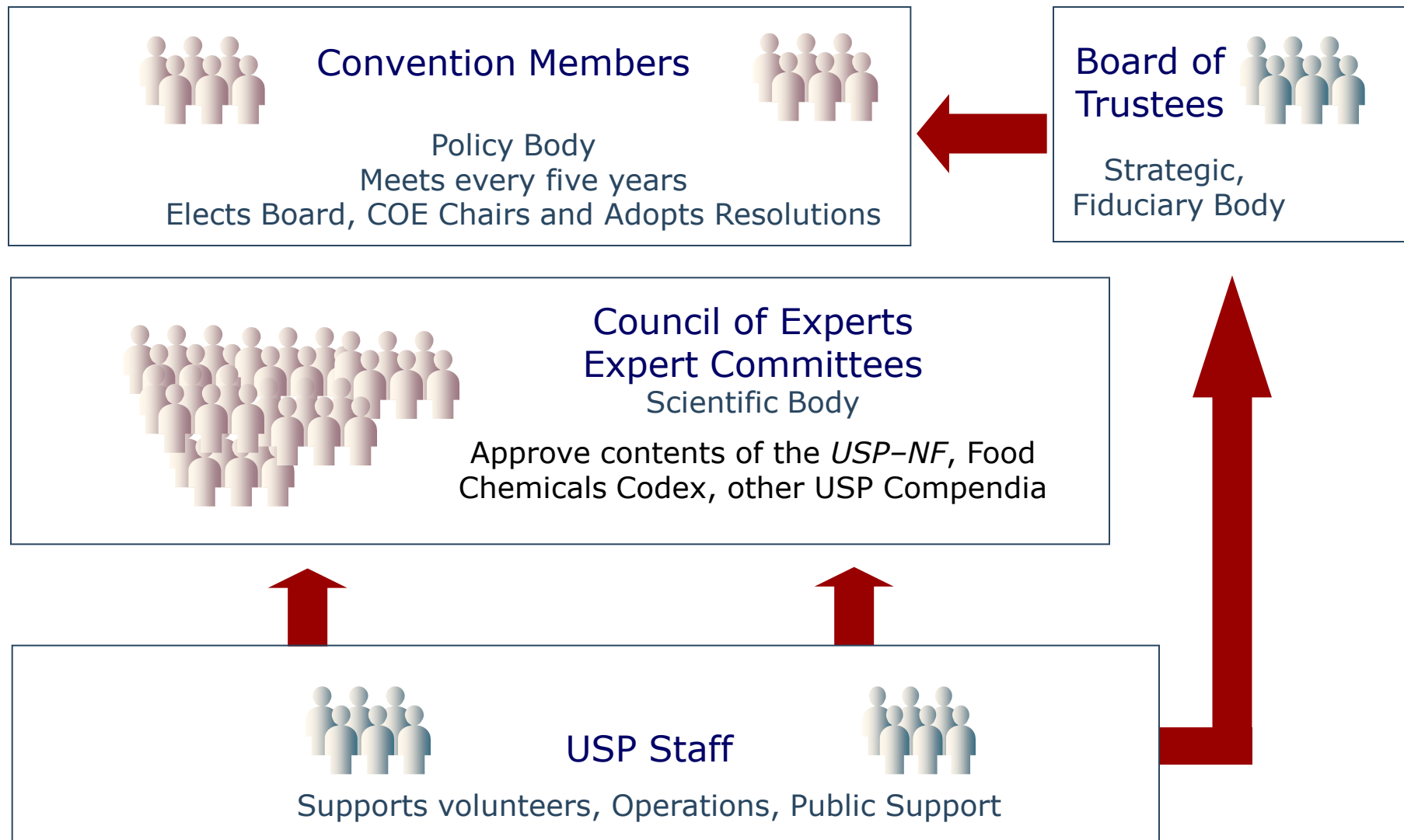
Robert Shimahara
Veterinary Drugs Stakeholder Forum
February 19-20, 2014

