

# USP Convention 'Call for Candidates' for the 2025-2030 Revision Cycle

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Editorial

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The United States Pharmacopeia Convention (USPC) has announced its 'Call for Candidates' to serve as Expert Volunteers during the 2025-2030 Revision Cycle. The United States Pharmacopeia (USP) along with the National Formulary (NF) (collectively, the USP-NF) are two of the three official standards for pharmaceutical materials and products recognized in the US Food and Drug Act. (The third standard is the Homeopathic Pharmacopeia of the United States which is completely separate from the USP and NF.) Originally, the USP and NF were separate. However, the USP took over the NF in the 1970s, and, although legally separate standards, they were published in the same set of volumes from 1980 to 2020. After the USP purchased the NF there was a rationalization, and today, the USP is largely focused on drug substances, whereas the NF is more focused on excipients. The USP-NF is now only available on-line.

The USP-NF operates on a five-year Revision Cycle, and relies on an extensive network of Expert Volunteers and Expert Advisors, and these are appointed/re-appointed for each new Revision Cycle. The current Revision Cycle will end in May 2025, and the 2025-2030 Revision Cycle will start in June 2025. For the new Revision Cycle the USP-NF is looking for several hundred Expert Volunteers and Expert Advisors. The proposed list of the different Expert Committees and Collaboration Groups for the 2025-2030 Revision Cycle is given in Table 1 (©2024 The United States Pharmacopeia Convention, published with permission).

I have been an Expert Volunteer for the USP-NF since 2000. I was very honored to be chosen for the 2000-2005 Revision Cycle. In the past five Revision Cycles I have worked on different Expert Committees dealing with excipient test methods and excipients monographs, but besides the excipient-related Expert Committees, there are many more Expert Committees

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**Table 1** Proposed USP Expert Committees for the 2025-2030 Revision Cycle

SMALL MOLECULES	BIOLOGICS	EXCIPIENTS	DIETARY SUPPLEMENTS & HERBAL MEDICINES, FOOD INGREDIENTS	HEALTHCARE QUALITY	GENERAL CHAPTERS
1. Small Molecules Therapeutic Areas 1	1. Therapeutic Peptides, Oligonucleotides and Complex Carbohydrates	1. Excipient Monographs 1	1. Botanical Dietary Supplements and Herbal Medicines	1. Healthcare Safety, Quality & Nomenclature	1. Dosage Forms
2. Small Molecules Therapeutic Areas 2	2. Therapeutic Proteins	2. Excipient Monographs 2	2. Non-botanical Dietary Supplements	2. Compounding	2. Chemical Analysis
3. Small Molecules Therapeutic Areas 3	3. Vaccines	3. Excipient Chapters	3. Dietary Supplements Admission, Evaluation & Labeling	3. Healthcare Information and Technology	3. Microbiology
4. Small Molecules Therapeutic Areas 4	4. Cell and Gene Therapies		4. Food ingredients	4. Personalized Medicines	4. Packaging and Distribution
5. Small Molecules Therapeutic Areas 5					5. Statistics
6. Small Molecules Therapeutic Areas 6					6. Pharmaceutical Analysis Lifecycle and Data Science
					7. Materials Physical Properties Characterization

Adapted from: <https://callforcandidates.usp.org/sites/default/files/Focus-Areas-Collaborative%20Groups.pdf>

dealing with small molecule drugs, biologic drugs, food and dietary supplements, general chapters, pharmacy compounding, etc. (for a total of 28 proposed Expert Committees for the 2025-2030 Revision Cycle as can be seen in the Table 1). I have found the work very interesting and rewarding, especially seeing the monographs or general chapters I have worked on in my Expert Committee finally published as part of the USP-NF. I have also made some good friends and contacts in the USP-NF community (both among volunteers and staff). I should also point out that it is not all serious scientific debate and work, and it pays to have a good sense of humor. There are also activities at some of the in-person meetings supporting outreach to local volunteer groups and charities in the Rockville, MD area.

As you can see from the table above, in the coming Revision Cycle, there will be three Expert Committees in the Excipient Collaborative Group: Excipient Monographs - 1, Excipient Monographs - 2, and Excipient General Chapters. The skill sets required for the two monograph committees will be quite similar. The skill sets required for the Excipients General Chapters Expert Committee will be a little different since the projects will likely cover such topics as GMP

and related topics as they apply to excipients, as well as some analytical methods, both chemical and physical.

