



# Quality standards and regulatory predictability:

A Q&A with USP





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Matt Vankoski, USP



**USP co-hosted a webinar with experts from the U.S. Food and Drug Administration (FDA) and the Association for Accessible Medicines (AAM) in December 2025 to examine how public quality standards help contribute to regulatory predictability. Attendees, including regulatory affairs professionals, scientific and technical professionals from across the industry, and consultants specializing in standards and compliance, submitted hundreds of questions for panelists—far too many to cover during the session. Read the most commonly asked audience questions answered by **Matt Vankoski, USP Director of Donations.****



**Q** | *When it comes to developing quality standards for medicines, how do USP, regulators, and industry interact? What are the distinct roles and how do they collaborate?*

**Matt** | Here's a very high-level overview: USP develops public quality standards through an independent, transparent, and scientifically rigorous process relying on Expert Committees comprised of independent Expert Volunteers and public comment. USP plays a critical role in establishing the scientific foundation of public standards that helps ensure the quality, consistency, and reliability of pharmaceutical products.

FDA is responsible for ensuring the safety and efficacy of pharmaceutical products marketed in the United States. Companies who want to market a pharmaceutical product in the U.S. must first apply for FDA approval, most commonly through the New Drug Application (NDA) or Abbreviated New Drug Application (ANDA) process. As a matter of policy, USP relies on scientific information provided by manufacturers whose articles were previously FDA-approved or otherwise legally marketed to support new and revised compendial standards.

FDA enforces laws and regulations designed to ensure the safety and effectiveness of pharmaceutical products and is also responsible for enforcement of USP standards. The agency maintains extensive coordination with USP—

including through dozens of FDA staff who participate as government liaisons on USP Expert Committees and Panels to promote alignment between USP's public standards and regulatory thinking.

Industry's role in the standards development process is to contribute scientific data, reference materials, and practical expertise to support the creation of robust, science-based standards that reflect their approved product. Active participation from industry helps ensure that standards keep pace with evolving technologies and reflect real-world conditions.

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**Q** | *How does early engagement with USP by industry lead to better regulatory outcomes, and how can companies engage?*

**A** | Early collaboration in the context of supporting standards development means engaging with USP at the onset of your product development or compendial planning process. This enables USP to incorporate contemporary practices, industry-proven validated methods, and diverse data sources into monographs and General Chapters. This helps improve clarity, broad applicability, and alignment with regulatory expectations. Pathways for engagement with USP include:

- Submission of a new proposed monograph or revision to existing USP standards to maintain alignment with current scientific advancements.
- Routine review of/commenting on proposals in *Pharmacopeial Forum (PF)* during public comment periods
- Contribution of analytical data and samples
- Involvement in Pending Monograph Process revisions during FDA application review
- Support for USP Reference Standards development

**Q** | **What do you mean by “regulatory predictability” when discussing the role of standards?**

**A** | Regulatory predictability refers to the degree of clarity and consistency that both manufacturers and regulators gain from robust, science-based, publicly available standards. USP monographs and associated General Chapters define identity, strength, quality, and purity specifications that reflect established regulatory expectations and form a common scientific foundation for product quality. In the U.S., these standards hold legal relevance under the Federal Food, Drug, and Cosmetic Act, helping reduce ambiguity during development, review, and inspection processes.

In addition, USP standards play a practical and often strategic role when companies prepare submissions or other communications to FDA. Because USP monographs and General Chapters articulate validated analytical procedures, system suitability criteria, and acceptance criteria that FDA already recognizes, sponsors frequently reference these standards in Investigational New Drug Applications (INDs), NDAs/ANDAs, supplements, comparability protocols, and formal responses to Information Requests. Doing so can help demonstrate that product quality testing is grounded in a publicly vetted, scientifically rigorous framework.

When applicants rely on USP methods, they can offer FDA a level of transparency and predictability that helps expedite regulatory assessments. For industry, this can mean fewer questions, clearer expectations, and a reduced risk of delays related to analytical methods, specifications, or test performance. By grounding submissions in compendial standards, companies signal alignment with well understood quality benchmarks, helping support more efficient review cycles and more predictable regulatory outcomes.

**Q** | **Can companies use their own validated analytical methods, or must they use USP monograph methods?**

**A** | USP permits the use of alternative methods when they are fully validated and demonstrated to be equivalent or better in meeting the intent of the compendial requirements. Under *General Notices 6.30*, validated alternative procedures are acceptable, provided they achieve

comparable accuracy, precision, and specificity. Relevant guidance on method validation is provided in <1225> *Validation of Compendial Methods* and, where applicable, <1223> *Validation of Alternative Microbiological Methods*.

When using compendial methods, users must verify suitability of methods under actual conditions of use. Guidance on verification of USP methods is provided in <1226> *Verification of Compendial Methods*. Compendial methods are designed to evolve over time, and USP strongly supports innovation in this area. If you have a qualified alternative method, we are open to working with you to review and update the compendial requirements as appropriate.

