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Trusted Standards
Improved Health

Standards Acquisition & its role in the Donor Recognition Program

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- Introduction to Standards Acquisition (StAcq)
 - Department teams
 - What we do
 - Standards-Setting Pipeline

- Acquisition of Monographs and Reference Material candidates
 - Acquisition of Monographs
 - Reference Material Acquisition Process
 - USP Donor Submission Portal

- Recognition of Donors/Sponsors
 - Benefits of Participation
 - Donor Recognition Program (DRP)

- Scientists responsible for the acquisition of monographs and reference materials
 - Standards Acquisition Managers
 - Reference Material Procurement Specialists
 - Program Manager (PPM)

- **Standards Acquisition Managers**
 - A global team of scientists specializing in obtaining and reviewing new and modernized monograph proposals from industry for the development of USP's standards

- **Reference Material Procurement Specialists**
 - Team that procures all reference material candidates intended for the development of USP reference standards (F lots & Replacement lots)

➤ Standards Acquisition Managers

Collaborate worldwide with:

- Pharmaceutical companies (innovator and generic)
- Food and Dietary Supplement Ingredient manufacturers
- Universities, Research Centers, Trade Associations, and others

➤ Reference Material Procurement Specialists

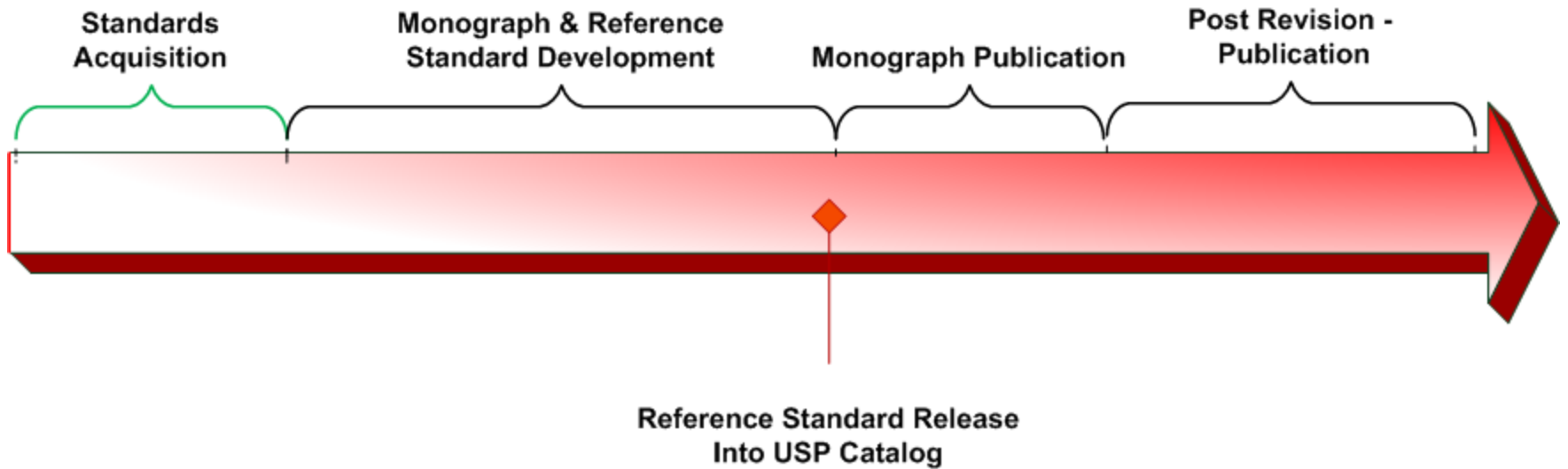
Collaborate worldwide with:

- Pharmaceutical Industry
- Custom Synthesis Organizations
- Catalog companies

To acquire scientific data and/or reference material candidates that are necessary to develop the monographs and RS for all compendia:

- 
- USP-NF (United States Pharmacopeia – National Formulary)
 - FCC (Food Chemicals Codex)
 - DSC (Dietary Supplements Compendium)
 - MC (Medicines Compendium)
 - HMC (Herbal Medicines Compendium)

Standards-Setting Pipeline (*USP-NF*)



