



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

Remediation of CRL Issues in Preparation for BLA Resubmission

The Ask

This client had late-stage experience....but not with cell or gene therapies. In a younger industry such as C>, previous agency guidance is not yet as robust as it is for fields that have been around longer. For that reason, sponsors benefit from C>-specific expertise. The client came to Dark Horse to request remediation and resolution of multiple areas for which their original submission was rejected. Due to the time constraints of resubmission, a sense of urgency accompanied getting the product back on track and executing each element of this process on time and with quality as a top priority.

Why DHC?

EXPAND CLIENT BANDWIDTH

PROVIDE ADDITIONAL TECHNICAL EXPERTISE

SOLVE EXISTING PROBLEM (REMEDiate)

DHC's Approach

This engagement addressed a wide range of overlapping service areas spanning at least six of DHC's twelve service offerings. Among the many services provided by DHC were:

1. Strategic regulatory support to identify the path to issue resolution and BLA resubmission
2. Tactical/operational regulatory support such as document authorship of briefing book and BLA subsections
3. Creation of a cross functional project plan detailing the range of necessary activities and sequencing; accompanying detailed project Gantt charts and dashboards for visibility and tracking completion as well as critical path mapping
4. Technical expertise relating to C> analytical, process development and manufacturing, to ensure technically sound remediation to quality and regulatory concerns in these areas
5. Management and oversight of relationship with an external testing house requiring special attention for deliverables on and near the critical path for resubmission
6. Root cause analysis of process failures to accelerate issue identification and remediation

The Impact

The client successfully completed their post-rejection regulatory agency meeting, allowing for next steps towards resubmission. Dark Horse's C>-specific project management plan provided necessary clarity and visibility for efficient and effective project remediation along with critical path mapping. Additionally, DHC's subject matter expertise and technical know-how, combined with project leadership skills, not only prepared the client for their resubmission (along with potential submissions in different regulatory jurisdictions), but also set them up for future successes.

Next/Concurrent Steps

- Regulatory support
- Analytical Development
- Quality Systems
- Process Development

