

Biotechnology

Process drives the facility – process engineering is the key to developing the path for your process advancement. Innovative creativity during conceptual design forms the foundation for the next step of your project.

When evaluating the feasibility of an anticipated process or process change, CRB can provide valuable assistance to predict capital and manufacturing costs and support you in planning capital expenditures that will contribute to long-term financial success. Our senior engineers form a diverse team coupling years of operating company and engineering design firm experience. CRB understands that process reliability, safety and environmental compliance need to be integrated into the design from the start.

CRB has experience in the technologies and processes that drive your business. We have assisted companies in the scale-up and design of processes for recombinant proteins, monoclonal antibodies, vaccines, and gene therapy products produced in various expression systems including yeast, E. coli, mammalian cell culture, insect cell culture, and transgenic animals and crops.



Whether you're designing a new facility, renovating an existing one, or working out the details for contract manufacturing of your product, we can provide the experience and resources you need. CRB's experience spans the range from early clinical manufacturing through commercial production. For example, CRB has designed some of the largest cell culture facilities in construction or operation today, with bioreactors up to 20,000 liters. CRB has also designed some of the most flexible clinical manufacturing facilities in the industry, providing our clients with unmatched value for producing their clinical products in a competitive and time-critical environment.

CRB understands the FDA regulatory environment and the impact process design has on facility start-up and process validation. Our standard practices include GMP oriented documentation and change control procedures that facilitate smooth transition from design to validation. CRB is experienced with the design requirements necessary for global licensure, including the EMEA, FDA, MCA, and many others. CRB is very active in ISPE's baseline guide committees, contributing our knowledge and experience to most of the baseline guides presently in use.



Experience with a wide range of unit operations, knowledge of cGMP design, the manufacturing background of our professional staff, and our ability to provide hands-on support through start-up and commissioning, combine to meet the challenges of the biotech industry.

Compliance

- Food and Drug Administration (FDA)
- European Union (EMA)
- Japan
- UK (MCA)
- GMP Mock Inspection Audits
- GMP Design Reviews
- FDA Pre-Construction Meetings

Process

- Process Definition and Scope Development
- Process Scale-up and Optimization
- Process Architecture and Space Planning
- Layout Development and Equipment Integration
- Cell Culture Systems, Bioreactors or Other Technologies
- Microbial Fermentation Processes and Fermentor Design
- Isolation and Purification Processes
- Blood/Plasma Fractionation
- Formulation and Bulk Fill Systems
- Biocontainment/Isolation
- Custom Equipment Design Modularization
- Value Engineering Reviews
- Hazards and Operability Reviews
- Technical and Economic Evaluations

Process Simulation

- Steady State Simulation – Continuous Process
– AspenPlus, Hysys, ChemCAD
- Economic Modeling/Risk Analysis
- Dynamic Simulation – Process Control and Batch Processes
– Differential-Algebraic Equations (MathCad, Matlab)
– Unit Operations Based (SuperPro Designer, Batches, PatchPlus, AspenDynamics, Hysys)
– Discrete Event (Extend, Arena, ProModel)

Process Utilities

- Central Utility Plants
- Integrated Clean-in-Place (CIP) System Designs
- Clean Steam and Steam-in-Place (SIP) Systems
- Water-for-Injection (WFI)
- Purified Water (USP, Non-Compensial)
- Sterile Gases
- Biowaste Inactivation Systems
- Process Waste and Environmental Containment
- Process Cooling/Temperature Control

Instrumentation/Automation

- Process Control and Automation Planning
- Process Variable Measurement and Control
- PLCs, SCADA, and Distributed Control Systems
- Single Loop and Relay Logic
- Equipment Automation

Facilities

- HVAC Mechanical Systems
- Biocontainment Labs
- Due Diligence Facility or Site Evaluations
- Master Planning

Construction & Commissioning

- Commissioning Planning & Protocols
- Factory Acceptance Testing (FAT)
- Site Acceptance Testing (SAT)
- Start-Up and Commissioning Services
- Testing and Balancing
- Constructability Reviews

