



A Single Source Solution Case Study (Cell Culture, Purification and Bioconjugation)

Overview of Project performed by Goodwin Biotechnology for a Client based in Europe:

- Project 382 – Increase monoclonal Antibody (mAb) Productivity in cell culture, create new Cell Banks, perform Upstream and Downstream Process Development, Scale-Up and cGMP manufacturing
- Project 384 – Perform Process Development, Scale-Up, cGMP and Aseptic Fill/Finish manufacturing of an ACC (Antibody Chelator Conjugate) vialled product for clinical studies

Client Project Goals:

- Increase productivity of murine hybridoma (from 200mg/L)
- Develop and scale-up bioreactor and purification processes
- Develop and scale-up conjugation process
- Complete projects (382 and 384) in about 18 months

Key Milestones:

- Transferred of Research Cell Bank, Assay Verification, Confirmed cell culture process at 200mg/L
- Doubled the productivity to 400mg/L through performing Media Optimization Studies and creation of new Research and Master Cell Banks
- Developed bioreactor and purification process
- Developed conjugation platform (Site-Directed vs. Random)
- Successfully scaled-up mAb and ACC production for GMP manufacturing
- Completed project from receipt of RCB to ACC vialled product in about 18 months and within budget.