

Standard-bearers: USP volunteers advance a 200-year-old mission

BY SAM PASSANISI

The United States Pharmacopeia (USP) turns 200 next year, making the venerable compendium older than most of the drugs for which it compiles monographs and analytical methods. First published in 1820 as a reference work intended to standardize the field of medicine, USP has grown over the centuries into a nonprofit organization whose mission—to catalogue and provide standards for the whole of the pharmaceutical universe—enlists experts from around the globe.

Revising the USP is a team effort. Twenty-four committees, each comprising 12 to 16 volunteer experts, review recommendations and requests for changes to the USP. Each committee focuses on a particular area of medicine—such as biologics, small-molecule drugs, excipients, packaging, and distribution—and makes revisions in that area to keep the pharmacopeia up to date. However, as USP's senior director for excipients Catherine Sheehan explains, there's a comprehensive process before any revisions are made.

"Anybody can sponsor a revision to the USP," Sheehan says. "A revision could be an update to an existing monograph or chapter, or the development of a new monograph or chapter." From there, the sponsored revision goes to the expert committee, whose members deliberate on the request and publish a proposal to USP's online Pharmacopeial Forum for public comment. After a public comment period, the expert committee reviews the input of forum users and subject-matter experts ballots, and finally publishes the new monograph or chapter.

This revision process, now largely digitized, has come far since USP's early history. Committees have been the backbone of the revision process since USP's inception. However, the revision process was

far more primitive when it was originally conceived by Charles Rice, a prominent 19th-century pharmacist and an influential figure in USP's history.

"We have always had a Committee of Revision, from 1820, that has been involved with revising the US Pharmacopeia. Charles Rice introduced a form of the current system of commenting and balloting in 1880, when he became the chair of the Committee of Revision," explains USP's historian and archivist Geeta Tirumalai. "He used a hectograph process [an early document-copying technology] to write and duplicate circulars, and the improved US mail service to communicate with USP's Committee of Revision members."

USP's current expert committee model, introduced in the late 20th century, is more technologically advanced. But it's still a painstaking effort in which no stone is left unturned. Long-time volunteer Chris Moreton, a member of the expert committee on excipients, points out that the safety of patients is the major part of USP's reason for being. Volunteers need time, expertise, and a great deal of collaboration to make sure they're publishing the best possible test methods and monographs.

"USP does not operate in isolation," says Moreton, a former drug formulation chemist turned industry consultant and USP volunteer, who has been volunteering for nearly 20 years. Recommendations for revisions often come from companies in the pharmaceutical industry, who may suggest modernizing a USP monograph or chapter based on their experiences using it. In some cases, recommendations may also come from the US Food and Drug Administration or other regulatory agencies.

Find out more about volunteer opportunities by visiting www.usp.org or by speaking to a USP representative at these sessions:

USP in the Supply Chain: More than Monographs (Part 1)

Wednesday, May 1
1:30–1:55 p.m.

John A. Giannone, MBA, US Pharmacopeia (USP)
Exhibitor Showcase Theater

USP in the Supply Chain: More than Monographs (Part 2)

Wednesday, May 1
2:00–2:25 p.m.

John A. Giannone, MBA, US Pharmacopeia (USP)
Exhibitor Showcase Theater

Impurities for Development

Wednesday, May 1
2:30–2:55 p.m.

Ashok Dang, PhD, US Pharmacopeia (USP)
Exhibitor Showcase Theater

"The USP is looking to keep up to date in general," Moreton adds. "In part, this is motivated by the need to stay ahead of the 'bad actors'—that is, manufacturers producing substandard or adulterated drug substances. In the upcoming revision cycle, it is hoped that USP's resolutions will include one that focuses specifically on excipient monograph modernization to include definitive tests for positive identification.

In addition to his work as an expert committee member, Moreton also serves as a recruitment ambassador, helping to fill USP's volunteer ranks for the future. The qualifications are relatively open ended: no specific degree is needed; USP accepts volunteers from both industry and academia. Moreton encourages knowledgeable, thoughtful people with relevant pharma experience to apply

to volunteer with USP, which he cites as not only a way to network with one's industry colleagues, but also a fascinating and rewarding endeavor in its own right.

"We have a lot of fun—serious, scientific fun," Moreton says.

Naturally, only a finite number of applicants will be selected to serve on an expert committee as one of the ultimate decision-makers. But that shouldn't discourage interested applicants, who can still help with USP's mission in other ways. "As part of the application, we ask whether an applicant would be willing to serve on one of the ad hoc advisory panels," Sheehan says. Ad hoc panels convene on a short-term basis to make recommendations on matters with which the expert committee may not have the direct experience they need to make a decision.

Despite the "US" in the name, USP's volunteers don't come from just the United States. Although many areas of the world have their own pharmacopeia—Europe and Japan are just a couple of the other big players—science is an international endeavor. USP seeks volunteers from all parts of the world.

"Our expert committees are composed of quite a diverse group of experts," Sheehan says. "They come from industry, they come from academia, and they come internationally." For excipients in particular, USP is interested in a global perspective, because excipients are also manufactured outside the United States. For that reason, USP has put out a call for candidates at user forums and conferences in India and China.

"You are in a constant state of learning and discovery" when working for USP, Sheehan says of why she enjoys her work. Volunteer experts, who often hold jobs in the very industries that use USP for guidance, bring a wealth of experience to bear at each revision cycle. They range widely in age, national origin, and experience, but, as Moreton recalls telling a younger colleague during a previous meeting, "You're here because you have something to offer."