- ▶ USP: The Organization
- ▶ USP Publications
- ▶ USP Reference Standards:
Physical Standards
- ▶ USP Pharmacopeial Education:
Teaching *USP–NF*
- ▶ Relationship Management

- ▶ Private Organization
- ▶ Non-Profit
- ▶ Volunteer based



USP Organizational Structure



- ▶ 1906 Pure Food and Drugs Act
- ▶ Federal Food, Drug and Cosmetic (FD&C) Act of 1938
 - defines the term "official compendium" as the official USP, the official NF, the official Homeopathic Pharmacopeia of the United States, or any supplement to them
- ▶ Dietary Supplement Health and Education Act of 1994
 - provide that a dietary supplement may be deemed misbranded if it is covered by a monograph in an official compendium, is represented as conforming to this monograph, but fails to so conform.

▶ **USP: Private Not-For-Profit Organization**

- Compendial standards: development and revision
- Public standards: identity, strength, quality, purity, packaging, and labeling

▶ **FDA: Government Agency**

- Enforcement
- Safety, efficacy; NDA, ANDA, BLA
(private license) approvals for marketing, manufacturing processes, etc.

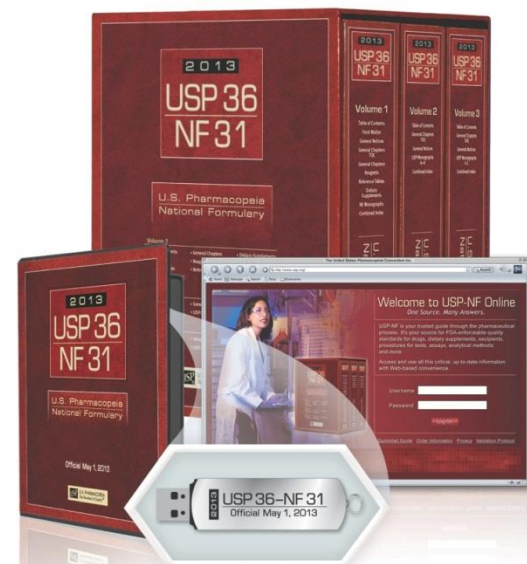
USP is the only major Non-Governmental Pharmacopeia in the World!



USP Publications

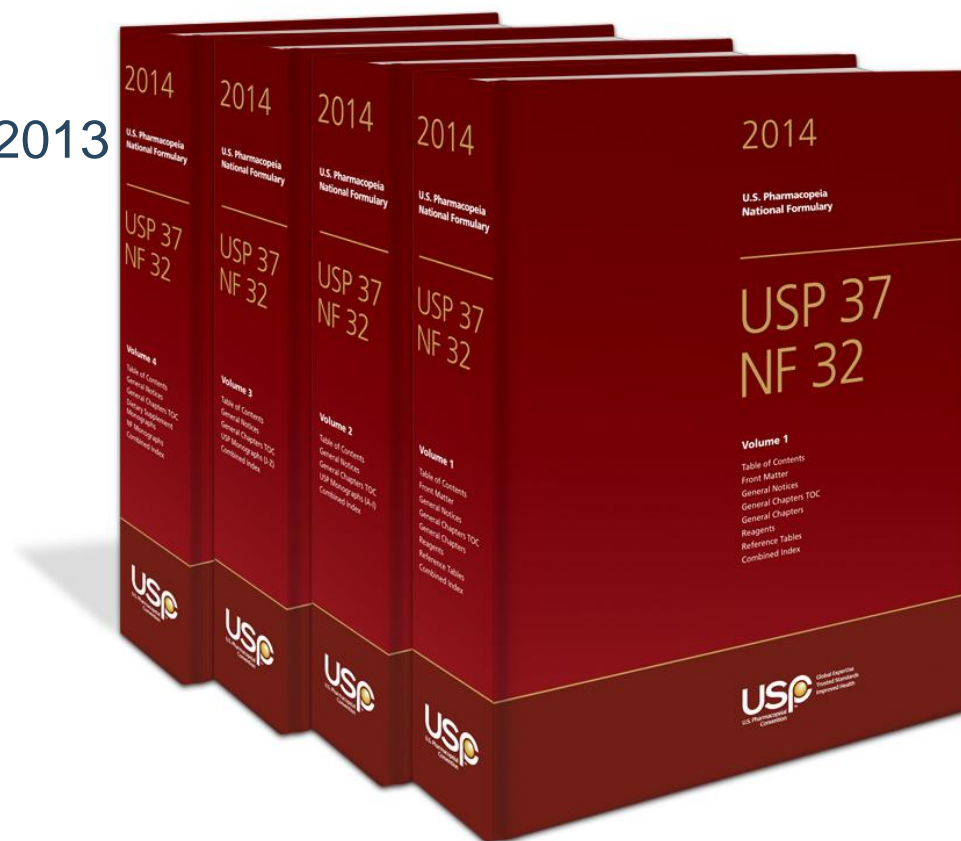
Internationally recognized standards for drugs, dosage forms, excipients, biologics, compounded preparations, dietary supplements, and more

