Unlocking the Secrets of Platform Analytical Procedures with a Dash of ICH Q2(R2) / Q14 Magic

WCBP 2025 Workshop Session 1

Welcome to the WCBP 2025 Workshop on Practical Implementation of Platform Analytical Procedures

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Before we start: 'Rules of Engagement'

- We invite full participation from all audience members
- Please be respectful of fellow participants
- Please wait for a microphone before commenting
- We will facilitate the microphones, please be patient with us!

Workshop Scope

Platform Analytical Procedure – Definition from ICH Q2(R2)

An analytical procedure that is suitable to **test quality attributes of different products** without significant change to its operational conditions, system suitability and reporting structure. This type of analytical procedure can be used to analyse molecules that are **sufficiently alike with respect to the attributes that the platform analytical procedure is intended to measure**.

In Scope

- Individual analytical procedures for application across multiple products
- Late phase / commercial assets (validation and submission)

Potential Platform Analytical Procedures (Examples)

- Protein content by UV spectrophotometry – applicable to any protein product
- Elemental impurities – wide applicability independent of product / modality
- ELISA detection of polysaccharides – applicable across vaccine products
- Process related impurities (HCP, DNA) – applicable across biotech products
- Product related impurities / substances e.g. charge variant analysis

Out of Scope

- PAT (Process Analytical Technology)
- Platform **manufacturing** processes
- Analytical techniques used to support a **manufacturing** platform

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This workshop is an opportunity to….

- Explore approaches to the development, validation, registration and lifecycle management of platform analytical procedures
- Share pressing challenges, concerns, and aspirations

Open Discussion

- What is your experience?
- What would you like to know?
- Have you had success with submitting platform analytical procedures?
- What learnings can you share?

ICH Q2(R2):
"When an established *platform analytical procedure* is used for a new purpose, validation testing can be abbreviated, if scientifically justified."

ICH Q14:
"In certain cases, an analytical procedure can be applied to multiple products with little or no modification of measurement conditions. For a new application of such platform analytical procedures, the subsequent development can be abbreviated, and certain validation tests can be omitted based on a science- and risk-based justification."

For thought:

- What are the potential advantages and/or challenges faced during regulatory submission?
- When can an analytical procedure be designated as 'platform' and how does it apply to your next product?
- Guidances are not gospel – justify your approach using science- and risk-based principles
- What is required for subsequent submissions, once a platform analytical procedure has been implemented?
- Prospective *vs.* retrospective implementation of a platform analytical procedure
- Do Q2 and Q14 provide sufficient guidance on the use of platform analytical procedures?
- Where can efficiencies be found? *E.g.,* abbreviated analytical procedure validations, streamlined analytical procedure transfer