Roundtable Session 2 – 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:

1. Defining Platform Methods and Their Scope

Platform methods are broadly applicable analytical procedures, typically originating from pharmacopeial or industry-standard sources, that serve as a validated starting point for product-specific method development. Key principles discussed include:

Platform methods draw on prior knowledge and established regulatory precedent; their boundaries are defined by clear scientific rationale rather than arbitrary categorization.
Not all analytical procedures are amenable to a platform approach. Potency assays, for example, are inherently product-specific and cannot be fully platformed. However, discrete components of bioassay methodology—such as cell culture conditions, reagent systems (e.g., ALPHA ELISA platforms), and instrument qualification protocols—can be standardized and leveraged across programs.
Understanding the design space and potential matrix effects is critical when adopting a platform approach. Feasibility assessments should be conducted prior to broad implementation, with any necessary method modifications formally documented.
Reagents, software, and instrumentation supporting a platform method can be qualified once and the data package leveraged across multiple products, provided the scientific rationale is sound and differences are systematically assessed.

2. Regulatory Documentation Requirements

2a. BLA Submission Expectations

Platform method documentation requirements for Biologics License Application (BLA) submissions were discussed in detail:

At a minimum, sponsors should include method development data summaries and a validation report in the submission package. Complete, detailed development reports must be maintained internally and made available to regulatory agencies upon request.
All product-specific information derived from platform methods must be available at the time of BLA submission.
ICH Q14 supports analytical procedure development and validation; sponsors should be prepared to articulate what data will be provided to regulatory agencies and in what format.
When filing a Drug Master File (DMF), platform methods and associated development activities should be thoroughly documented and referenced.

2b. Explaining the Platform Strategy in Regulatory Documents
A recurring theme was the importance of clearly articulating the platform strategy within regulatory submissions:

Sponsors must explain what is being platformed, the scientific basis for that decision, and how the platform approach ensures method suitability for each specific product.
ICH Q14 articulates the rationale for why platform methods are appropriate but deliberately does not prescribe how to implement them, recognizing that product-specific considerations will vary. Sponsors must bridge this gap with their own platform framework documentation.
There is currently no single regulatory guidance document that defines a comprehensive platform method framework. Companies are expected to develop internal frameworks aligned with applicable guidelines and then apply these frameworks to product-specific contexts.

3. Qualification and Validation Strategy
3a. General Principles
Even when a platform method has been previously validated for other products, qualification and validation activities are still required. The extent of these activities, however, may be reduced based on the prior knowledge package:

Companies must define their platform system and articulate the procedural, qualification, and validation strategy encompassing both technical and quality system aspects.
When a new product is introduced into a validated platform method, sponsors must define what has changed and what additional qualification is required to demonstrate method suitability for the new analyte or matrix.
Intermediate precision is a key parameter for platform method qualification; the required precision acceptance criteria should be defined based on the method type and intended use.

3b. Early- vs. Late-Stage Development
The appropriate level of rigor differs across the development continuum:

Early-stage products: A verification approach is appropriate. The product and test controls are evaluated to confirm the method performs as expected (i.e., the method is “plug-and-play” for the new molecule). This constitutes method verification rather than full qualification.
Late-stage products: Product-specific qualification is required, leveraging the platform method as the foundation. This constitutes formal method qualification and must meet the standards expected for GMP release testing.

3c. Characterization Methods as Platform Methods

The feasibility of applying characterization methods within a platform framework was raised as an area for further exploration. Key considerations include:

Verification reports for characterization platform methods should include cross-references to the relevant qualification reports and contain sufficient data to demonstrate method fitness for purpose.
Regulatory documents should clearly explain what characterization methods are being platformed and the basis for that determination.

4. CRO–Sponsor Collaboration and Generic Platform Methods

The use of platform methods in contract research organization (CRO) settings introduces unique operational and regulatory considerations:

Communication between CROs and sponsors is critical when transferring or implementing generic platform methods. Alignment on method scope, qualification expectations, and documentation responsibilities must be established early.
Generic validated methods from CROs may be adapted for sponsor pipelines, but the level of rigor at adoption must be commensurate with the development stage (verification for early-stage; qualification for late-stage).
Standard coordinating body publications (e.g., pharmacopeial chapters, industry consortium guidance) can serve as source documents for designing platform methods and may be referenced in method design documentation.

5. Software and Instrument Considerations

An often-overlooked components of platform method implementation is the role of software and instrumentation:

Software used for data acquisition and analysis may not be directly interchangeable across instruments. Algorithmic differences between platforms can introduce variability—in some cases approaching 10%—which could result in assay failure if not adequately characterized.
The design and version of analysis software should be considered when defining the platform and assessed as part of the platform qualification.
Sponsors using multiple instruments or software versions under a single platform method must assess and document any differences in method performance to ensure that all configurations meet acceptance criteria.

6. Multi-Product Platform Performance Assessment

For organizations managing multiple molecules under a single platform method, ongoing performance monitoring is essential:

Method validity rates and performance metrics across the product portfolio should be systematically tracked and evaluated.
Regulatory agencies, including FDA, may request validation reports and method performance data for any or all products covered under a platform method. Sponsors should ensure that product-specific performance data are maintained and readily accessible.

7. Platform Method Lifecycle