So, who can apply to become an Expert Volunteer or Expert Advisor with the USP-NF? The simple answer is anyone with the requisite skills needed by the USP-NF Expert Committees. For the Expert Committees in the current Revision Cycle, the USP-NF has an active policy concerning diversity, equality, inclusivity and belonging (DEIB), and this will be maintained for the next Revision Cycle. On the Expert Committee I have been a member of in the current Revision Cycle, while many members are based in the US, there are members also who are based in Europe and Asia, and there are no restrictions regarding gender, age or ethnicity. Indeed, USPC actively encourages participation from volunteers based overseas because they realize that there may be different thinking and ideas in different regions of the world, and these different points of view can help in the development of robust monographs and General Chapters that are accepted globally. One point to consider is that the USP-NF is headquartered in Rockville, MD and all the scheduling of meetings and conference calls are based on Eastern US time. This has not deterred our overseas members from active participation; however, Expert Committee members in

Asia, should note that this may mean being on meeting calls quite late in the evening.

Another topic that often comes up is the time commitment. For Expert Volunteers and Advisors there is typically a call via MS Teams once every four to six weeks. In addition, there is background reading and writing. There may also be membership of Expert Panels and Joint Subcommittees. In my experience this typically amounts to an average of up to 1 – 2 hours per week, in addition to the formal meetings, which can last 1 – 2 hours each. In addition, there are annual in-person Expert Committee meetings in Rockville. At the start of the Revision Cycle, the members of each Expert Committee will be invited to Rockville for the on-boarding process. Thereafter there is typically an annual in-person meeting, also held in Rockville. In the future, there is likely to be more use of hybrid meetings; however, there is no substitute for in person (face to face) meetings, as there is so much more understanding that can be gained than over an internet video link. Obviously, this all takes time out of your working day/week and you should get permission from your employer to become an Expert Volunteer. It is important to let your employer know that the only part of the commitment they have to accommodate is your time. USP pays for all travel and accommodation costs associated with all approved USP activities.

For Expert Committee Chairs, there are additional time commitments, notably attendance at meetings of the Council of Experts. There are monthly conference calls and typically an annual in-person meeting in Rockville. There are also calls of the different Collaborative Groups (groups of Expert Committees that are closely related (for example, the Excipients Collaborative Group, General Chapters Collaborative Group, etc.). These occur every four to six weeks through the Revision Cycle.

A further issue that may arise is a potential conflict of interest on a particular topic. The USP-NF recognizes this, and has a policy for conflicts of interest which allows Expert Volunteers to declare a conflict and then abstain from voting on the issue. In my experience, it does not happen very often, but it can. However,

potential conflicts of interest are not a bar to becoming an Expert Volunteer with USP-NF.

All applications must be submitted online. The website to submit applications can be found at <https://callforcandidates.usp.org/node>. You will be asked to set up your profile and add in the relevant information. From the USP's perspective, they are interested in your activities and experience over the last 10 – 15 years. There is an option to upload your CV and the software will then populate your application with relevant information. However, be careful about what you include in your CV, as too much older information can create issues. One further point is that the application website is set up by Collaboration Group, rather than by individual Expert Committee, and you will be asked to select the Collaboration Group you wish to apply for. There are videos linked to the website that explain the process in more detail.

The deadline for applications is May 2025. The applications will then be sorted according to the expressed preferences. The USP staff will then assess the candidates and the suitability of their qualifications and experience, and a final list will be assembled of potential members for each Expert Committee.

The Chairs of the Expert Committees are selected at the quinquennial USP Convention Meeting which will be held in May 2025. The elected Chairs and USP staff will then review the list of volunteers for their committee and make the final selection based on the skill set(s) required for the projected projects, and achieving a balance for Diversity, Equality, Inclusivity and Belonging. This selection process can take a couple of weeks. The reason I mention this is to make sure you understand that the notifications will not go out on June 1<sup>st</sup>, 2025, but they should be sent by the end of June/early July.

Each Expert Committee will consist of 14 members plus the Chair. One or two Expert Advisors will also be assigned to each Expert Committee. Not everybody will be selected as an Expert Committee member. However, your name will be in the pool for Expert Advisors or members of Expert Panels that can be

set up for projects where extra skills and experience, beyond those of the Expert Committee members, are required. In addition, if a serving Expert Committee member is unable to continue in their role for any reason, then their replacement will be selected from the final pool of candidates considered for the Committee at the beginning of the Revision Cycle.

In summary, the USP Call for Candidates is an opportunity for scientists and technologists to volunteer to contribute to the standard-setting process, and to help maintain the standards and integrity of drugs and medicinal products, in the United States and globally. If selected, you will have an opportunity to make a contribution to these standards. You will also be able to make connections that may assist you in the years to come, and also lasting friendships. I have thoroughly enjoyed my time as an Expert Volunteer with the USP-NF, and I hope to continue in the next revision cycle. Whether your expertise is in excipients, or another relevant field, I hope you will join me in applying to be considered as an Expert Volunteer for the 2025-2030 Revision Cycle.