



The Challenges of Biopharmaceutical Assay Transfer

The Devil is in the Details

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Case Studies in Transfers to CMO

- **Baxter's BioPharma Solutions business**
 - Contract Manufacturer of Parenterals
 - Vials, Cartridges, Syringes, Kits
 - Solution or Lyophilized
- **Pharmaceutical Development Department**
 - Method Development, Validation and Transfers
 - Final Product, In-Process, Residue Analysis
 - Large and Small Molecules
 - HPLC, CE, GC, ELISA, SDS-PAGE, IEF, Western Blots

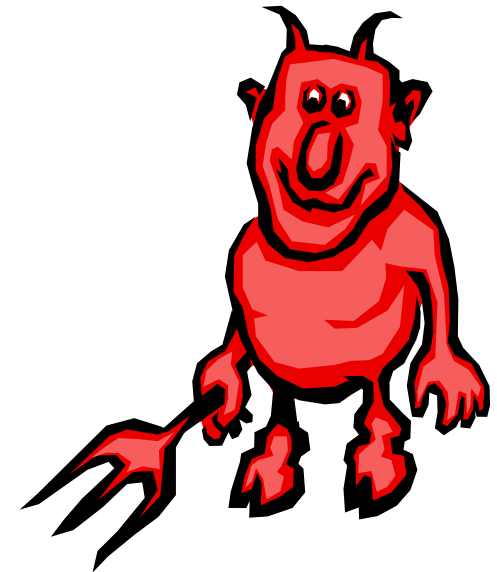


How does Baxter minimize transfer problems?

- Reorganization of method transfer process in 2005
- All method transfers occur through development group
 - Development group also performs Method Validations
 - Single path for all methods into company
- Methods are given a thorough paper evaluation and laboratory evaluation in the development laboratory prior to drafting the Transfer Protocol
- Research Associates are responsible for training QC analysts and supervising the execution of the protocol in the QC laboratory under actual conditions of use.

Case Studies in Transfers to CMO

- Demons which cause transfers to fail:
 - Poorly written or obsolete Procedures
 - Parameters in written procedure not tested in validation or used at Transferring Lab
 - Differences in reagents or instrumentation
 - Differences in expectations of method performance
 - Lack of Robustness of Method
 - “Method Validated on the edge of a cliff”
 - Subtle differences in technique



In Conclusion

- The Devil is in the Details
 - Minor issues such as technique, pipet type, and reagent storage temperature can cause the delay or failure of a method transfer
 - The best way to prevent problems? [Open and Responsive Communication with Technical Experts at the Transferring Lab](#)
- How does Baxter minimize transfer problems?
 - [Experienced analysts in method transfer group](#)
 - [All methods receive a preliminary evaluation in the development laboratory before the SOP or transfer protocol is approved.](#)

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