

Workshop Session 1: Managing Product-Specific Reference Standards: Challenges and Best Practices

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Workshop Objectives:

Share experiences and discuss best practices for:

- Establishing reference standards for early-phase and late-phase products
- Selecting optimal storage and handling conditions (vial configuration, temperature and freeze/thaws etc.)
- Ensuring reference standard stability throughout the product lifecycle (RS stability monitoring plan and RS data trending analysis)
- Managing lifecycle changes across product reference standards, including implementation of a two-tier reference standard strategy (Primary RS and Working RS)

Points for Discussion

1. **Considerations for selection of reference standards**
 - a. *Early stage*
 - b. *Late stage*
 - i. *Introduction of two-tier RS system (how and when)*
2. **Considerations for qualification of RS**
 - a. *Primary RS*
 - b. *Working RS*
3. **Considerations for re-qualification/re-evaluation of RS**
 - a. *Re-qualification strategy and frequency*
4. **Management of RS (container closure, storage temperature and handling etc.)**
 - a. *Container closure*
 - i. *Cryovials*
 - ii. *Glass vials (eg: 2R)*
 1. *Single use or Multiple use*
 - b. *Storage temperature*
 - i. *Storage temperature same as DS?*
 - ii. *Storage temperature lower than DS?*
 - iii. *Others*
5. **Are there any special considerations for reference standards in the context of potency testing (example: how to monitor drifting of potency)?**