



# Resolution

## Year 1 Resolution Update: Innovations

### Resolution

USP will explore the development of quality standards and other fit-for-purpose solutions to help stakeholders safeguard the quality of promising healthcare innovations that address patient and public health needs.

### Alignment with USP's Mission

For two centuries, USP has leveraged its capabilities and standards-setting across many areas of biomedical innovation. Given the abundance of new medicine modalities and manufacturing advances, the opportunity to support product development, quality assurance, and market and patient access through standards and other guidance is enormous, as is its potential to impact patient care and public health.

### Year 1 Update

Key progress areas over the past fiscal year include:

**3-D Printing of Pharmaceuticals** – USP held a virtual workshop with over 600 participants on three-dimensional printing (3DP) and is cohosting a 10-part seminar series on the topic with Purdue University and Apreece, known as the “International 3DP Pharma Technology Forum.” We are also conducting research on 3-D printing of

dosage forms using ZipDose technology in collaboration with Purdue University.

**Drug Dissolution** – We published a proposed revision to *USP General Chapter <711> Dissolution* in the *Pharmacopeial Forum*. We also worked to develop a major proposed revision to *USP General Chapter <1724> Semisolid Drug Products—Performance Tests* slated for publication in 2022. In addition, we published research on evaluation of dissolution performance using particle image velocimetry—an innovative application of the technology for fluid velocity measurement within a dissolution vessel—to help understand the mechanical dynamics of drug release.

**Quantitative Nuclear Magnetic Resonance** – qNMR provides the ability to identify and quantitate molecules in a solution to help ensure quality. USP continues to expand internal evaluation and integration of qNMR analytical procedures in our reference standard operations. We are working to revise *USP General Chapters <761> Nuclear Magnetic Resonance Spectroscopy* and *<1761> Applications of Nuclear Magnetic Resonance Spectroscopy*, with the proposed revisions slated for publication in 2022.

- ▶ qNMR methods for determining the strength of remdesivir, a medicine used to treat COVID-19, were included in USP's toolkit for addressing the potential for substandard and falsified

remdesivir. The toolkit was part of USP's broader suite of resources created to respond to the pandemic and related medicines quality challenges.

### **Knowledge Graphs and Natural Language**

**Processing** – USP's work to adopt and integrate advanced technologies includes knowledge graph applications such as: Skill Seeker, which is used to identify staff and volunteers with specific skill sets; Regulatory Document Associator, which is used to identify links between USP documents and FDA guidance and laws; and a Nitrosamine Landscaping Tool that evaluates USP's impact on work to address the impurities. In addition, SciBite, a natural language processing offering, is being applied to each of these efforts to automate data extraction, taxonomy development, and knowledge graph creation. We also developed a drug pronunciation tool using artificial intelligence technology.

### **Emerging Technologies for Manufacturing**

– USP sponsored research into understanding and developing predictive algorithms to help ensure product quality with the utilization of current and emerging manufacturing technologies, including process monitoring using residence time distribution and applications for real time release testing. We are also exploring advancements in spectroscopy, data evaluation, and inter-comparability for quality control and assessment in current and future manufacturing technologies.

**Phlow Strategic Alliance** – USP forged a strategic alliance with Phlow, a public benefit corporation, to develop early scientific guidelines for high-quality pharmaceutical continuous manufacturing (PCM) processes. The alliance will support certification and validation of PCM processes supporting high-

quality, U.S.-manufactured essential medicines.

**Complex Generics** – Complex generics—defined as drug products that have a complex active ingredient, formulation, route of delivery, or are part of a drug/device combination—are becoming increasingly predominant. Accordingly, USP launched an initiative to identify related standards, physical materials, and services as well as gaps and opportunities for future standards to support our stakeholders.

**Polymers** – USP initiated an incubation project to identify and evaluate technologies that address material characterization requirements for polymers, which is expected to contribute to the development of related documentary and physical reference standards.

**Early Technology Identification** – USP launched the “Radar” program to bolster our ability to identify and evaluate early technologies and prioritize emerging ideas and trends in pharmaceutical development to help anticipate and support stakeholder needs. We identified and researched over 20 ideas and trends during the year.

### **Planned for Year 2**

- ▶ USP will continue to evaluate mechanisms to help industry, regulators, and other stakeholders ensure consistency and quality in advancing promising healthcare innovations.
- ▶ USP will complete ongoing lab work on 3-D printing to evaluate the need for documentary and reference standards as well as a small-vessel incubation project related to drug dissolution. USP will continue to engage with stakeholders and regulators as this work progresses.



- ▶ USP–China will host a symposium in November 2021 to promote acceptance of qNMR in China following USP’s 6th International qNMR Summit in October.
- ▶ USP will identify priority polymers with pharmaceutical applications and begin lab work on related quality assessments.

- ▶ USP will expand our ability to identify and evaluate early technologies and collect and prioritize trends around emerging science.

### **Contact**

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