Roundtable Session 2 – Table 17 – Tech Transfer Challenges and How to Avoid Common Mistakes

Facilitator: Dawn Cohen, *Amgen*

Scribe: Jace Fogle, *Abbvie*

Abstract:

Tech-transfers play an increasingly vital role in the regulated pharmaceutical and biopharmaceutical industries. Expanded use of contract manufacturing and testing organizations, supply risk mitigation strategies, increased corporate mergers and acquisitions, and evolving global regulatory complexity all contribute to the need for technology transfer to ensure consistent supply for patients. Digital tools and modern guidelines such as PDA Technical Report No. 65 on Technology Transfer and ICH Q2 (R2) offer opportunities to streamline tech-transfer, yet familiar challenges remain. Trends such as accelerated timelines, new modalities, new manufacturing and testing technologies and various forms of external partnerships flavor tech transfer challenges facing teams today.

At this roundtable we will discuss common tech transfer challenges and strategies for mitigation, with a focus on the transfer of analytical methods.

Discussion Questions:

1. What best practices do you deploy for transfer of in-licensed products (vs. ones that your organization knows well)?

2. How have you been leveraging digitals tools in method transfer?

3. Communication challenges between method & process teams can sometimes lead to misunderstandings about in-process sample types. In addition, a method transfer may begin before the control strategy is finalized leading to late identification of an additional method or sample type that needs to be validated. Are there strategies that your company deploys to avoid these types of issues?

4. Is there a key lesson learned from your tech-transfer experience that you would like to share, or topic that you would like to seek advice on?

Notes:

Tech transfer best practices for in-licensed products…where you may not have in depth history with the analytical methods:

- May do a “mini-validation” upon tech transfer
- Do you do verification of methods when you have the validation report from the sending site? Not usually…becomes a method transfer
- Challenge: aligning on definition of “too much bias”. Need to have understanding of how integration was done historically

- Have worked with statistician to define quantitative acceptance criteria for method transfer. Can be good approach, but also have been backed into a corner, defining criteria differently now. Can write protocol in two steps: system suitability, followed by qualitative assessment of results. This is an opportunity for regulatory guidance.
- May be good to do feasibility work before you start protocol work. This may be limited by sample availability.
- Can be good when methods are very specific wrt reagents, but can also be difficult when items are not available
- Some receiving sites do gap assessment of each method to derisk. Can help identify documentation gaps.
- May write a "supplemental information sheet" to address gaps in method info ("tribal knowledge")
- Site-to-site differences in whether info is captured in method or job aid
- Need white paper/consortium to drive broad alignment on method transfer standard practices
- Also helpful to have trending data from sending site
- If you get unexpected result during transfer, it can be grey area as to what procedure to follow. Ideally this should be spelled out in the Quality agreement
- Some are using templates for method transfer protocols, but can be difficult because there are so many different methods
- AI tools are beginning to be employed for generating tech transfer documents. Need to train the tools on example reports

Need for actual product vs surrogate manufacturing during PAI

- Has been acceptable for drug product in several instances

When electronic batch records are used, how do you provide these to agency when requested?

- Need to be able to generate pdf's. Can lead to redundant effort to maintain electronic and pdf records. In some cases need to translate the entire batch record.

Recent FDA PAI observation has cited process characterization data generated in a development lab.

- This is typical practice at most sponsors. Also sponsors are not usually analyzing validation chemical hold time samples or impurity mapping samples in the QC lab.