A Transfer of Technology and Knowledge

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Kenneth A. Wilson, Ph.D.

Abbott Laboratories

What is Technology Transfer

- The **systematic procedure** that is followed in order to pass the **documented knowledge** and **experience** gained during **development and/or commercialization** to an appropriate, and authorized party. It embodies both the transfer of documentation and the **demonstrated ability of a receiving unit** to effectively perform the **critical elements of transferred technology**, to the **satisfaction** of all parties and any/all **regulatory bodies**.

What does it apply to?

- Active Pharmaceutical Ingredient (API)
- Drug Product
- Analytical Methods
- Pre-launch (R&D to operations)
- Post-launch (site to site)
- Local and international
- Internal or Third Party

Why is the Transfer Process important?

- Cost of failed batches.
- Critical for ensuring successful commercial launch.
- Reduces loss of knowledge gained through the development process.
- Reduces regulatory risk at a PAI.
- Essential to ongoing manufacturing site success.

Process Development Timeline

Phase I

Process Development

Phase II

Registration Runs

Phase III

Process Validation

Transfer to commercial site

Launch

Site to Site Transfer

Challenges of transferring a process from R&D

- Development of a robust process.
- Capturing all of the data generated through development.
- Providing operations with user friendly documents.
- Ensuring that all parties are participating.
  - Does the process meet operations needs?
  - Is the equipment compatible with the process?
  - Are the compliance and regulatory needs met?

Challenges of site to site transfers.

- Older processes with technical gaps.
- Is the development well documented and are the documents still relevant?
- Cost of remediation.
- Friendly or hostile transfer.
- How accessible is the production data.

What makes a successful transfer?

- Well documented development.
- Formal transfer process.
- Dedicated transfer team.
- Early participation of operations in the development process.
- Full evaluation of scope of transfer (site to site).
- Scale-up prior to validation.

Success Criteria

- Technology transfer can be considered successful if a **receiving unit** can **routinely** reproduce the transferred product, process or method against a **predefined set of specifications** as agreed with a **sending unit** and/or a **development unit**.

Validation

- Objective of validation is to ensure and demonstrate that all **facilities, process, systems, procedures** and **equipment** that may affect the quality of pharmaceutical products operate **reliably** and **reproducibly**.

Performance Metrics

- Product quality (chemical/physical).
- Yields, cycle times and cost targets met.
- Validation batch success.
- Commercial batch success rate.
- Analytical metrics.
- Successful PAI.

Post-Validation Monitoring

- Plan identified as part of validation close out.
- Identified ongoing performance metrics.
- Generation of knowledge.
- Feedback to R&D.