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**Q** | *How does USP maintain consistency and regulatory alignment when modernizing monographs and updating analytical technologies?*

**A** | We acknowledge that technology is constantly advancing, and USP has implemented a process that actively involves industry and FDA to ensure that standards remain accurate, consistent, and fit for purpose.

USP follows a rigorous, transparent revision process involving scientific data evaluation, Expert Committee review including participation from FDA government liaisons, and public notice and comment. USP communicates implementation timelines to ensure laboratories can adopt changes appropriately. This structured communication helps manufacturers, regulators, and testing laboratories understand the scientific basis for revisions and prepare for their integration into quality systems. The result is a standards framework that remains current with evolving analytical capabilities while continuing to align with regulatory expectations for clarity, reliability, and public health protection.

**Q** | *How is USP harmonized with other pharmacopeias globally?*

**A** | WUSP engages in several mechanisms to support global alignment of pharmacopeial standards through:

- **Pharmacopeial Discussion Group (PDG):** USP works with the European, Indian, Korean and Japanese pharmacopeias (and World Health Organization (WHO) as an observer) to harmonize excipient monographs and general chapters, helping ensure that tests yield equivalent results and decisions across regions.
- **International Meeting of the World Pharmacopeias (IMWP):** USP collaborates with WHO and pharmacopeias from around the world to share knowledge, advance Good Pharmacopeial Practices, and coordinate rapid responses to public health emergencies such as COVID-19.
- **Adopt Agreements:** USP authorizes other pharmacopeias to reproduce USP standards.
- **Bilateral Agreements:** USP jointly develops standards via prospective harmonization—aligning methodologies for selected small molecule medicines, typically sponsored by innovators, until the resulting pharmacopeial standards become official across all participating compendia

**Q** | *How does USP prioritize which standards to develop?*

**A** | USP maintains a dedicated cross-functional team responsible for identifying medicines with the greatest potential to improve people's health around the world and deliver meaningful impact for patients. As an example, the small molecules team uses a machine learning model that utilizes various data sources including the number of prescriptions, units produced, manufacturers, dosage forms, market size, and other relevant data to forecast how USP standards will be used in the future. By linking these inputs directly to patterns of medicine utilization, the model helps anticipate where standards will have the greatest impact on patient availability, product quality and overall public health. USP uses this assessment, along with human judgment, to develop USP's priority standards list. This evaluation process is ongoing on a bi-annual basis to ensure we incorporate any changes within the data sources. This priority list is published as part of the USP pipeline.

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**Q** | *How can organizations participate in USP's standards-setting activities?*

**A** | Organizations may contribute by submitting data, methods or materials to help develop or revise monographs. They can also provide feedback during Pharmacopeial Forum (PF) public comment periods. Additionally, individuals from all corners of the health ecosystem can volunteer to serve on USP Expert Committees or Panels. These are the independent Expert Volunteers who, serving up to 5-year terms, work





alongside USP staff to develop and revise our standards. USP welcomes participation from across industry, academia, healthcare, and regulatory bodies. USP also regularly hosts workshops and other public events, to solicit industry insights and feedback from all interested stakeholders, including industry and regulators.

**Q** | **How can industry work with USP (and FDA) to develop new monographs or monograph revisions based on products awaiting regulatory approval?**

**A** | The USP Pending Monograph Process (PMP) is specifically designed to allow USP, FDA, and industry to collaborate on monographs while a product is awaiting approval by FDA.

This approach allows for development of monographs or monograph revisions for articles awaiting approval by FDA, and it permits publication of these proposals in the Pharmacopeial Forum for notice and comment where required in accordance with USP's standard revision processes. Following PF publication, these proposals remain in an unofficial status until FDA approval of the marketing application held by the donor. The PMP

allows the new or revised monograph to become official more rapidly than would be possible if development began only after final FDA approval. For additional information, including recommendations for applicants and frequently asked questions, please see the draft guidance on USP's website: [Harmonizing Compendial Standards With Drug Application Approval Using the USP Pending Monograph Process Guidance for Industry](#).

**Q** | **What education and training resources does USP offer to promote consistent application of standards?**

**A** | USP offers a comprehensive portfolio of education and training resources—including instructor-led courses, virtual workshops and on-demand modules—designed to support consistent interpretation and application of compendial standards. These programs help organizations strengthen their understanding of USP-NF requirements, proper use of reference standards and best practices for integrating compendial expectations into quality and regulatory systems.

## Resources:



Contact the [USP Donations Team](#) to learn more about the process, how to get involved, or to work with USP to develop or revise a monograph through the PMP



Contribute to or learn more about the [USP Donations Program](#)



See what's coming in USP's [Small Molecules Pipeline](#)



Learn more about the Pending [Monographs Program \(PMP\)](#)



Check out [USP Events & Training](#) to help promote consistent application of standards