Roundtable Session 1 – Table 2 – Platform Methods: Practical Considerations for the Implementation of Updated ICH Q14, ICH Q2, and USP <1220>

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Abstract:

The implementation of ICH Q14 and the revised ICH Q2 introduces a more science- and risk-based framework for analytical procedure development, validation, and lifecycle management. This roundtable will explore practical approaches to applying these guidelines, including defining analytical target profiles, aligning validation strategies, managing documentation expectations, and supporting post-approval change management. Interactive discussion will highlight challenges, opportunities, and lessons learned from real-world implementation. This discussion will examine:

Advantages of adopting platform assays in late-stage development and commercial control strategies.

Limitations and risk factors that can arise when "one-size-fits-all" methods meet product-specific nuances.

Practical challenges in assay validation, lifecycle management, and global regulatory acceptance.

Notes:

What is the definition of Platform Assay?

- There is actual definition in ICH Q14: *A platform analytical procedure can be defined as a multi-product method suitable to test quality attributes of different products without significant change to its operational conditions, system suitability and reporting structure. This type of method would apply to molecules that are sufficiently alike with respect to the attributes that the platform method is intended to measure. (ICH Q2)*.

How is platform different from compendial?

- Compendial is a historical method shown across globe to be authoritative and standardized.
- Platform assays use the same core, some room for variation from molecule to molecule, but most reagents and conditions remain unchanged.

- One control sample across different methods in same platform can be used for trending.

Key Question for Adding New Method to Platform

- Does new method really fall within the platform?
    - Answering this question can save time and money in the long-run.
    - If the control is the same, likely can be considered platform.
    - If control is different, is it really a platform method?
- Manufacturing sites use platforms often, not many yet for Bioassays.

Main Challenges

- How to deal with reagent expiry?
    - Critical reagents in one method on platform have Expiration Date set at date of qualification; now second method is qualified using same reagent. What is best expiration date to use?
    - If 20 methods exist on platform, do you have to requalify new lots in each method, or can you pick random methods, or can you just use platform system?
    - If truly a platform method, one reagent qual should be good across all methods.
        - FC Receptor assay were prime example of "easy" assays to put on platform.
    - Changing the way or working with QC and R&D can help. If R&D are using same platform control, the R&D data can be leveraged for trending.

Off-Topic Discussion on Validations with Development and QC Teams

- Use historical data to come up with a general approach to set confidence interval
    - A small subset of data prior to going into validation can save time and money
- Different ways to validation/co-validate
    - Development and QC work together (usually in same space/building)
    - Development transfers to QC; can be risky if no training is planned.
    - Development transfers to "Check Lab" where training occurs prior to QC lab; good assessment of robustness.