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 2 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 1) ensure that the standards-setting process can accommodate the rapidly evolving world of computational informatics, and 2) develop or otherwise support data services that meet stakeholder needs across USP nomenclature as well as pharmaceutical and healthcare informatics platforms that align with and complement USP standards.

Key areas of progress over the past fiscal year include:

**Transition to Modern Platforms** – USP implemented use of two technology platforms that are being leveraged to fundamentally change the way USP curates and disseminates scientific content as machine-readable, structured data. These platforms were purchased in the prior fiscal year and went live with production data in Fiscal Year 2022.

- 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 used Symedical to maintain the USP Drug Classification (USP DC) and Medicare Model Guidelines for drug classification. *USP DC 2022* was released on the Symedical platform. Symedical is also being used to model the work of the Exchange of Compounded Drug Preparation Information in Health IT Systems Expert Panel, the Pronunciation Expert Panel, and the Nomenclature and Labeling Expert Committee.

- USP continued to implement the Global Substance Registration System (GSRS) for curation and dissemination of high-quality sources of record for substance information. The platform
was used to launch a redesigned USP Dictionary of United States Adopted Names and International Drug Names.

- USP also worked to integrate GSRS with USP’s business process management system to improve information and data management throughout standards development. The GSRS platform also continued to support USP’s exchange of structured data with FDA as part of a Collaborative Research and Development Agreement.

Transition to Structured Content – To integrate USP data into stakeholders’ digital environments – thereby facilitating the ongoing industry modernization and digitization trend known as “Pharma 4.0” – USP has been working to shift to structured content. The effort will increase efficiency and decrease transcription errors through increased automation. To that end, USP created a data model for documentary standards content and began evaluating the use of natural language processing to extract assay methods from a subset of monographs. This will add granularity and structure to content through alignment with industry standards developed by the Allotrope Foundation. 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.

Digital Reference Standards – USP developed a software platform that allows quantitative nuclear magnetic resonance (qNMR) data to function as a digital reference to help ensure quality. By characterizing a physical Reference Standard using high-field qNMR, the resulting data can be compared with experimental qNMR data through this process. Beta testing of the software, which uses smart algorithms to automate identity and purity analysis of molecules in complex mixtures, was completed with academic and industry partners. USP also formed a Council of Experts subgroup to examine potential compendial applications for digital reference standards. Separately, USP revised and published USP General Chapters <761> Nuclear Magnetic Resonance Spectroscopy and <1761> Applications of Nuclear Magnetic Resonance Spectroscopy to facilitate use of qNMR.

Planned for Year 3
- USP will continue to expand application of the Symedical platform. This will include adding updated content from the Centers for Disease Control and Prevention’s National Institute for Occupational Safety and Health related to the handling of hazardous drugs in healthcare settings, and modeling the work of the Allergies and Intolerances Expert Panel.
- USP will continue to expand use of GSRS. We will integrate it further with the business process management system for use in standards setting. USP will also integrate it with other internal systems (e.g., Oracle Commerce Cloud) to consolidate chemical information about reference standards, thereby establishing GSRS as the definitive source for all uses of chemical information at USP.
- USP will embark on a pilot with a major LIMS vendor focusing on the distribution and execution of machine-readable analytical methods found in USP monographs.
- USP will target benchtop R&D applications in launching its qNMR-based software platform.
USP will continue to advance understanding of stakeholder needs for digital solutions through customer outreach, including through focus groups and surveys.

USP will develop new direct and indirect distribution capabilities for getting USP content to external customers.

USP will continue to monitor and prioritize upstream advances in science where USP standards setting and solutions development may advance public health through digital implementations.

**Contact**
For additional information on this Resolution, contact Jeff Shick at jeff.shick@usp.org.