Analytical method transfer is the process that qualifies a lab to execute an analytical test method/procedure. This is an exercise that almost every company conducts routinely, yet strategies and practices across the Industry are diverse. This table will discuss and share current Industry and Regulatory perspectives on method transfers, at all times, weaving in considerations related to the recently issued FDA guidance on this topic, and feedback from Health Authorities for filings.

QUESTIONS FOR DISCUSSION:

1. What is your strategy for analytical method transfers?  
   For example: comparative testing, co-qualification approach, complete/ partial validation or revalidation, transfer waiver

2. Do you use a ‘one size fits all’ or a life-cyle phase-appropriate transfer strategy?  
   For example: early development, late development, and approved (commercial) product approach?

3. What is your specific experimental design for successful transfers?  
   For example:  
   a. number of: operators at each site, instruments, lots of test article  
   b. details on: approach to demonstrate repeatability, intermediate precision. LOQ, spiked or stressed sample for impurities, linearity, LOD etc (if applicable)

4. What is your acceptance criteria approach to demonstrate successful transfer?

5. How do you ensure analytical method performance is similar at different sites?

6. Do you transfer to multiple labs simultaneously, or to only one, and how does/ would this impact your analytical transfer strategy approach?

7. Does your transfer strategy and design differ depending on the type of analytical method?  
   For example: release and stability assays, IPC assays, characterization assays, platform methods already successfully transferred to a site/ lab

8. Post transfer, and as part of Life Cycle Management for late stage and commercial products, how frequently and extensively do you compare data and method performance across sites?

9. For International transfers to government labs and Health Authority labs, for example, what considerations and specific regional requirements should be take into consideration

NOTES:

1. What is your strategy for analytical method transfers?  
   For example: comparative testing, co-qualification approach, complete/ partial validation or revalidation, transfer waiver  
   ○ Waiver only for compendia methods  
   ○ Performance verification (reduced testing) e.g., intermediate precision over 2 days and 2 analysts at receiving site. Applied to similar methods. Not for bioassays.
Co-validation can be cumbersome.

2. Do you use a ‘one size fits all’ or a life-cycle phase-appropriate transfer strategy?
   For example: early development, late development, and approved (commercial) product approach?
   - Early phase “co-qualification” prior to FIH. Get head start with bioassays.
   - Late phase “on-site verification” or comparability/re-validation (due to method optimization)
   - CRO to industry transfers: for example mass spec based. If needed qualify QC surrogate (e.g., UPLC) and transfer back to sponsor. Validation at sponsor site.
   - Refer to qualification/development report if available prior to co-validation in QC labs

3. What is your specific experimental design for successful transfers?
   For example:
   - c. number of: operators at each site, instruments, lots of test article
   - d. details on: approach to demonstrate repeatability, intermediate precision. LOQ, spiked or stressed sample for impurities, linearity, LOD etc (if applicable)
   - Health Authorities want multiple lots; some say only 1 lot. May be phase appropriate
   - Use control samples or reference standard (for comparability) and stability samples (for stability indication).
   - Multiple analysts (2) per site. For bioassay: 12 tests per site.
   - What to use as gold standard during LCM?
   - Initially co-validation; full transfers thereafter.
   - LOQ verification as appropriate.

4. What is your acceptance criteria approach to demonstrate successful transfer?
   - Historical transfer data used to justify acceptance criteria
   - Specs are too wide to be used as criteria
   - Use method variation from validation as criteria? One SD?
   - Use criteria so that OOS rate does not change
   - Transfers to CRO: may be higher stringency but more responsive
   - CRO data typically not filed in BLA

5. How do you ensure analytical method performance is similar at different sites?
   - Equivalence evaluation over time: need active monitoring across sites
   - LIMS trending. Automated except for CROs

6. Do you transfer to multiple labs simultaneously, or to only one, and how does/ would this impact your analytical transfer strategy approach?
   - Co-validation approach across 4 labs proved effective.
   - Co-validation at Phase3/PPQ was beneficial from resource and alignment perspective.
   - Leverage active training programs at receiving site.

7. Does your transfer strategy and design differ depending on the type of analytical method?
   For example: release and stability assays, IPC assays, characterization assays, platform methods already successfully transferred to a site/ lab
   - No regulatory framework for transfers
   - Industry needs guidance
   - Get regulatory feedback early in lieu of guidance
   - Transfer strategy not filed, but be prepared to provide during BLA review

8. Post transfer, and as part of Life Cycle Management for late stage and commercial products, how frequently and extensively do you compare data and method performance across sites?
   - Questions during inspections: one HA just asked if program existed
   - Monitor stability, method success rate
9. For International transfers to government labs and Health Authority labs, for example, what considerations and specific regional requirements should be taken into consideration:
   - Health Canada required method transfers. And China
   - Start with transfer protocols, raw data if needed
   - Critical methods transferred separately
   - No transfer, just methods. Sometimes equipment.
   - Less stringency
   - Specific guidance needed for in-country transfers