- ▶ More than 4,500 monographs with specifications for identity, purity, quality, and strength
- ▶ Over 260 General Chapters, with step-by-step tests and methods
- ▶ FDA enforceable for drugs marketed in or exported to the U.S.
- ▶ Available in English (print, online, and USB flash drive) and Spanish (print)
- ▶ One-year subscription includes main edition and two *Supplements*



The *USP 37—NF 32* contains 104 new and revised Monographs and 8 new and revised General Chapters

- ▶ NEW! - 4 Volume Set
- ▶ Published on November 1, 2013
- ▶ Official May 1, 2014



All changes and additions to the *USP–NF* are first proposed in *PF* for public review and comment.

- ▶ Provides early notification of official changes to *USP–NF*
- ▶ Serves as the public forum for your comments, suggestions, and submissions
- ▶ Now a complimentary online-only service



*New monographs requested from industry
on FDA approval*

Submission to Include

- ▶ Proposed limits and validation
 - 98%–102% for bulk materials
 - 90%–110% for dosage forms
- ▶ Identification test(s) [IR/UV/chromatographic]
- ▶ Packaging, storage, and labeling requirements

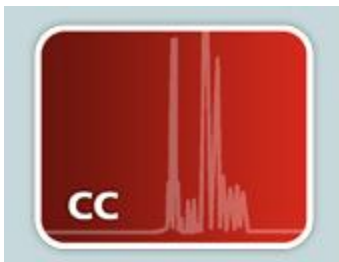
Submission to USP Must Include

- ▶ Reasonable justification
- ▶ Adequate supporting methods, specifications, and data

**Consult USP Web site, staff liaison,
or draft guidelines for more information.**

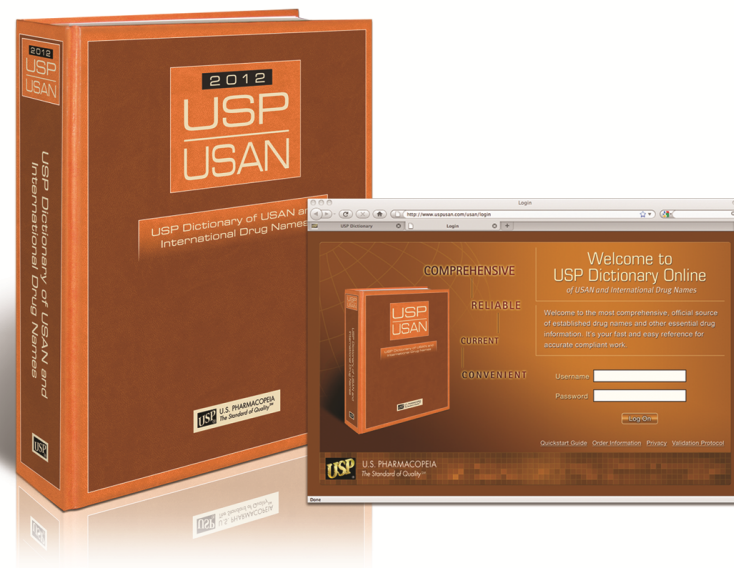
Now a **Free** online-only resource!

