

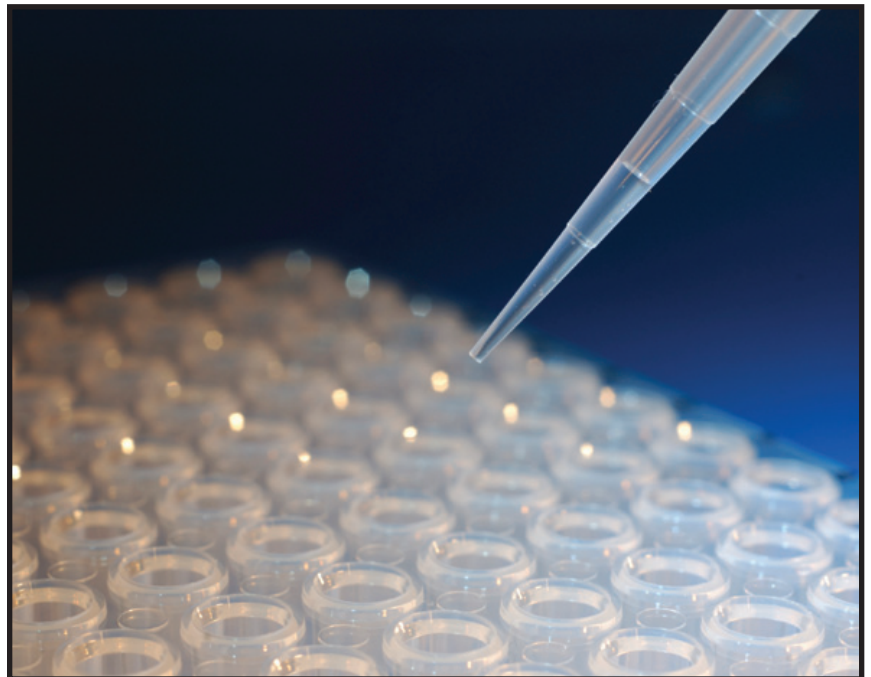
Process Development

A process that runs smoothly and cost-effectively gives you a competitive advantage.

CRB specializes in biopharmaceutical process design. We have assisted companies in the scale-up, design and commercialization of processes from bench through large scale production. To better support your development efforts, we can evaluate your current scale and model the commercial viability of your process. Your strengths and capabilities are considered as we help develop your strategic production plan.

CRB's vast experience in biopharmaceutical manufacturing processes positions us well to help you design an optimized production facility for your pipeline of products. Our ability to support you from idea through design to production, allows you to achieve your commercialization objectives.

Our expertise in compliance, cGXP documentation and change control procedures also facilitates the transition from design to a validated process. CRB is intimately familiar with the design requirements necessary for global licensure, including FDA, EMEA, RDA, MCA and others.



PROCESS DEVELOPMENT

Areas of Expertise

- Fermentation/Cell Culture
- Purification Processes
- API, Pharmaceutical and Biologics
- Fill Finish
- Sterile/Aseptic Processes

Services

- Simulation
- Scale-Up
- Optimization
- Critical Control Parameter/
Attribution Evaluation
- Media Development
- Pilot Plant Design
- Process Architecture and
Space Planning
- Process Equipment Design
- Process Validation
- Single Use Technology Evaluation

Additional Services

- Document Control / Management
- Master Planning (Site,
Commissioning, Validation)
- Process Development Programs
- cGMP Reviews
- SOP, Validation Protocol and Batch
Record Development
- Vendor Audits
- Feasibility Studies
- Technology Transfer
- Facility Designs
- Start-Up and Commissioning Services
- Equipment Qualifications

