

Chapter 1

The *Glossary of Terms* is usually included at the end of a manuscript. In the case of this book, it is the opinion of the author that the terms required to interpret the *United States Pharmacopeia (USP)* and the *National Formulary (NF)* and understand their processes is more appropriately placed upfront in the volume. Further, the language for understanding the United States Pharmacopeial Convention, Inc. (USPC) also is unique and should be reviewed by readers before they venture into the demystification process.

The following terms are used repeatedly throughout this book and will help the reader become familiar with the specific language and definitions critical for developing a complete and thorough understanding of the standards setting process.

Glossary of Terms

Ad-hoc Committees: These committees differ from Project Team because they are appointed by the Expert Committee. The members for these committees are chosen for their expertise in a specific area. Recommendations from ad-hoc committee deliberations are not binding on the Expert Committee.

Board of Trustees: Elected by the members of the United States Pharmacopeial Convention (USPC), this governing body has fiduciary responsibilities and defines the strategic direction of the USP through their policy and operational decisions.

Compendium: Generic term referring to an accounting of information on a specific topic. Pharmacopeias are a specific type of compendia.

Council of Experts: This is the official standard setting body of the USP. The council is comprised of the Expert Committee Chairs elected to serve five year terms by the members of USPC.

Expert Committee: The group of individuals assigned to address, deliberate and vote on issues affecting monographs, general notices and requirements, general test chapters and general information chapters in the USP that fall within the jurisdiction of their assigned committee. The chairs of the various committees are elected by the members of the USPC and subsequently, members of the committees are selected at a meeting of the chairs. Committee members vote to approve or disapprove information scheduled to be officially adopted in the USP or NF and their associated supplements or via an Interim Revision Announcement.

Expert Committee Member: An individual, elected by the committee chairs, to serve a five year term on an Expert Committee. Candidates are selected based on the details of their applications for membership and their expertise and knowledge in a specific scientific discipline.

Expert Committee Chair: Elected by the members of the USPC, the chairs of Expert Committees serve five-year terms and are responsible for executing the work plan of the committee they lead.

Food and Drug Administration (FDA): The U.S. government agency which has enforcement discretion for the standards published in the United States Pharmacopeia / National Formulary (USP/NF) for products or materials distributed within the United States of America.

General Test Chapter: Instructions for performing certain test methodologies repeatedly referenced in the monographs. Typically, the methodology is independent of the item being tested (e.g., Loss on Drying, pH, Residue on Ignition). General test chapters are assigned numbers from 1 to 999.

General Information Chapter: Usually theoretical and interpretive in nature these chapters discuss methodology and manufacturing concepts not referenced by an individual monograph. General information chapters are assigned chapter numbers from 1000 to 1999.

In-process Revision Announcements: Proposed changes affecting the official standards published for public comment in the Pharmacopeial Forum. In-process Revisions indicate the monograph change being considered and the proposed USP/NF volume in which it will become official adopted (e.g., USP 30, NF25, 2S (USP30), etc.) The appearance of items in this section of the PF officially starts the public review comment period.

Interim Revision Announcement (IRA): Published in the Pharmacopeial Forum (PF), the IRA is the mechanism for adopting official changes in-between the issuance of the annual publication or its supplements and is typically reserved for items requiring immediate implementation.

Monograph: The specific tests, analytical procedures, and acceptance criteria for determining the strength, quality, purity, and potency for a given compendial article. Additional information such as storage conditions, nomenclature, chemical formulae, and the applicable USP Reference Standards also are included in the monograph.

National Formulary (NF): Originally published as a separate collection of standards, it was purchased by the USP and merged into one volume with the *USP* in 1974. This compendium now contains monographs for items typically used only as excipients. It is revised on the same publication cycle as the *USP* and its contents become official on January 1 of a given year unless otherwise noted in the text.

Pharmacopeia: Legally binding document governing the quality, strength and purity of medical items of commerce in a specific geographical region. The *USP-NF* apply to products marketed in the United States of America as well as many other countries around the world, the *European Pharmacopoeia (EP)* applies to products marketed in the European Union and the *Japanese Pharmacopoeia (JP)* applies to products marketed in Japan.

Pharmacopeial Discussion Group (PDG):): Representatives from the EP, the JP and the USP that generally meet twice per calendar year to harmonize excipient monographs and general chapters common to all three compendia.

Pharmacopeial Forum (PF): Published 6 times per calendar year it is used to introduce proposed changes to official items contained in the USP/NF and begin the public review process where interested parties can comment on the merit of these proposals. Items included in the PF have not been formally adopted by USP. IRAs are published in *PF*.

Project Team: USP Project Teams are working groups associated with and sanctioned by the Stakeholder Forum participants. The majority of these Teams work under the auspices of the Prescription/Non-Prescription Stakeholder Forum (P/NP SF). Project Teams have specific goals and are not intended to be long term committees. Project Team members are chosen representatives from

the Stakeholder Forum member organizations. USP Expert Committees are welcome to attend Project Team meetings but must do so as representatives of the USP. Recommendations made by the project teams are not binding on the USP.

Resolution: The start of the standard setting process, resolutions are voted on by the USPC members and define the strategic direction of the USP in a given five year cycle. Resolutions may be carried over from one five year cycle to another but would have to be voted on again at the Convention leading up to the second cycle.

Revision Cycle: The five year period between conventions in which the elected Expert Committee chairs and their elected members conduct the standard setting business of the USPC. The current revision cycle is 2005-2010.

Scientific Liaison: An employee of the USP who is responsible for facilitating discussion between the Expert Committee and various sectors of the pharmaceutical industry. The scientific liaison is responsible for briefing the Expert Committee members on the issues (pros and cons) related to specific change requests to official items in the USP/NF.

Stakeholder Forum: Stakeholder Forums were initiated in 1999 and became an officially recognized component of the USP family by a vote at the 2005 convention. The most active Stakeholder Forum has been the P/NP SF. P/NP SF meetings are held biannually on an established schedule and provide the opportunity for USP to interact with representatives from scientific and trade associations. Among the participating organizations sending representatives to these meeting are the Generic Pharmaceutical Association (GPhA), Parenteral Drug Association (PDA) and the Pharmaceutical Research and Manufacturers of

America (PhRMA). Representatives from FDA generally attend these meetings as well. There are currently three active stakeholder forums: 1) P/NP SF, 2) Compounding, and 3) Biotechnology and Biological. In addition, USP plans to reestablish the Patient Safety Stakeholder Forum.

Supplements: Published twice per calendar year, Supplements are USP's mechanism for officially adopting changes in-between the annual publication of the main volume. The 1st and 2nd Supplements become official on April 1 and August 1, respectively, of any given calendar year.

United States Pharmacopeia (USP): Originally published in 1820 on a periodic schedule and yearly since 2002, this compendium contains monographs for drug substances, drug products, biologics, biotechnology products, dietary supplement, general test methodology and general information used to establish quality standards for these articles that are legally marketed in the United States. This volume's contents become official on January 1 of a given year unless otherwise noted in the text.

United States Pharmacopeial Convention (USPC): Previously called the Quinquennial meeting, the convention meets every five years. Member organizations send delegates to vote on changes to the USP by-laws and constitution, elect the members of the Council of Expert, elect Board of Trustee members, conduct business meetings, and debate and vote on Resolutions.

Now that you are armed with an understanding of some of the specific pharmacopeial terms and language, you are ready to begin the journey of demystifying the USP processes. Through this journey you will learn how you can participate and, more importantly, how you can impact this standard setting organization.