

MANUFACTURE OF A CELL-BASED BIOLOGIC FOR THE CLINIC

GOAL: To develop processes and assays and to manufacture a cell-culture based biopharmaceutical for a phase I clinical trial

CHALLENGE: optimize the yield and stability of the final product

OUTCOME: Our scientific team helped the client refine and scale-up their manufacturing and purification processes to optimize yield and stability. The team developed analytical tests and successfully manufactured, tested, released and shipped the material to multiple sites by the required deadline.

PROCESS DEVELOPMENT STEPS:

- Sourced raw materials
- Developed technology from a bench process to a cGMP-compliant process
- Selected optimal clone for project
- Scaled-up and refined client manufacturing process
- Optimized chromatographic and filtration steps for purification
- Conducted filtration studies for post-purification bulk filtration
- Developed product-specific analytical methods
- Developed all relevant supporting documentation

cGMP ACTIVITIES:

- Produced cell banks (Master and Working)
- Qualified all assays needed for product testing
- Engineering and production runs for bulk substance production
 - Set up and validated processes specific to client's requirements
 - Produced multiple batches of product
 - Purified the harvest material
 - Formulated, vialled, labeled and stored purified bulk
- QC release tested vialled product and QA reviewed process documentation
- Designed and executed stability studies
- Shipped to multiple sites using validated shipping procedures
- Prepared regulatory documentation