



Volunteering with the United States Pharmacopeia

By Chris Moreton, FinnBrit Consulting

The United States Pharmacopeia (USP) is one of three sets of official standards recognized under the US Food Drug and Cosmetic Act; the other two are the National Formulary (NF) and the Homeopathic Pharmacopeia of the United States. The USP is published by the United States Pharmacopeial Convention, Inc. (also called USP), headquartered in Rockville, MD. The current CEO of USP is Dr. Ron Piervincenzi. USP has a permanent staff and laboratories at its headquarters in Rockville, MD and satellite laboratories in China, India and Brazil. It also has further satellite office in Switzerland, Brazil and Ghana and it recently expanded its presence to Ethiopia, Indonesia, Nigeria and the Philippines. USP's work is supported by a network of Expert Committees and Expert Panels staffed by volunteer experts. I have been a volunteer with USP since the year 2000.

The USP was first published in 1820. This makes it one of the oldest of the modern pharmacopeias. Originally, it was revised every 10 years. The first Committee of Revision was established in 1830. Later, it was revised every five years, and the USP continues to operate on a five-year Revision Cycle. However, the book is now revised and re-issued annually with two supplements per year. This change in the revision schedules reflects the increasing number, range and complexity of pharmaceutical products, the ever-increasing sophistication of drug substances, and the need for better specifications and control methods for modern medicines.

In 1975, the administration of the NF was taken over by USP. Officially, the USP and the NF are two separate books. However, they are now published together in the same set of volumes and the title is now the United States Pharmacopeia-National Formulary (USP–NF). There is also one further set of standards published by USP: The Food Chemicals Codex (FCC). This does not have the official recognition in US law that the USP–NF has, but it is nevertheless a well-recognized set of standards for food ingredients.

The USP-NF 5-year Revision Cycle coincides with quinquennial USP Convention meeting. The next meeting will be in May 2020. There are more than 300 official delegates to the USP Convention including representatives from state medical boards, pharmacy boards, nursing boards, and dental boards, trade organizations and government departments. At this meeting, the members of the Board of Trustees (USP's governing body) and the chairs of the Expert Committees will be elected for the 2020–2025 revision

cycle. The chairs of the different Expert Committees comprise the members of the Council of Experts. The Chair of the Council of Experts is USP's Chief Scientific Officer, Dr. Jaap Venema.

Following the election of the chairs of the Expert Committees, the new chairs, together with USP staff, will select the other members of the Expert Committees who will serve for the duration of the revision cycle. In addition, during the course of the revision cycle, Expert Panels will also very likely be set up. These panels are typically set up to address a specific issue where extra expertise in a particular field, beyond that of the members of the expert committee is required. All in all, USP is looking for several thousand potential volunteers, from both academia and industry. Not all volunteers will get elected to an Expert Committee, but there will then be further opportunities as Expert Panels are formed. The independent experts selected for the Expert Panels will typically come from those people whose names are on the list of volunteers.

As I mentioned, I have been a USP–NF volunteer since 2000. During my time as a volunteer, I have been involved in the development of new monographs, revision of existing monographs, development of new general chapters, revision of existing general chapters, and preparation of Stimuli articles. I have also given presentations on behalf of USP–NF in the US at different conferences, and also in Brazil and China. I enjoy the work with USP–NF very much. I have met some very good friends through my USP–NF volunteer work. I find the work interesting and stimulating; it is a pleasant interlude to my day job. I also find it very satisfying to be able to contribute to improving the lives of people in the US and around the world.

The USP–NF is looking for a wide variety of scientific expertise and skills, and not just experts based in the United States. In the current Expert Committees, we have members from Europe, Asia and South America. The skills USP is looking for include (in no particular order):

- Analytical methods
- Small molecule drugs
- Proteins and biotechnology drugs
- Product development
- Formulation science
- Regulatory science
- Microbiology
- Pharmaceutical materials science
- Pharmacology
- Safety/toxicology
- Pharmaceutical packaging technology

- Statistics
- Dietary supplements
- Food ingredients
- Pharmaceutical compounding

The list of areas for the Expert Committees in the 2020 – 2025 Revision Cycle include:

- Excipients
- Reference Materials
- Statistics
- Compounding
- Food Ingredients
- Dietary Supplements and Herbal Medicines
- Biological Medicines
- Health Information and Technology
- Nomenclature and Labeling
- Healthcare Safety and Quality
- Microbiology
- Packaging and Distribution
- Physical Analytical Methods
- Dosage Forms
- Measurement and Data Quality
- Chemical Analytical Methods
- Chemical Medicines

[Please note, there may be more than one Expert Committee in a particular area.]

So, what are the commitments of being a USP-NF volunteer? Typically, volunteers spend two to four hours per week on official USP business outside of any travel to meetings. As a member of a USP–NF Expert Committee, you will be invited to attend face-to-face meetings in Rockville once or twice per year. These typically are two-day meetings and USP will pay all travel and accommodation expenses, but it does mean time away from the office. Attendance is not compulsory, but you will be asked to make every effort to attend. These face-to-face meetings are very valuable for resolving any differences, and they are also great networking opportunities. There is typically a monthly conference call lasting from one to two hours as well. In addition, there are email inquiries and documents to read ahead to prepare for conference calls and meetings. Necessarily, these calls will take place during the normal working day. For these reasons, if you are interested in becoming a volunteer, you should get permission from your employer. There are some other aspects of being a USP–NF volunteer you should be aware of. First and foremost, if selected for an Expert Committee, you are there as an independent

scientist. You are not representing your company or institution, or any other organization with which you may be associated. The USP–NF has a strict conflict of interest policy. It is recognized that volunteers will have conflicts of interest from time to time, but as long as these are properly declared, they can be managed. You will also be expected to take part in all aspects of the work of your Expert Committee; this includes participation in the monthly conference calls, attendance at the face-to-face meetings and participation in e-mail discussions. All the proceedings of USP–NF committees are confidential and you will be required to sign a confidentiality agreement.

Expert Panels work somewhat differently. However, if selected you would still be required to declare any potential conflicts of interest and abide by the confidentiality rules. Expert Panels are typically set up for a shorter term (one to two years). Similar commitments in terms of time are likely. A face-to-face meeting may be arranged, but it is not certain.

It is recognized that there will be scheduling conflicts from time to time – we all have day jobs; however, if you are considered not to be pulling your weight, you will be contacted and asked if you want to continue. Occasionally, an Expert Committee volunteer finds that they cannot continue to take a full part in the Committee’s work. If this happens, for whatever reason, you are allowed to resign from your committee. A replacement will be found from the USP–NF’s list of volunteers.

To volunteer for the USP–NF 2020–2025 Revision Cycle is quite easy. Go to the USP website (www.usp.org). Place your cursor over ‘About’, and click on Volunteer Experts. Click on ‘Become a Volunteer Expert’ and then click on ‘Apply Now’. Alternatively, contact me at a NESACS Meeting and ask me for a card with the QR code to take you straight to the site and page. Once at the page you will be asked to provide a summary of your expertise and to select which type of Expert Committee(s) you wish to apply for (you are allowed to apply for more than one type or field).

One final point, to reiterate, not everyone who volunteers will be selected for an Expert Committee on the first round. Do not be disheartened, there will very likely be other opportunities as Expert Panels are set up, existing members step down, etc. The pharmaceutical and nutraceutical worlds are very dynamic; things are changing almost every day and the USP–NF and FCC have to change accordingly. This will create opportunities for yet more people to become involved.