

traditional Content Development

USP P/NP Stakeholder Forum
13 October 2016



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Agenda

☞ Application

- Grandfathering
- <191> Identification - General

☞ Functionality/Flexibility

- Validation
- Dosage Form Chapters

Application

∞ Benchmark – Salt Nomenclature Grandfathering

- Significant stakeholder discussion in PF and public forums
 - USP <1121> Nomenclature
 - USP Web: Salt Nomenclature Policy
- FDA Guidance: Naming of Drug Products Containing Salt Drug Substances

∞ Opportunities

- Connection between chapter and supporting documents
- FDA Orange Book (and other public postings)



Application

∞ Case Study – <661.1> Plastic Materials of Construction Grandfathering

- PF 40.5 → USP 39

Scope:

... Alternatively, individual plastic materials of construction are deemed to be well characterized and appropriate for use if they are used in a packaging system that meets the requirements in <661.2> or if the packaging system has been deemed appropriate for pharmaceutical use by the appropriate regulatory authority.

Application

Discussion

- Communication
 - Visibility (USP Leadership/Industry/FDA)
 - Discussions following implementation
 - USP Web: FAQ
- Implementation vs Enforcement
 - FDA guidance?
 - Any regulatory approval?
 - Established products: Visibility of date after USP 39
 - Grandfathering becoming traditional?



Application

☞ Chapter Case Study – <191> Identification

- PF 41.2 Briefing

The existing wet-chemistry procedures are now listed in the Chemical Identification Tests section. The specific changes are as follows:

The flame tests under Sodium, Calcium, Barium, Potassium, Lithium, and Borate were removed to address safety concerns.

Complementary wet-chemistry identification tests currently listed under Chemical Identification Tests for these ions are sufficient to verify the identity.

Application

Discussion <191> Identification

- Challenges of USP Online – Monographs with current applications link new chapter on delayed implementation (May 2017)
- Safety
 - Harmonization (Committees/Pharmacopoeias)
 - Monographs (USP Notices)
 - Specific monograph references to flame test
 - Other flame applications?
- Regulatory impact



Functionality/Flexibility

∞ Benchmark – General Notices Requirements

- Ongoing stakeholder discussion in PF and public forums
- Methods – Adopt/Equivalency/Submission
- Limits – Meet/Exceed/Submission
- Monographs/General Notices apply the Chapters

∞ Benchmark – Residual Solvents (ICH/Compendial)

- Significant stakeholder discussion in PF and public forums
- Simplified monograph content
 - Meets requirements (General Notices)
 - Alternative limits via regulatory approval

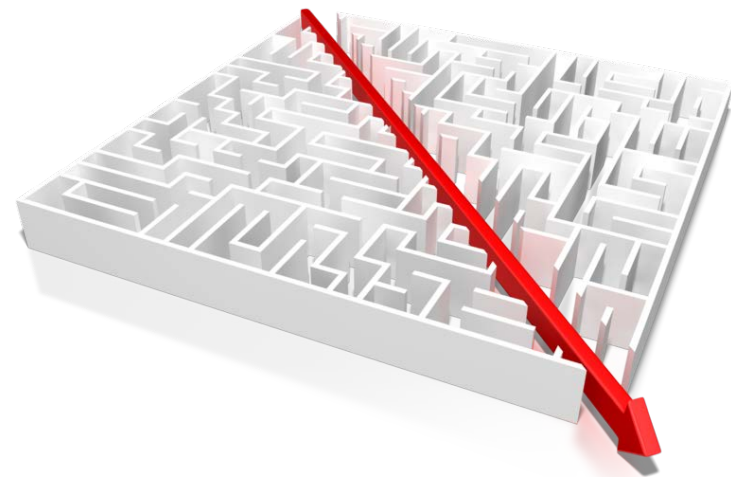
Functionality/Flexibility

☞ Validation Case Study – Individual chapter application

- <233> Elemental Impurity Procedures
- <730> Plasma Spectrochemistry

☞ Discussion

- Chapter content leading monograph content
- Linked chapter prioritization
- Monographed articles
 - Established methods in USP/Industry
 - Grandfathering applications?
- Non-monographed articles
- Flexibility?



Functionality/Flexibility

∞ Case Study – Dosage form chapter application

- <1> Injections... - <5> Inhalation..., <771> Ophthalmic..., etc.

∞ Discussion

- Established application (<1>)
 - Chapter supplementing monograph
 - Applicable content mixed with informational content
 - Revision Bulletin
 - Theoretical limits mixed with mandatory
- Monograph application variable
 - Nothing → Full chapter application

Functionality/Flexibility

Discussion

- Retrospective application (<771>)
 - Chapter supplementing monograph
 - Applicable content mixed with informational content
 - Monograph application
 - Revision Bulletin
 - Particulate matter



Key Points

∞ Signs

- Non-traditional content
- Retrospective applications

∞ Responses

- Communication
- Consistency
- Application/Impact
- Functionality/Flexibility



Thank You