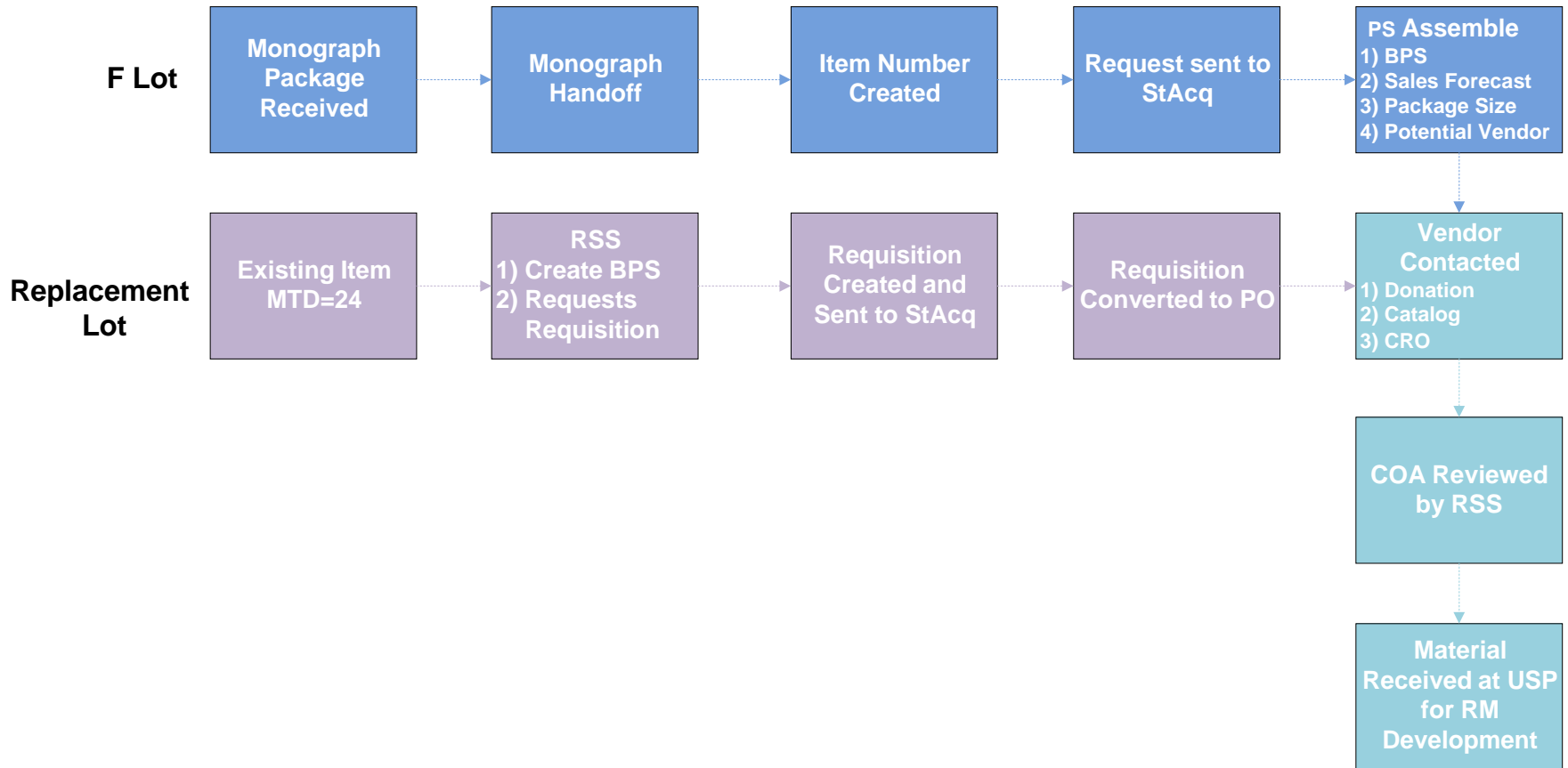
Acquisition of Monographs

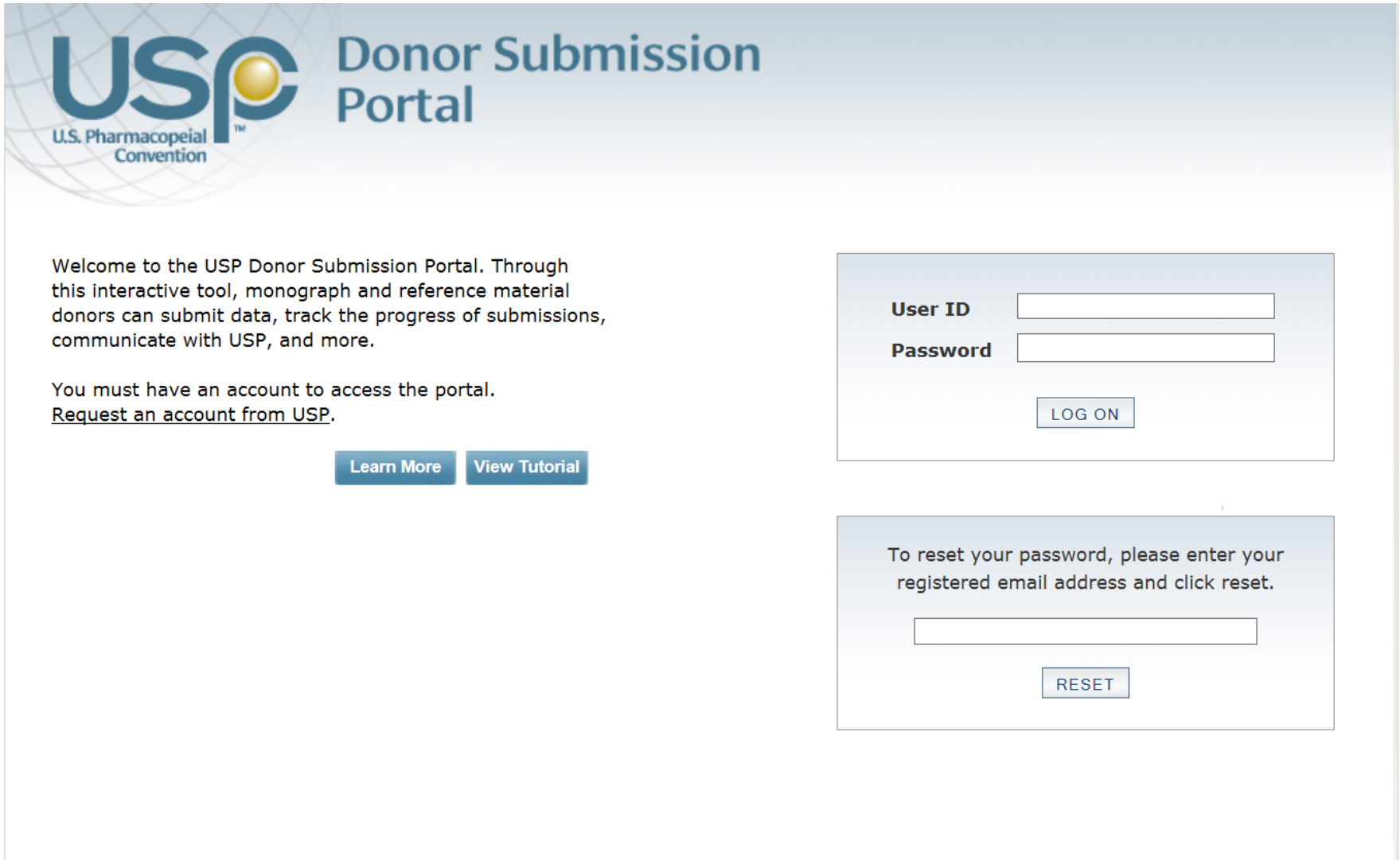
- Each compendium has criteria for inclusion
 - NF
 - Used as an excipient in a US approved drug product

- Universe = Official + In development + Missing
 - Missing universe
 - <http://www.usp.org/usp-nf/development-process/priority-new-monographs/priority-new-monograph-list>

- Monograph Modernization
 - Replacing outdated technology and methodology with more current procedures
 - Seek current analytical methods, validation, acceptance criteria
 - Request sample amounts of the article for USP's internal lab development
 - <http://www.usp.org/usp-nf/development-process/monograph-modernization>

Reference Materials Acquisition Process





USP
U.S. Pharmacopeial
Convention

Donor Submission Portal

Welcome to the USP Donor Submission Portal. Through this interactive tool, monograph and reference material donors can submit data, track the progress of submissions, communicate with USP, and more.