- ▶ Provides brand names of columns used in validating all proposed and official gas- and liquid-chromatographic procedures in *PF* and *USP–NF*
- ▶ Includes an index of manufacturers
- ▶ Increases accuracy and consistency of results in official tests and assays
- ▶ Go to www.uspchromcolumns.com to access this resource (a one time registration is required)



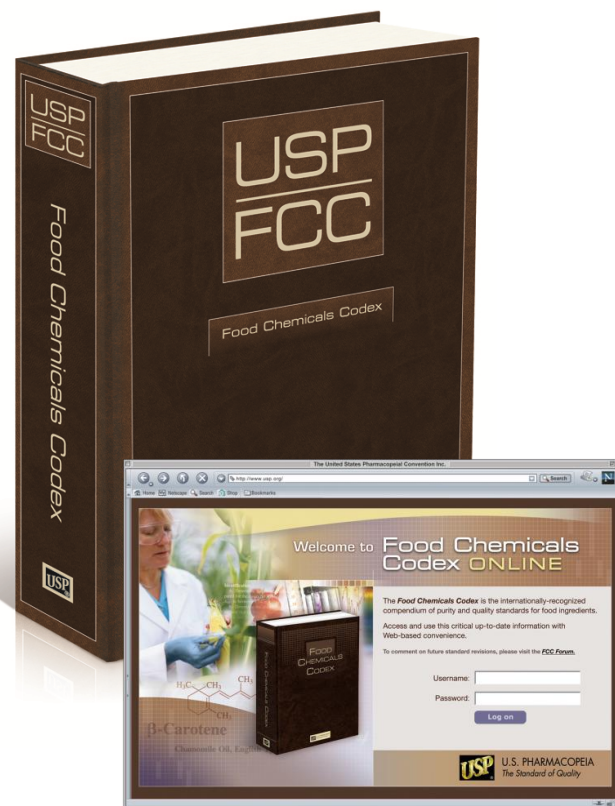
The *USP Dictionary* provides U.S. generic drug names (USANs), International Nonproprietary Names (INNs), pronunciations, brand names, manufacturers, chemical structures, formulas, UNII codes, and more.

- ▶ Only comprehensive source of USANs, from inception of program in 1961 through today
- ▶ Contains more than 1,458 new and revised entries!
- ▶ Updated and published annually, in print and online



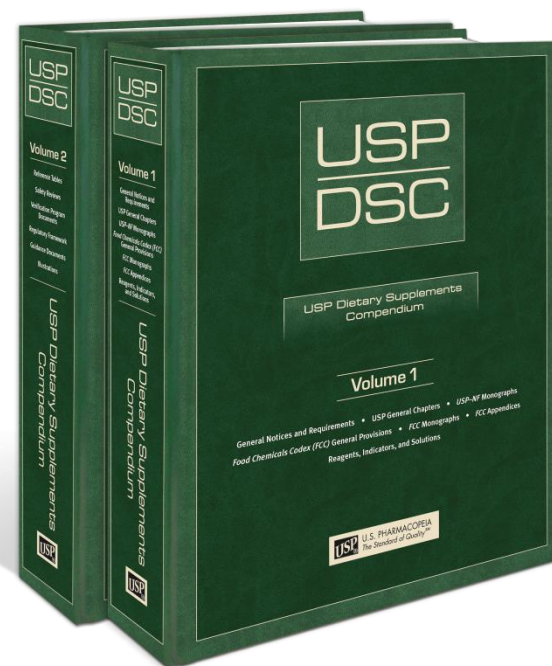
Internationally recognized standards for determining the quality and purity of food ingredients

- ▶ Contents:
 - More than 1,100 monographs
 - 14 appendices detailing more than 150 tests and assays
 - 1,300+ page excerpt from new USP Food Fraud Database
- ▶ Print and online formats, English only
- ▶ Published every two years with three supplements published between editions
- ▶ Updated via the free online *FCC Forum*, two 90-day comment periods each year



