Table 29 - Process Technology Transfer: Opportunities and Challenges

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Keywords:

Comparability, Regulatory strategy, Product lifecycle

Scope:

Process technology transfer is a common occurrence to ensure global availability of products during the entire lifecycle of the product. The transfer can be internal or to an external partner. The historical approach would be a comprehensive transfer strategy to ensure comparability of both manufacturing and/or testing sites. The comprehensive transfer strategy is costly and resource intensive at the transferring and receiving site. The discussion for this round table will focus on the opportunities and challenges to streamline the transfer process to gain efficiencies without a risk to quality. Some concepts include:

Discussion Notes:

- Requirements for comparability and comparability assessment for tech transfers
- Important to execute robust risk assessments:
    - Internal Cross functional team to assess process and product to execute a risk assessment
        - What CQAs and quality attributes are impacted if there are changes
        - Assess E2E process (cell line to DS, DP)
        - Assess pre and post changes and mitigation planning
            - If high/severe, focus on level of risk
        - Assess level of change (low/high risk)
            - Raw material is also included as part of this assessment
    - Assess development data and/or additional studies to be executed to support changes
    - Development data = small scale data representative of the final commercialized process.

Shared experience? DS is comparable – what is the requirements for DP

- There is mixed feedback on number of batches to be placed on stability when DS is comparable and request for DP data (3 vs 1 confirmatory batch).
- 1 confirmatory batch placed on long term and accelerated stability
- For post approval, Health Authority specific depending on number of batches (full 3 batches/full comparability, pre and post change)

Characterization Data and protocol:

- Need assessment on characterization testing and data
- HCP and glyo comparison (pre-post change)
- Create a statistical range for method attributes
- Need a robust justification for statistical analysis on comparability analysis.

- If a company is outside the range, the attributes would need further assessment for impact to product quality.
- For commercial process changes, consider totality of batch history of product manufactured
- For characterization and comparability there could be some attributes that are “report results”
    - Side by side analysis is by pre and post change. Side by side analysis is critical to alleviate method variability/reagents changes, etc.
    - Characterization is aligned with S.3.1 sections (extended characterization)
    - Tox material (pre-clinical) – comparability does not need to be extensive.

Development (Phase 3): Criticality of material and sourcing of raw materials (i.e. cell culture, excipient).

- Leverage a small scale model (2L/10L) to demonstrate CQSs/comparability
- Additional request demonstration batch/Engineering batch with new raw material at scale.
- Number of batches to support changes: Sponsor to assess the level of changes (facility fit, process changes) to justify # batches (3 vs 1)
- Stability protocol timepoints per ICH
    - Stability assessment on if extended characterization is required for the program.
- Standard to run forced degradation (side-by-side comparison to alleviate variability).