



January 29, 2026

## **Workshop: Qualification of Potency Reference Standards, Considerations for Reference Standards for Multispecifics, Multiple Antigens, or Multiple Mechanisms of Action**

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Scope: This workshop will discuss reference standard qualification focused on potency methods. They include therapeutic antibodies (monoclonal and multi-specific antibodies), therapeutic proteins, vaccines, as well as cell & gene therapies. For products with multiple modes of actions, additive vs. synergistic effects will be evaluated. Single vs. multiple reference standard for the same products will also be explored.

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## Questions to Discuss

1. What are the pros and cons of using single vs. multiple reference standards for one product?
2. How should cases be handled when one mechanism of action interferes with the measurement of another in potency assays?
3. How to differentiate between additive vs. synergistic effects of a product?
  - a) Individual or separate Reference Standards when mechanisms of action (MOAs) function additively or independently.
  - b) Individual or separate Reference Standards when mechanisms of action (MOAs) function synergistically or in a dependent manner.
  - c) Should all MOAs be covered by qualification or only critically important/depended/independent?
4. Common practices of calibration against WHO standards.
5. Typical challenges with reference standard programs (supply, qualification/requalification, drifting, health agency inquiries, etc.)

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## Additional Questions

6. What criteria should be used to decide when a reference standard needs requalification or replacement?
  7. How do you establish shelf-life or retest intervals for reference standards with limited stability data? Using modeling (forced degradation studies) or real-time stability data?
  8. How should changes in manufacturing processes affect the qualification of reference standards?
  9. How do you determine suitability of reference standards when transition to another category of analytical testing (e.g., animal testing to in vitro bioassay)?
  10. Lessons learned, best practices, wish list, etc.
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