

Resolution

Culture of Excellence

USP will model operational excellence, continuous improvement, stakeholder responsiveness, and transparency.

Year 3 Update

A culture of excellence at USP means people, processes, and systems are aligned and working optimally in pursuit of the organization's mission. With a foundation of rigorous process and data management that is continually improved, USP strengthens its decision making, stakeholder engagement, and information sharing. By focusing on improving effective and reliable procedures and systems, USP is better positioned to expand access to quality medicines, facilitate innovation, and improve public health.

Key areas of progress over the past fiscal year include:

Knowledge Management – USP knowledge management (KM) tools help identify, receive, share, and store content, and enhance internal and external transparency. This year, USP continued to enhance its Oasis KM tool following its launch in Fiscal Year 2022. Oasis helps USP staff conduct curated searches of information repositories and dynamic content types, and it facilitates access from core business applications and websites. Work this year included integrating Oasis with additional systems; creating dashboards for tracking performance, utilization, and user adoption; and development of reports for technical monitoring.

Business Process Management – USP marked significant progress in its ongoing implementation of a Business Process Management (BPM) application for standards development that facilitates automation of select processes with increased consistency and control. USP launched the first release of the platform for documentary standards in February 2023. Additionally, USP continued to develop enhancements for its existing BPM platform for reference standards to improve functionality of the system.

User-Friendly Online Products and

Services – USP has developed a long-term plan to provide support for the online *United States Pharmacopeia–National Formulary* (*USP–NF*) publication; this includes additional infrastructure, enhanced software applications, and optimization of processes. USP commenced development of a new integrated platform called OneUSP to support three-to-five additional languages and reduce the amount of time it takes USP to prepare regular updates by 20-40%.



Digital Integration – USP developed a roadmap and vision for machine-readable digital standards. USP's nuclear magnetic resonance (NMR) analysis software platform, USP-ID, also received initial approval to launch from USP's Digital Impact Committee, although USP elected to delay the launch 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 is a software application that allows NMR spectral data to function as digital references to help ensure quality. The application combines high-quality chemical reference databases with smart algorithms to automate identity, strength, and purity analysis of molecules in complex mixtures. In the future, digital delivery of both reference standards and documentary standards will allow machines to perform automated data analysis that facilitates stakeholders' ability to deliver quality medicines. (See Digital Transformation of Standards Resolution update.)

Data Quality – USP developed a data governance structure for its Salesforce/Master Data Hub application. It includes data quality metrics and reports for the key data elements, which allows for continuous monitoring and improvement of data accuracy. In addition, USP enlisted a leading expert in data quality to conduct an organization-wide data quality audit. Based on the resulting recommendations, USP is developing a roadmap to improve data quality across the organization.

Quality Management System – USP continues to centralize quality processes into one system, MasterControl, a Quality Management System (QMS) software program. It includes document management, training, audits, deviations, corrective and preventive actions, lab investigations, risk management, and supplier quality management. A Supplier Management module was developed in MasterControl to track supplier metrics, risk, and performance.

Employee Survey Initiative – USP continued administering a weekly pulse survey, Employee Voice, committed to gathering employee feedback, measuring progress, and informing leadership action to strengthen five areas of focus: employee recruitment and retention, workplace flexibility, inclusivity, people management, and USP's "speak-up" culture. Data is collected, evaluated, and distributed to all employees to provide real-time visibility into the organization's progress against key metrics. In addition, team leaders are encouraged to use the data to better identify strengths and inform decisions on how to continuously improve USP's support of its employees.

Planned for Remainder of the Cycle

- USP will continue to add additional data sources to the Oasis KM tool to enhance the sharing of knowledge across the organization.
- USP will continue to build out the BPM system with multiple enhancements for reference standards and documentary standards to improve functionality.
- USP will launch the first version of the OneUSP integrated platform in Fiscal Year 2024.
- ► USP is aiming for a formal launch of USP-ID in Fiscal Year 2024.
- USP will continue to expand data quality activities to the Global Substance Registration System (GSRS) and other applications.
- USP will collect and track QMS data on supplier metrics and performance.
- USP will review and roll out recommendations of the Strategic Initiative for Women Thriving at USP. This initiative, built on previous



efforts, aims to examine and learn from past adverse experiences of women at USP and determine how best to ensure that all women have equal opportunity to thrive.

<u>Contact</u>

For additional information on this Resolution, contact Alice Tira at amt@usp.org.