Combines *USP–NF* dietary supplements standards, *FCC* specifications, and other valuable information

- ▶ More than 550 monographs
- ▶ Step-by-step tests and assays from *USP* General Chapters and *FCC* Appendices
- ▶ 23 new and revised *DSC* Admissions Criteria Safety Reviews
- ▶ Nearly 300 pages of full-color illustrations
- ▶ Two-volume print set, English only
- ▶ Updated and published every two years



USP Reference Standards

Physical Standards

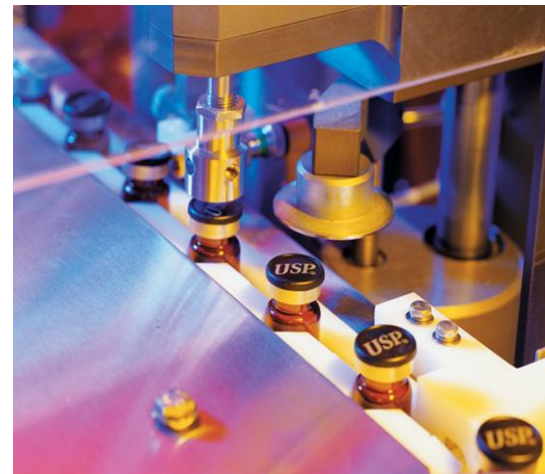
USP Reference Standards

- ▶ Trusted for pharmaceutical quality control worldwide
- ▶ Over 3,100 Reference Standards now available
- ▶ Support FDA-enforceable standards and tests in the *USP–NF*
- ▶ Stocked and ready to ship same day (2-day delivery within U.S.)