You must have an account to access the portal. [Request an account from USP.](#)

[Learn More](#) [View Tutorial](#)

User ID

Password

[LOG ON](#)

To reset your password, please enter your registered email address and click reset.

[RESET](#)

➤ Donor Submission Portal (DSP)

– secure, user-friendly, and interactive electronic platform for the exchange of information between sponsors and USP, in particular the transfer of monograph and reference material data to USP's Standards Acquisition Department

– Allows sponsors to:

- Submit documents in various formats for the development of a monograph
- discuss acquisition activities with the Standards Acquisition manager responsible for their submission
- view and share the compendial work of their organization
- track their company's compendial activities for reporting to management and project planning
- track progress of their submissions

– 312 Registered Users, >390 Submissions

- Direct impact in setting the USP specifications for the donated material/monograph
- Competitive advantage, sponsor's own standard becomes official in *USP-NF*, which is enforceable by regulatory authorities
- Enhanced corporate citizenship image
- Copies of the multi-laboratory collaborative testing results with traceability to sponsor's reference standard
- Public recognition by USP through its Donor Recognition Program

Donor Recognition Program

- Originated with the presentation of Certificates of Appreciation to recognize donors of bulk reference material candidates and sponsors of monographs

- Expanded in 2010 by StAcq to include several recognition options based on level of participation and donation

- Milestones for recognition
 - Monographs
Draft published for comment in PF, *FCC* Forum or on website
 - Reference Material (RM) Candidates
Released as USP Reference Standards (RS) in the catalog

- <http://www.usp.org/usp-nf/development-process/donor-program>

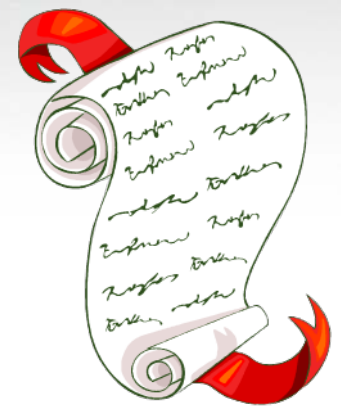
Recognition Options

- Recognition at the Science and Standards Symposiums, GPhA conferences
- Discounted/complimentary registration to USP Science and Standards Symposiums
- Complimentary USP Workshop Registrations
- One year print subscription to either *USP-NF*, *FCC*, or *DSC*
- One year, multiple user license of electronic *USP-NF* or *FCC* (up to 10 single user licenses)
- USP Reference Standards

http://www.usp.org/sites/default/files/usp_pdf/EN/referenceStandards/rs324f_stacq_sheet_2012-11.pdf

	CY2010	CY2011	CY2012	CY2013
MONOGRAPHS (new & modz)	8	9	5	6
RS	17	18	9	11

Excipient Monograph & RS Donors



- ❖ Aveva
- ❖ American Sugar
- ❖ BASF
- ❖ Buy Chem
- ❖ CBC Co.
- ❖ CHP Carbohydrate
- ❖ Cognis Corp
- ❖ Coloron
- ❖ Croda
- ❖ Cydex
- ❖ Danisco
- ❖ Davisco
- ❖ Degussa
- ❖ DMV-Fonterra
- ❖ Domino Sugar
- ❖ Dow Chemical
- ❖ Dow Corning
- ❖ Dupont
- ❖ Dupont Tate & Lyle
Bioproducts
- ❖ Evonik
- ❖ Galaxy Surfactants
- ❖ Gattefosse
- ❖ Hayashibara
- ❖ International Specialty
Products Technology, Inc.
- ❖ JRS Pharma
- ❖ Lipoid
- ❖ Mafco
- ❖ Medinex
- ❖ Merck
- ❖ Novartis
- ❖ Polydrug
- ❖ Polygal
- ❖ Procter & Gamble
- ❖ Rhodia Inc.
- ❖ Rockwood Italia
- ❖ Roquette Europe
- ❖ Sasol
- ❖ Tate & Lyle
- ❖ Vertellus
- ❖ Wacker Chemical
- ❖ Welch, Holme & Clark



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Questions



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Thank You