Exponent®

ACCELERATE PHARMA MANUFACTURING IN THE U.S.

Pharmaceutical Onshoring Support

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

How We Help Clients

Pharmaceutical manufacturers face formidable technical, regulatory, supply chain, and production challenges when onshoring manufacturing facilities in the U.S. Overcoming those challenges requires speed, efficiency, quality, consistency, and above all, deep multidisciplinary knowledge of the interconnected systems and disciplines that support pharmaceutical manufacturing.

Exponent has expertise in construction consulting, pharmaceutical manufacturing, mechanical engineering, materials and corrosion evaluation, manufacturing machinery setup and optimization, pharmaceutical testing, and regulatory support. We can assist with pharma manufacturing facility onshoring from start to finish, providing expert consultation for every step of the process from 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 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.

Pharmaceutical Manufacturing

Exponent provides comprehensive support services for pharmaceutical manufacturers, helping innovators develop premarket evaluations for new and current pharmaceutical products as well as supporting a full spectrum of technology transfer, process development, validation testing, modeling, gap assessments, and root-cause analysis.

Our chemists, polymer scientists, and chemical engineers regularly assist pharmaceutical manufacturers throughout all stages of the product lifecycle — from early-stage product and process development and testing services to quality management and manufacturing support, facility inspections, delivery, compliance, and corrective action.

We help our clients manage chemistry, manufacturing, and controls (CMC) issues, develop specifications, assess material composition, evaluate chemical stability and/or degradation mechanisms, and investigate product failures such as contamination or non-uniformity. We also support investigations into pharmaceutical products that lack compendial methods.

Building Systems

Pharmaceutical manufacturing facilities have much more stringent requirements on the indoor air environment than a typical manufacturing facility, making the heating, ventilation, and air conditioning (HVAC) design especially critical. For example, maintaining tight control over particulates, temperature, relative humidity, and pressure differences between adjacent spaces are all crucial for ensuring product quality and safety. Exponent's mechanical engineers have decades of experience investigating and remedying inadequate control of these parameters across a variety of applications including pharmaceutical manufacturing facilities and other critical applications like hospitals, laboratories, cleanrooms, and wafer fabrication facilities and can apply this experience during the design, construction, and commissioning stages of a pharmaceutical manufacturing facility project.

TECHNICAL SERVICE EXPERTISE VALUE PROPOSITION

Building & Operations
Design, Procurement, Construction, Commissioning

Facility and Product/Process Qualification
Planning, Specification, Operational, Process

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
- Product and Process Transfer Support
- Identification of Critical Process Parameters and Critical Product Quality Attributes
- Review of Historical Deviations, Investigations and CAPAs

Installation Qualification

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

Operational Qualification

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

Performance Qualification

- Development of Performance Qualification Plan(s)
- Laboratory Test Method Development and Validation
- Process Performance Qualification (PPQ) Planning and Execution Support
- Pharmaceutical 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