**Roundtable Session 2 – Table 10: Full Technical Transfer of Analytical Procedures – Approach for Streamlining and Discussion of Regulatory Submission Experiences**

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**Abstract:**

The technical transfer of analytical procedures, also referred to as method transfer, is the documented process that qualifies a laboratory (the receiving unit) to use an analytical test procedure that originated in another laboratory (the transferring unit), thus ensuring that the receiving unit has the procedural knowledge and ability to perform the transferred analytical procedure as intended. Transfers can occur between laboratories at the same site, between sites at the same company, or between companies and/or regulatory laboratories. The requirements for such transfers change throughout the lifecycle of a method. As noted in USP <1224>, method transfer can be performed and demonstrated by several approaches including comparative testing, covalidation between laboratories, the complete or partial validation of the analytical procedures by the receiving unit, and the transfer waiver. The tests that will be transferred, the extent of the transfer activities, and the implementation strategy should be based on a risk analysis that considers the previous experience and knowledge of the receiving unit, the complexity and specifications of the product, and the procedure.

**Discussion Questions:**

1. What are major challenges encountered while transferring analytical procedures? Do you have any un-successful experience to share?
2. Describe best practices used within your organization for method transfer.
3. How do you set and justify statistical acceptance criteria for the transfer of quantitative methods?
4. Has the COVID pandemic affected or changed routine strategies for method transfers?
5. Discuss successes and roadblocks to select regulatory pathways for reporting testing laboratory changes post-transfer. What's the filing strategy and category for method transfer? Has your organization received any inquiry on method transfer?
6. Does your organization have any experience or plan to use ICH Q12 concept for post-approval method testing site changes? For example, the method transfer protocol is included in the initial filing.

**Notes:**

- Major challenges encountered while transferring analytical procedures: lack of knowledge / experience of the receiving lab can lead to challenges. A lot of time is spent training inexperienced analysts at the receiving lab. High turnover of analysts at receiving labs leads to additional support from the donor labs.
- Consensus that most companies are providing support for training through detailed documents, videos, on-site support.

- Discussion on challenges faced during method transfer:
    - Quality of reagents at transfer labs have led to un-successful experiences, especially when the criticality of the reagents is unknown.
    - Cell-based and activity assays are particularly challenging during method transfer.
    - Example discussion where method transfers were challenging: donor labs no longer being in business, and therefore validation data not being available, and repetition of validation activities.
    - Recommendation from multiple participants that receiving labs should show the proof for the trainings
    - USP <1224> defines different options for analytical transfers
- Discussion around the following questions: How are people performing method transfer? How many batches? Is reference standard included? How many batches of material? Stability samples?
    - There are similar approaches to perform method transfers in terms of how many batches are included and types of samples being included.
    - The strategy for transfer depends on initial gap assessment performed prior to method transfer.
    - The consensus was that the number of batches used for method transfer is method dependent.
    - USP <1224> defines different options for analytical transfers.
    - Micro methods verification at receiving lab: 3 batches at late phase
- Discussion on whether stress samples are required as part of method transfer. The experience was that this was not a requirement, but rather an expectation from HA as part of method transfer data package. Only one stressed sample is sufficient.
- Filing of master method transfer protocol in BLA as part of PACMP would be challenging, no experience with this approach for companies at the table
- Discussion on ways to streamline method transfer
    - Consensus at the table that gap assessment is necessary to determine what level of validation is needed during method transfer
    - SOPs need to be in place to decide strategy for method transfer