USP Informatics Activities

Allotrope Foundation Meeting
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Building foundations for a healthier world
200 years building quality foundations for a healthier world
Advocating for Quality

- USP-NF is recognized in 40+ countries

- Diverse and strong partnerships
  - > 450 Organizations
    - Academic Institutions and Associations
    - Health Practitioner, Professional, and Scientific Associations
    - Manufacturer, Trade, and Affiliated Associations
    - Governmental Bodies, Divisions and Associations
    - Consumer and Other Organizations Representing the Public Interest
    - Non-governmental Standards-setting and Conformity Assessment Bodies

- Expert engagement
2020-2025 Strategic Priorities

USP is building informatics capacity and thinking into the standards setting process

- **Strategy:** Aligning strategic vision with informatics in mind
- **Science:** Creation of Health IT Expert Committee
- **Execution/Operation:** Creation of Informatics framework within the organization
  - Proof of concepts and future standards landscape
  - Enhance informatics capabilities
  - Translational Informatics
    - Pharma manufacturing
    - Healthcare Practitioner
- **Stakeholders:** Expand and strengthen partnerships with key stakeholders in informatics
USP standards impact many points along the value chain

- Substance verification
- Impurities, Excipients

Manufacturer

Regulatory

- Compounding,
- Safe handling of HDs

Healthcare Practitioners

Medication error prevention (NCC MERP)

Patients

Formulary Design

Access

Translational Informatics

- USP Compendial Nomenclature
- API/Impurity Data Services*

- Encoded compounded drug formulations
- HazRx®

- Drug Allergies and Intolerances*
- Pharmacogenomics*

- USP Drug Classification
- Medicare Model Guidelines
Informatics Framework: Inputs and Outputs

Input Sources

- **R&I**
  - Research & Innovation

- **Science**
  - Chapters & Standards

- **VOC**
  - End users, Industry, Research...

Output types

- **Prototypes**
- **Pilots**

- **Translational Informatics**
- **Related Services**

- **Product Development**
- **Modernizations**
Possible efficiencies and innovations of USP & Allotrope working together

- **Monograph use cases**
  - Reduce/eliminate manual transcription of content from monographs
  - Fully automate the QC run and validate against the monograph

- **Data Science and Machine Learning**
  - Machine-readable library of compendial content

- **Regulatory Support**
  - Synergy to support PQ/CMC, KASA, other regulatory use cases
Get involved!

- Call for Candidates
- Sign up for updates
- Provide input
- spe@usp.org

Fill out our brief questionnaire to help us better understand your needs (use the QR code below to access the questionnaire)