Table 11: Technical Transfer of Analytical Methods (particularly within sites and buildings)

Facilitator: Parastoo Azadi, *University of Georgia*

Scribe: Carol Krantz, *Seagen Inc.*

Key Words:

transfer methods, analytical methods, NMR and MS

Scope:

Transfer of analytical methods between labs can be associated with significant difficulties, leading to error, downtime, and loss of productivity. This roundtable will discuss common sources of failure in transfer of analytical methods and how these pitfalls can be avoided. How can full transfer of all relevant method details be ensured? What is the role of hands-on training vs. paper training in method transfer? How can failures in method transfer be detected early? In addition to these questions, the panel will also discuss strategies to mitigate failures in method transfer, as well as future developments in method transfer.

Discussion Notes:

1. What approach has been applied for transferring method from one lab to another lab?

   Multiple approaches can be applied for analytical method transfer at a case-by-case basis.

   a. Transfer platform method: the key is to ensure transfer knowledge from donor lab to the receiver lab, the receiver lab may not need to perform method if the method has been established. Otherwise, donor lab Subject Matter Expert (SME) can go to receiving lab, and train the personnel in receiving lab.
   b. Two labs, donor and receiving, can perform intermediate precision experiments to demonstrate the method is successfully transferred.
   c. Development validation group use the same type of instrument to conduct method validation and demonstrate assay performance consistent between the donor and receiving labs. The development lab can also be qualified as the backup of QC lab.
   d. Transfer waiver may be leveraged for simple method and platform method transfer such as SoloVPE method. Analytical knowledge should be completed transferred to new labs. The transfer waiver is submitted as a part of PAS.
      i. FDA challenged the sponsor and required more data to support the assay performance data to show equivalence. EMA is more open to the transfer waiver.
   e. Points to consider during complicated assay transfer, i.e. mass spec, peptide mapping, potency assay
      i. Different instruments can introduce unnecessary challenge, it's critical to have same type of instrument and software between the donor and receiver lab
      ii. Specific points for bioassay transfer: training in person, side by side training, troubleshooting in person, RealWear or similar device can be leveraged to

facilitate the details of technique of bioassay transfer if in-person training isn't available

iii. Generate videos and pictures of assay performance and include them into the method transfer document, including detailed equipment setting, critical reagents preparation, etc.

iv. It's critical to establish the accurate assay conditions at the receiving lab and send the trainer of donor lab to the receiving lab for tech transfer training and troubleshooting

f. Biggest challenges:

i. Unable to send trainer to the receiving lab at different location, different countries, etc.

2. How many lots of material should be used in the method transfer?
    a. For stability indicating assay, stressed material should be included in the method transfer exercise.
    b. Three lots of material are commonly utilized for post approval method transfer.
    c. For cell and gene therapy, due to the material limitation, may not have three batches of material available for the method transfer.
3. How many analysts should be trained in the receiving lab?
    a. Ideally two analysts.
    b. Automation is an approach to address analyst inconsistencies and manpower shortage.
    c. Lab job rotation can facilitate the assay performance, after certain time analysts need to be requalified for performing curtain type of assays.
4. Takeaway for analytical method transfer:
    a. Precise transfer protocol, well written analytical procedure including all detailed information, equipment vendor, catalog number of reagent or material, main frame of information.
    b. Donor lab and receiving lab have same model of instrument and software.
    c. Sufficient time for trainer and trainee from both labs to transfer knowledge and discuss transfer protocol, analytical procedure, etc.
    d. The transfer acceptance criteria should be established based on the assay performance, control chart, and historical data.
    e. Robust method is the key of successful method transfer