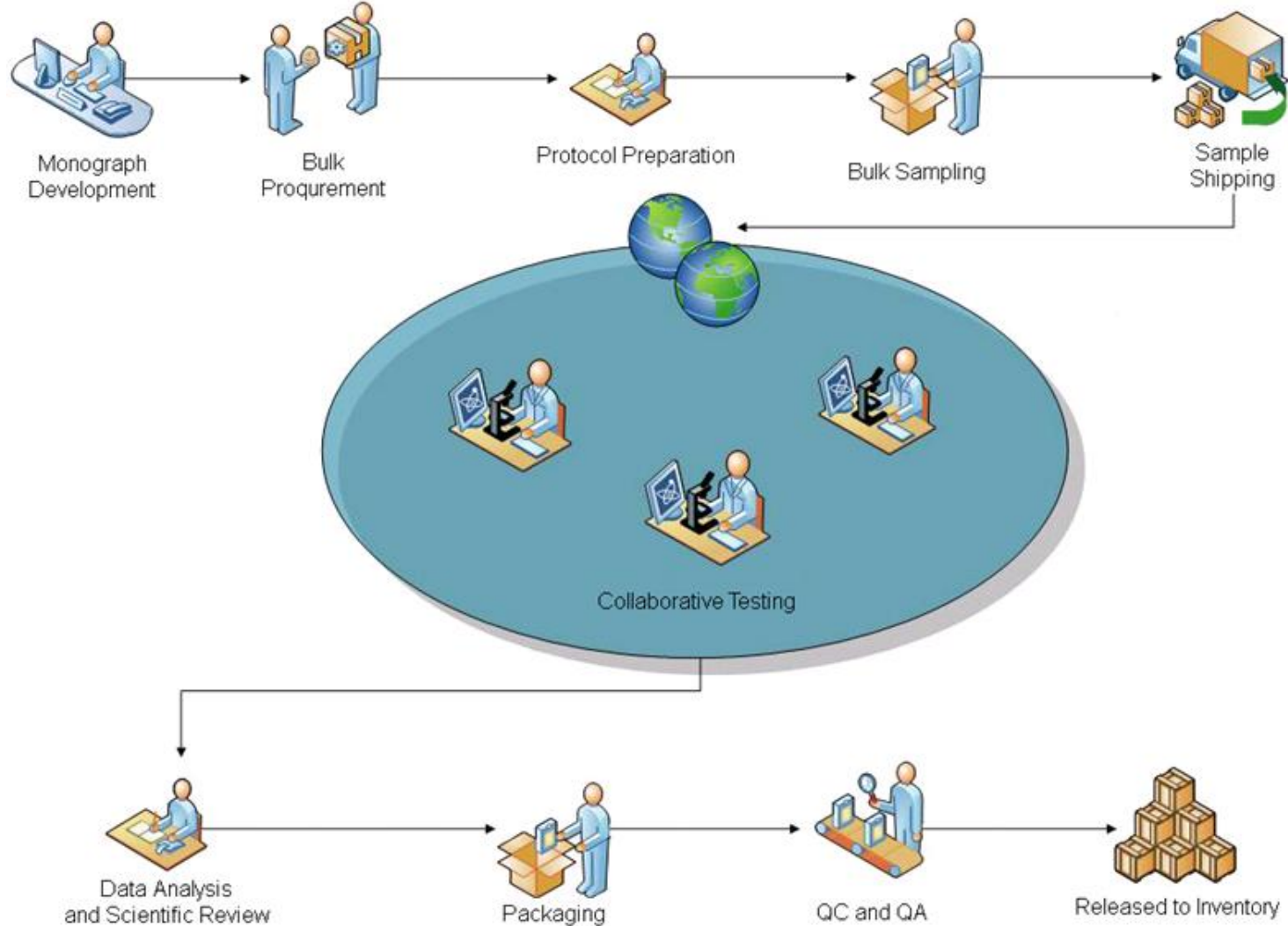


What is a USP Reference Standard?

- ▶ Highly characterized specimens of:
 - drug substances
 - excipients
 - impurities
 - degradation products
 - biologics
 - food ingredients
 - dietary supplements
 - compendial reagents
 - performance test tablets
- ▶ Rigorously tested by USP, industry, and government scientists
- ▶ Vast majority are intended for use in compendial methods; however a few Reference Standards are available for customer convenience as a service to the industry
- ▶ Established and released under the authority of the USP Board of Trustees and Council of Experts

