Comprehensive approach for technology transfers: to PACMP or not to PACMP?

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Content Overview

Workshop will explore critical aspects of site tech transfers, including addressing capacity needs, ensuring regulatory compliance, mitigating supply chain risks, optimizing costs, and gaining strategic benefits. Attendees will share insights into risk-based analytical comparability study design, derivation of appropriate acceptance criteria, risk assessment on facility readiness to support reduced reporting category, and regulatory strategies for successful implementation.

Disclaimer

- The thoughts presented herein are the viewpoints of the moderators as individual scientists who are familiar with this subject matter.
- These viewpoints are not intended to reflect the views, policies, procedures, or evaluation criteria of the organizations where these individuals are employed.

Why Perform a site tech transfer?

- **Capacity Needs**: Addressing urgent or chronic needs for capacity
- **Regulatory Compliance**: Ensuring that the product is manufactured in compliance with cGMP standards.
- **Risk Management**: Mitigating risks associated with supply chain disruptions by having multiple manufacturing sites.
- **Cost Optimization**: Reducing manufacturing costs by transferring production to a site with lower operational costs
- **Localization:** Gaining strategic benefits by producing the product closer to the market where it is distributed.

Site tech transfers address internal drivers but are also influenced by external factors

Elements of Analytical Comparability

- Risk-based study design
  - Pre-Change: identify population of batches for baseline comparison
  - Post-Change: testing parameters to assess, analytical tools, samples to measure, number of batches to assess
- Derivation of appropriate acceptance criterion
  - How to ensure comparable product safety and efficacy using analytical measures that can be implemented in the CMC space?
- Risk assessments to support change implementation
  - Can support reduced reporting category (e.g. when using PACMP).
  - May be useful to justify reduced GMP inspectional burden.

Regulatory Strategies for success

- Clearly identify any significant process or equipment changes
  - Be clear about what's not changing, and what prior knowledge is being leveraged: experience from other transfers, facility GMP compliance history, etc.
  - If facility has GMP compliance history, consider how this might impact likelihood of inspection as part of tech transfer.
- Describe qualification and comparability plans (including acceptance criteria)
- Seek regulatory engagement early, with follow-ups as plans continue to develop.
- When using the PACMP approach, clearly define the objectives:
  - Alignment on success criteria and data to report
  - Filing category reduction? Might not be possible based on totality of risk associated with the tech transfer or if GMP inspection required during review.
- Consider if there are collaborative review options or reliance opportunities when filing to multiple jurisdictions

Discussion Topic Questions for the Audience

- What are the biggest challenges you have faced during a site tech transfer, and how did you overcome them?
- What novel approaches have you taken to setting comparability criteria? What was the reaction from regulators?
  - Statistical assessment is not the only way to establish comparability – better characterized products could leverage firm's prior knowledge.
- What approaches have you used to engage with regulatory bodies?
  - Formal meetings?
  - Product correspondence?
  - Informal contacts?
  - How do you balance speed of the project vs time required for preparedness?
- How have you dealt with differing requirements from regulators when filing to multiple jurisdictions?

Discussion Topic Questions for the Audience

- Experience in sharing facility readiness information:
  - How much PQS information is too much to include?
- What is your experience in terms of GMP inspection associated with tech transfers?
  - How frequently do they occur vs successfully justifying they are not necessary?
  - Can this inspection be decoupled from supplement review?
- If using a PACMP approach can you share experience on:
  - Repeat use of a PACMP for multiple new facilities.
  - Repeat use PACMP for multiple product introduction into same facility.
  - Experience using PACMP approach outside of US.
- What advice would you offer to someone going through this process for the first time?

Final Discussion Topic Question…

- Keeping in mind the need to demonstrate product comparability and continued safety and efficacy of the product after a change, if there was one thing that you could ask to change in the regulatory domain, what would it be?
  - How would you envision this could be implemented?