Roundtable Session 1 - Table 14 - Challenges and Best Practices for Global Implementation of Analytical Procedures – Use of the ATP as Described in ICH Q14

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Abstract:
The global pharmaceutical industry is increasingly adopting harmonized approaches to analytical procedure development, driven by the principles outlined in ICH Q14. Central to this guideline is the Analytical Target Profile (ATP), which defines the intended purpose and performance criteria for analytical methods. The ATP serves as a foundation for method development, validation, and lifecycle management, ensuring that analytical procedures are robust, reliable, and fit for their intended use. By providing a clear framework for both minimal and enhanced development strategies, ICH Q14 enables organizations to tailor their approaches to product complexity and regulatory expectations.

Global implementation of analytical procedures through use of the ATP presents several challenges. Organizations must navigate varying regional regulatory requirements, integrate ATP principles into established quality systems, and foster cross-functional collaboration to ensure effective knowledge and risk management. The ATP requires precise definition and documentation, while risk management tools must be applied throughout the analytical procedure lifecycle. In this way, the ATP can support method selection and optimization through to analytical procedure transfer and post approval change management.

This round table will bring together industry leaders to share experiences, discuss practical strategies, and explore solutions to common barriers in global ATP implementation. Participants will examine how best to leverage the ATP and other ICH Q14 concepts to optimize efficiency, maintain compliance, and drive scientific rigor in analytical procedures.

Discussion Questions

What are the most significant challenges organizations face when defining and implementing ATPs for analytical procedures, and how can these be addressed?

How can risk management and knowledge management tools be leveraged to support the lifecycle of analytical procedures under ICH Q14?

What strategies have proven most effective for integrating ATP-driven approaches into existing pharmaceutical quality systems and ensuring regulatory compliance across regions?

Notes:

Challenges

- Convincing management/company that the effort is worth it to implement
    - Long term value of submitting ATP's in BLA / NDA is still unclear, particularly when considering front-loading of effort.
- It is still unclear what the practical implementation of Q14 will look like
- Based on ICH, we can't expect global acceptance of Q14 concepts like ATP

Opportunities

- ATP concept supports analytical life cycle management (LCM), eg could help with replacement of obsolete analytical technology
- Required limits in ATP link to the specs and method validation criteria

Connection between ATP and QTTP

- QTTP treated as "aspirational" – needs to be distilled to CQAs
    - ATP should be a living document that is updated as needed
- How can ATP be developed if specifications are not yet established?
    - Early iterations of the ATP would typically have wide limits.

Has anyone submitted ATP in clinical phase? No, limited benefit seen. For commercial, ATP in theory provides the opportunity to change the method within the ATP with lower reporting requirements – but no experience yet as to how to make this work.

- If we were to submit, would this be considered EC and therefore require approval for updates?
- Leverage Q14 framework to "buy down" level of approval required
- Provides prior agreement with regulators as to the proposed approval levels for changes.

How are DOEs used to support Q14 concepts in analytical development?

- Some methods derive more value from multivariate development (eg CEX) – software packages like Fusion can make this work automated
    - Also JMP, Minitab
- Workhorse methods like SEC may not benefit in the majority of cases
- New products/modalities may benefit
- DOEs are often used for robustness
- DOEs are valuable for optimization of continuous variables eg for HPLC methods
- Recent requests have been received for sharing details of robustness studies (when summary data has already been submitted in BLA/MAA)