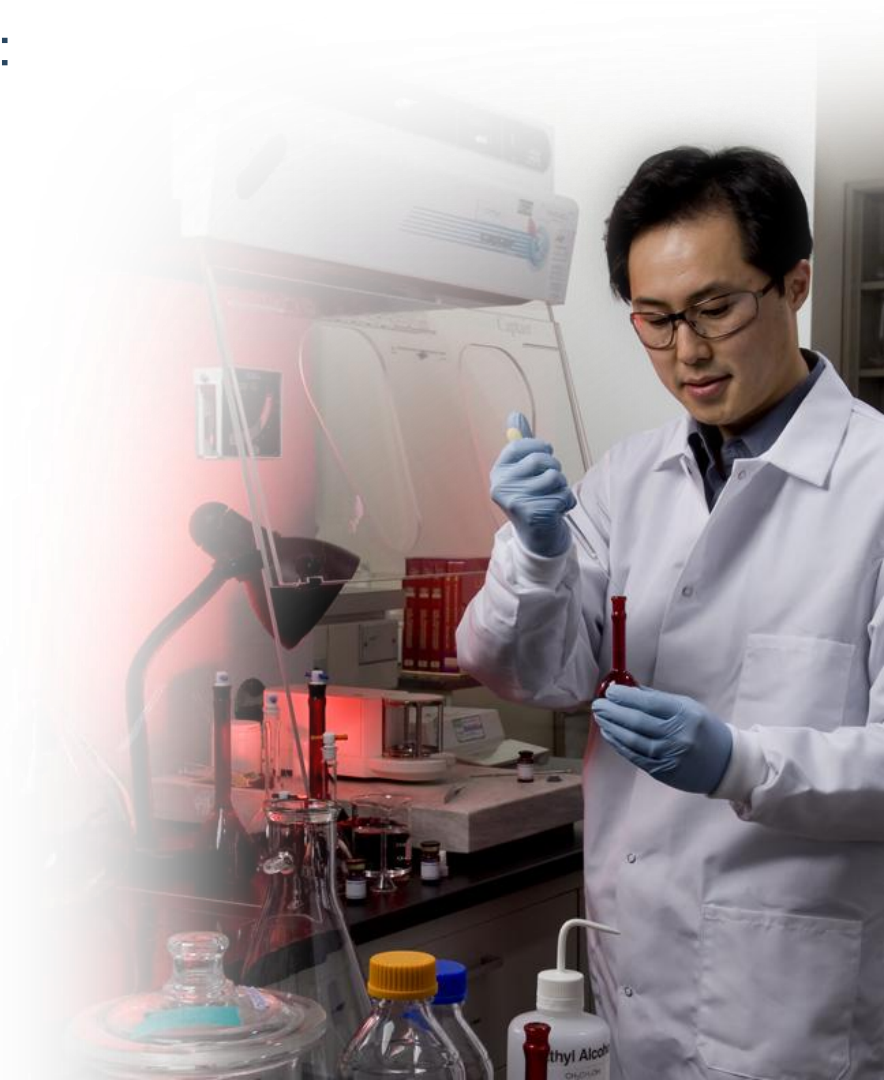


Reference Standards



Testing

- ▶ Collaborative testing in multiple labs: USP, industry, and regulatory labs
- ▶ Extensive testing beyond the compendial tests





Global Education and Training

USP Teaching *USP–NF* and *FCC*

- ▶ Teaching efficient use of USP standards
- ▶ Providing the tools to maintain compliance with *USP–NF* and *FCC* public standards
- ▶ Ideal opportunity to discuss compendial issues with knowledgeable USP staff





Classroom:

USP offers face-to-face sessions in traditional classroom settings around the world. Engage with experts and peers and get immediate answers to questions. ***Classroom courses can be customized to your specific needs and delivered at your company location.***



Laboratory:

USP laboratory sessions provide hands-on training in a working laboratory facility. Many courses combine a classroom lecture with a laboratory segment to ensure that you gain comprehensive and practical knowledge of USP standards and how to apply them effectively in your work.



Online:

USP online courses are designed with flexibility and easy access in mind. Through the Internet from anywhere in the world, you can view interactive presentations, listen to live and/or recorded lectures, and contact USP experts. We offer three types of online courses: Live; On-Demand; Self-Paced eLearning

- ▶ Location designated by company
- ▶ Opportunity to put course content within the context of your organization
- ▶ Contact Account Management Team or send an email to **PharmEd@usp.org**



USP Account Managers

- ▶ Understanding your goals and needs
- ▶ Connecting you to the right USP staff
- ▶ Making your voice heard
- ▶ Looking for USP solutions to your problems
- ▶ Providing order management assistance
- ▶ Keeping you informed
 - Email notification program
 - Customer visits/USP updates
 - User Forums

USP Account Managers

Joe Eaton

Holly Chang

Kevin Correa

Christine Hiemer

Diana Lenahan

Laura McCurry

Doreen McDonald

Science Support for Documentary & Reference Standards

- ▶ rstech@usp.org for Reference Standard queries
- ▶ stdsmonographs@usp.org for Small Molecules/Biologics
- ▶ nfmonographs@usp.org for Excipients

- ▶ 24/7 order access
- ▶ Updated every 24 hours
- ▶ Order tracking and order history
- ▶ Ability to personalize your ordering and shipping requirements
- ▶ Order confirmation
- ▶ All products (except controlled substances)

**<https://store.usp.org>
or www.usp.org**



Why and How to Work with USP

- ▶ Active participation in monograph development
- ▶ Bulk donations to qualify USP Reference Standards
- ▶ Comment on *Pharmacopeial Forum*
- ▶ Attend USP events
 - Stakeholder Forums
 - Workshops
 - Global Education and Training

Thank You