STREAMLINE BIOTECH MANUFACTURING IN THE U.S.

Biotech Onshoring Consulting

Biotech manufacturers face technical, logistical, and regulatory challenges to onshoring manufacturing facilities. Exponent offers total biotech manufacturing onshoring support, from construction consulting to manufacturing setup to regulatory support to final product testing.

How We Help Clients

Biotech manufacturers face complex technical, regulatory, supply chain, and production challenges when onshoring U.S. manufacturing. Addressing them requires speed, quality, consistency, and deep multidisciplinary expertise. Exponent brings capabilities across construction consulting, biotech manufacturing, engineering, materials evaluation, equipment optimization, testing, and regulatory support, providing end-to-end guidance from project initiation through commissioning and qualification.

Construction Consulting

Our construction planning and consulting experts provide integrated project and program management, schedule and cost controls, and technical advisory services for biotech manufacturing facilities. We apply risk-based project lifecycle management — including phased project scheduling, change control, process validation, and integration with commissioning and qualification — to support complex, highly regulated capital projects from early planning through facility turnover. Through rigorous preconstruction planning, proven governance frameworks, and early collaboration with project stakeholders, Exponent helps mitigate cost, schedule, quality, and regulatory risks to achieve on-time and on-budget project delivery.

Biotech Manufacturing

Exponent provides comprehensive support for biotech manufacturers, from premarket evaluations to technology transfer, process development, validation testing, modeling, gap assessments, and root-cause analysis. Our mechanical engineers, polymer scientists, and electrical engineers support manufacturers across the full product lifecycle — from early development and testing through quality management, manufacturing support, inspections, compliance, and corrective action.

Building Systems

Biotech manufacturing facilities require far tighter control of indoor air conditions than typical manufacturing environments, making HVAC design critical. Precise control of particulates, temperature, humidity, and pressure differentials is essential to product quality and safety. Exponent's mechanical engineers bring decades of experience addressing these challenges across biomedical manufacturing and other critical environments — including hospitals, laboratories, cleanrooms, and wafer fabrication facilities — applying this expertise throughout facility design, construction, and commissioning.

TECHNICAL SERVICE EXPERTISE VALUE PROPOSITION

Building & Operations
Design, Procurement, Construction, Commissioning

Facility Qualification
Design, Installation, Operational, Performance

Regulatory
Planning, Review & Monitoring, Agency Interfacing, Submission

Design

- Validation Master Plan Development
- Project Risk & Contingency Assessments
- Estimate Validation
- Predictive Modeling
- Review of Process Utilities and Systems
- Automation Concepts and Mechanical Engineering Objectives
- Permitting Strategy
- Contracting Strategy
- Safety Compliance Evaluations
- Design Peer Review

Procurement

- Supply Chain Strategy and Risk Review
- Supply Chain Management and Execution Oversight
- Materials Cost Evaluation
- Material Document Conformance Validation
- Supplier Review and Validation
- Pre-Shipment Acceptance Testing
- Vendor Audits and Liaison Activities

Construction

- Project Management
- Risk Management and Readiness Assessment
- Schedule Development, Management, and Analysis
- Budget Review and Assessment, Financial Forecasting, and Cost Control
- Installation Review and Audits
- Performance Monitoring and Project Health Audit
- Scope Change Management
- Data Governance, Management, and Analytics

Commissioning

- Validation Master Plan Execution
- Calibration
- Facility Inspection
- Chemistry, Manufacturing, and Controls (CMC) Assessment
- Root-Cause Analysis of Commissioning Issues and Equipment Performance
- HVAC Commissioning Assessment and Test, Adjust, and Balance (TAB) Reports vs. Design Requirements
- Complete Systems Evaluations
- ISO-Certified Audits, Including ISO 9001:2008 and ISO 33000 Standards
- PFMEA and General Risk Assessments

Design Qualification

- Development and Verification of the Quality Plan
- Development of User Requirement Specifications (URS)
- Quantitative Risk Assessment and Modeling
- Design Qualification Plan
- Design Qualification Review, Execution and Gap Assessment

Installation Qualification

- Development of Installation Qualification Plan
- Installation Qualification Review, Execution and Gap Assessment
- Development of the Installation Qualification Report
- Risk Assessment Review
- Analytical Method Transfer Support
- Process Gap Assessment and Risk Analysis

Operational Qualification

- Development of Operational Qualification Plan
- Operational Qualification Review, Execution and Gap Assessment
- Development of the Operational Qualification Report
- Risk Assessment Review

Performance Qualification

- Development of Performance Qualification Plan(s)
- Laboratory Test Method Development and Validation
- Process Performance Qualification (PPQ) Planning and Execution Support
- Medical Device Testing
- Support Services: Calibration, microbiological environment testing and monitoring, cleanroom testing and monitoring, chemical testing, validation equipment, materials, and component requirements
- Clinical research studies, including Phase 3 randomized controlled trials and post-market surveillance studies

Planning

- Quality system assessment for new site(s)

Review & Monitoring

- Type V DMF Review
- Current Good Manufacturing Practice (CGMP) compliance with facility and manufacturing operations

Agency Interfacing

- FDA interactions associated with CGMP compliance
- FDA interactions associated with manufacturing validation

Submission Assistance

- Technical support for CMC responses to FDA
- Third-party review of submission documents