MANUFACTURING SUPPORT | PROCESS DEV & COMPARABILITY | ANALYTICAL DEVELOPMENT | QUANTITATIVE MODELING | QUALITY SYSTEMS | DEVICE DEVELOPMENT

REGULATORY SUPPORT | PRECLINICAL DEVELOPMENT | PROJECT & PROGRAM MGMT | MARKET RESEARCH | INTELLECTUAL PROPERTY | FINANCING & DILIGENCE

Retrospective Failure Analysis and Remediation

Why DHC?

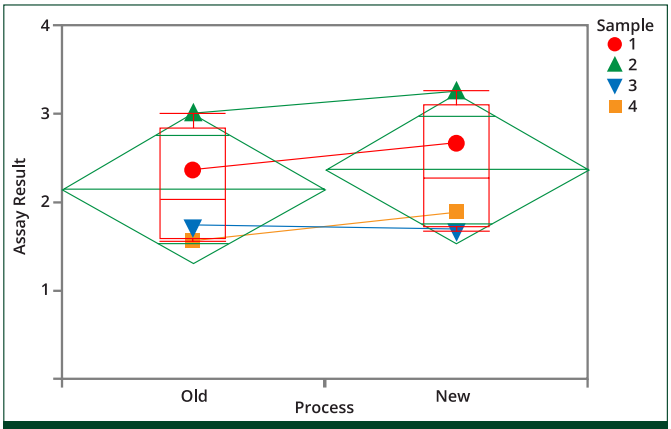
- EXPAND CLIENT BANDWIDTH
- PROVIDE ADDITIONAL TECHNICAL EXPERTISE
- SOLVE EXISTING PROBLEM (REMEDIATE)

The Ask

Sometimes during an analysis of data, manufacturers will identify nonsensical or counterintuitive results. Recognizing that the data is somehow "off" is a first step. A second step is to call in someone like Dark Horse with remediation experience to investigate and ask the necessary questions, with a goal of identifying the source(s) of the issue. This client, an established biotech, was facing problematic data from performance of a new assay at its CDMO and needed assistance in tracking the problem(s) back to the source.

DHC's Approach

- In this case, the client was implementing a new assay format at its CDMO in response to an FDA request for increased characterization of product potency as part of a comparability study.
- The CDMO was unfamiliar with the assay format in question, and initial attempts to run the assay generated nonsensical data.
- As an initial step, DHC requested and analyzed the raw data in order to generate hypotheses about the likely failure mode(s) at play.
- Next, DHC designed an experiment to test the generated hypothesis regarding likely failure mode.
- A DHC Consultant was on site as a 'Person in Plant' during the experiment to observe CDMO staff performing the assay and to ensure successful execution of the experimental plan.
- Data analysis was performed in real time to enable timely and meaningful feedback during study execution, maximizing the opportunity to identify a definitive root cause without need for further experimentation.
- Following successful remediation of the immediate issue, DHC equipped the CDMO with a training guide describing data analysis procedures, as well as common failure modes and what to look for, to enable greater self-sufficiency in future.



Once the assay was remediated, the client was able to generate data at the CDMO supporting comparability of the new process to that of the old process.

The Impact

The client's project was back on track and the CDMO was able to generate the additional comparability data, as requested by the FDA. Additionally, the manufacturer now had a greater in-depth understanding of the assay methodology and the client had an increased sense of confidence in their manufacturing partner. The CDMO was also now prepared to be able to explain the "why" the next time an assay yielded unexpected or undesired data.

Next/Concurrent Steps

- Further Manufacturing Support
- Further Process Development & Comparability
- Regulatory Support