Why and How to Work with USP

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Veterinary Drugs Stakeholder Forum
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Topics

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

- Private Organization
- Non-Profit
- Volunteer based
USP Organizational Structure

**Convention Members**
- Policy Body
- Meets every five years
- Elects Board, COE Chairs and Adopts Resolutions

**Board of Trustees**
- Strategic, Fiduciary Body

**Council of Experts**
- Expert Committees
- Scientific Body
- Approve contents of the *USP–NF*, Food Chemicals Codex, other USP Compendia

**USP Staff**
- Supports volunteers, Operations, Public Support
Legal Basis for USP Standards

- 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’s Relationship to FDA

- **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!**
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](http://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.)
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

Monograph Development → Bulk Procurement → Protocol Preparation → Bulk Sampling → Sample Shipping

Collaborative Testing

→ Data Analysis and Scientific Review → Packaging → QC and QA → Released to Inventory
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
Convenient Format Options

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.
On-site Delivery

- 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  
Kevin Correa  
Diana Lenahan  
Doreen McDonald

Holly Chang  
Christine Hiemer  
Laura McCurry

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
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