



Resolution

Digital Transformation of Standards

USP will create interoperable core digital solutions that leverage USP data and standards to improve public health through global access to quality medicines.

Year 3 Update

In a rapidly evolving, increasingly digital and interconnected world, USP is working to transform quality standards into interoperable digital components of the healthcare ecosystem to facilitate the ability of regulators, manufacturers, healthcare professionals, and other stakeholders to deliver quality medicines and help ensure a resilient medicines supply chain. To achieve this goal, USP has worked to structure our content for enhanced machine readability, transitioned to a more modern clinical informatics platform, advanced the development of digital reference standards, and leveraged data through advanced analytics to enhance visibility into the upstream medicines supply chain.

Key areas of progress over the past fiscal year include:

Transition to Structured Content – To integrate USP data into stakeholders’ digital environments – thereby facilitating the ongoing industry modernization and digitization evolution known as “Pharma 4.0” – USP has been working to shift to machine-readable, structured documentary content. The effort will increase efficiency and decrease transcription errors through increased

automation. Building upon the data model created for documentary standards content, USP developed a mechanism to extract assay methods from raw substance monographs and used natural language processing to add granularity and structure to content through alignment with industry standards developed by the Allotrope Foundation. The scope was further expanded to include assay methods for identification of substances, and for impurities, as well as finished dosage form monographs. These efforts are foundational in establishing the capability to publish documentary standards content directly into Laboratory Information Management System (LIMS) vendors’ software platforms, which are used in research and development and quality assurance/quality control labs.

Transition to Modern Platforms – USP continues to utilize two technology platforms to curate and disseminate scientific content as machine-readable, structured data.

- ▶ Clinical Architecture’s Symedical platform provides a robust and scalable solution for USP to efficiently curate and publish standards and solutions as structured data directly into health IT systems used in healthcare delivery. During the year, USP staff and Expert Volunteers applied Symedical for a range of applications, including to



maintain the USP Drug Classification (USP DC), Medicare Model Guidelines, and *HazRx* <800> database for drug classification. Symedical also facilitated creation of a new audio pronunciation product with an artificial intelligence (AI) voice avatar, based on the work of the Pronunciation Expert Panel. In addition, Symedical was utilized to develop content for the Compounded Prescription Information Exchange, and initial data modeling was completed to maintain content developed by the Allergies and Intolerances Expert Panel.

- ▶ USP continued to utilize the Global Substance Registration System (GSRS) for curation and dissemination of chemical substance information, which serves as the source of record for chemical information. USP identified related quality metrics and a data governance framework and continued to refine integration of GSRS with USP's business process management system to improve information and data management throughout standards development. GSRS also continues to support the exchange of structured data with FDA as part of a Collaborative Research and Development Agreement.

Digital Reference Standards – USP made progress on efforts to advance digital reference standards during the year.

- ▶ USP's nuclear magnetic resonance (NMR) analysis software platform USP-ID received initial approval to launch from USP's Digital Impact Committee. USP elected to delay the launch of USP-ID when a late-breaking opportunity arose to integrate USP-ID into an industry-leading NMR analysis software package, which would facilitate access to a broader market. USP-ID allows NMR spectral data to function as digital references by combining high-quality chemical reference databases with smart algorithms that automate identity, strength, and

purity analysis of molecules in complex mixtures.

- ▶ A Council of Experts (CoE) subgroup, the Digital Standards Working Group, was formed, bringing together subject matter experts from across USP and the CoE to define the process by which digital standards become compendial. The working group defined digital standards at USP and began the process of drafting a monograph that references an NMR-based digital reference standard. Gaps in the existing compendial process for digital standards development were identified to inform gap-closing activities planned for Fiscal Year 2024.
- ▶ The first good manufacturing practices-validated method to use USP-ID and digital references for identity and assay testing was developed for ascorbic acid in collaboration with Steelyard Analytics.
- ▶ Collaboration with the University of British Columbia yielded a draft manuscript for automated reaction monitoring with benchtop NMR and USP-ID.

Medicine Supply Map – Embodying USP's desire to make better use of data through advanced analytics, USP continued to develop and improve its Medicine Supply Map surveillance system to identify, characterize, and quantify vulnerabilities in the upstream pharmaceutical supply chain; deliver insights that can guide risk mitigation strategies and investments; and help inform policy changes that advance supply chain resilience. During the year, Medicine Supply Map focus areas included insights into the geographic concentration of pharmaceutical manufacturing and related risks of shortages for critical medicines, including antimicrobials. USP shared related insights with stakeholders, including U.S. federal agencies and the U.S. Congress, to facilitate decision-making aimed at bolstering supply chain resilience. (See *Evidence Generation to Inform Policy* Resolution update.)

Planned for Remainder of the Cycle

- ▶ USP will integrate its USP-ID software into an industry-leading NMR analysis software package and plans to launch the joint product in the second quarter of Fiscal Year 2024.
- ▶ The Digital Standards Working Group aims to have the first monograph with a digital reference standard submitted to *Pharmacopeial Forum* by the end of the fourth quarter of Fiscal Year 2024.
- ▶ USP will implement and monitor data quality metrics and a data governance framework for GSRS.
- ▶ USP will further integrate GSRS as the source of record for chemical information with other internal systems, such as the USP Store.
- ▶ USP will establish an Executable Methods Advisory Group of key external stakeholders to evaluate sample data from *USP-NF* monographs and provide feedback to USP on the level of granularity of the data model and mapping to external ontologies, acceptable delivery formats and methods, and customer insights on how the data can be used within their workflows.
- ▶ USP will further expand its natural language processing engine to cover all types of methods (e.g., spectroscopy).
- ▶ USP will define a roadmap to incorporate structured monographs back into the editorial process.

Contact

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