

General Chapter Prospectus: <1220> The Analytical Procedure Lifecycle

Type of Posting: General Announcement

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Expert Committee: General Chapters—Chemical Analysis

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Current or Proposed GC Title: <1220> The Analytical Procedure Lifecycle

Suggested audience: Drug product manufacturers, dietary supplement manufacturers, testing organizations, and drug product related regulatory agencies.

Estimated proposal PF: 43 (1) [Jan.–Feb. 2017]

Background and objective(s): An analytical procedure must be shown to be fit for its intended purpose. It is useful to consider the entire lifecycle of an analytical procedure when approaching development of the procedure, i.e. its design, development, qualification, and continued verification. The current concepts of validation, verification, and transfer of procedures address portions of the lifecycle but do not consider them holistically. This General Chapter intends to more fully address the entire procedure lifecycle and define concepts which may be useful. This approach is consistent with the concepts of Quality by Design (QbD) as described in ICH Q8 (R2), 9, 10, and 11.

Preliminary outline:

- THE LIFECYCLE APPROACH
 - Analytical target profile
- STAGE 1: PROCEDURE DESIGN, DEVELOPMENT, AND UNDERSTANDING
 - Procedure design and development
 - Procedure understanding
 - Preparing for qualification
- STAGE 2—PROCEDURE PERFORMANCE QUALIFICATION
- STAGE 3—IMPLEMENTATION AND CONTINUED PROCEDURE PERFORMANCE VERIFICATION
 - Routine monitoring
 - Analytical control strategy
 - Knowledge management
 - Change control

Anticipated proposed design phase activities:

- Two *Stimuli* articles are scheduled for *PF* 42(5) [Sep.–Oct. 2016]
 - Analytical Target Profile: Structure and Application throughout the Analytical Lifecycle.
 - Analytical Control Strategy.
- In addition to the USP workshop held in December 2014, a [USP and ECA Joint Conference and Workshop on Lifecycle Approach of Analytical Procedures](#) will be held November 8–9, 2016 in Prague, Czech Republic.

Other USP sources of related information:

- *Stimuli* Article: Lifecycle Management of Analytical Procedures: Method Development, Procedure Performance Qualification, and Procedure Performance Verification. *PF* 39(5) [Sep.–Oct. 2014].
- *Stimuli* Article: Fitness for Use: Decision Rules and Target Measurement Uncertainty. *PF* 42(2) [Mar.–Apr. 2016].

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