Trinity Consultants

Advent Engineering
Life Science Solutions

Engineering Design and Compliance Service for Biopharmaceutical Manufacturing

Project Management

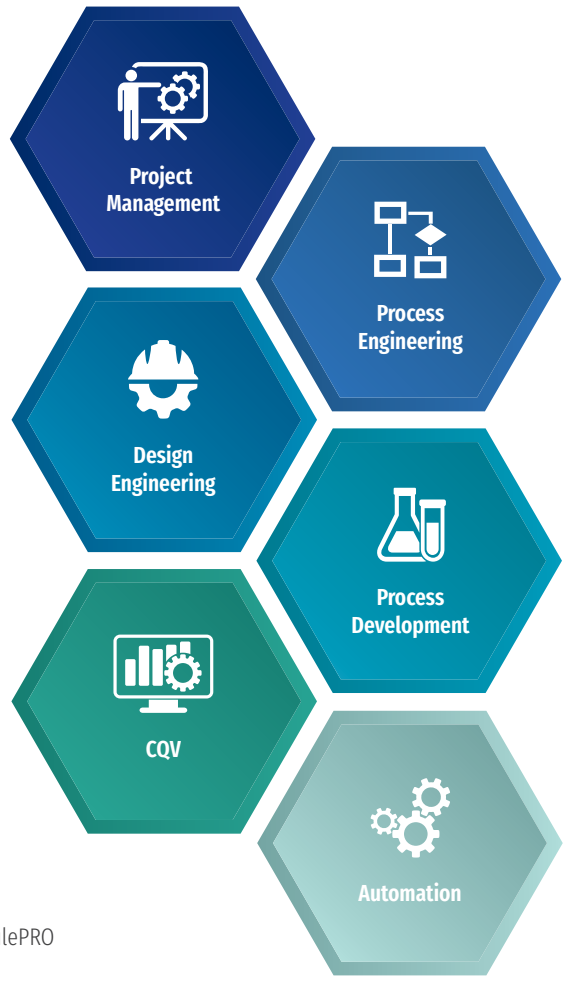
- Phase gate planning
- Budget development and tracking
- Earned value reporting
- Schedule analysis (P6, MS Project)
- Resource planning/allocation
- KT Analysis
- Total cost of ownership
- Change management

Design Engineering

- Good Engineering Practice development
- Feasibility study, conceptual design, detailed design
- Multi-discipline coordinated design (process, MEP, architectural, structural, and automation)
- Single-use design integration
- Utilities design and capacity studies
- Process system design (upstream, down stream, fill/finish, and support systems)
- Equipment sizing and specification
- Instrument data sheet development
- CFD modeling
- Construction administration & shutdown support
- As-built drawings
- 2D & 3D modeling (p-con, AutoCAD, Solid Works, NavisWorks, Sketchup)
- Process modeling using SuperPRO
- Optimize production schedule using SchedulePRO

Automation

- ISA S-88 process automation design
- PLC/DCS/SCADA platforms (e.g. Emerson DeltaV, Rockwell PlantPax, Allen-Bradley PLCs)
- HVAC/BAS/BMS (e.g. Johnson Controls Metasys, Siemens Desigo, Honeywell HC900)
- MES (SAP, Werum PAS-X)
- Historian/data analytics (e.g. OSI PI, Seeq)
- LIMS
- Design and review of process automation and IT/OT infrastructure
- IEC selection and technology recommendation
- Instrumentation and control design



CQV

- Master planning
- Risk assessments
- ASTM E-2500 verification
- Process/cleaning validation
- Computer system validation
- Data integrity assessment
- Re-qualification
- Consent decree remediation
- Environmental monitoring PQ
- Process equipment, utilities, facilities commissioning and qualification
- Startup/shakedown of facilities and systems
- Change control management
- Thermal validation (SIP)

Process Engineering

- Bioprocess equipment
  - Bioreactors/fermenters
  - Solution prep/hold
  - HTST/UHT
  - Chromatography
  - Centrifugation
  - UF/DF
  - CIP/SIP
  - Moist heat sterilizers
  - Parts washer
  - Freeze/thaw
  - Formulation
  - Fill-finish, inspection, and packaging
  - Isolators
  - Lyophilizer
  - Cell disruption
  - Single use technology
  - Clean utilities (WFI, PW, RODI, process gas, pure steam)
  - Support system (Biowaste, VHP)

Process Development

- Design of experiments
- Method/assay development
- Column packing studies
- Mixing studies (conventional and single-use)
- Formulation development
- Scale up/scale down
- Technology transfer

Trinity Consultants' Advent Engineering and Life Science Solutions team are experts in the commercialization of biopharmaceutical processes. We provide a wide array of engineering services and project management supporting the entire product life cycle. Our engineers bring many years of experience along with a complete understanding of industry regulations and requirements. We provide project engineering and design, automation, commissioning, and compliance-related services for clients across the U.S. and in Canada, Europe, and Asia.

Project Management

We provide project planning and project management support including pre-implementation, design, and implementation. Our deep understanding of project management and compliance requirements for pharmaceutical manufacturing enable us to provide the support you need to complete projects on time, within budget, and within specifications.

Process Engineering & Design

We provide design and engineering support in all project phases including pre-conceptual design, conceptual design, basic design, and detailed design. Our services include planning, feasibility assessment, scheduling, and costing for different design phases. Our design teams include talented and experienced process engineers with extensive depth and breadth of experience and knowledge in different processes and various products from small scale to full scale GMP manufacturing.

Process Development

Our expertise spans the entire bioprocess from host cell line generation to drug product formulation and filling. Our process development experts can assist by generating a process blueprint through the development of a commercially feasible process for biologics.

CQV

Our Commissioning, Qualification & Validation (CQV) capabilities for all technical systems rely upon a phased approach including pre-implementation risk assessments, design qualifications, and implementation of cGMP operations. We provide CQV support for process equipment, facilities and utilities, automated and computerized systems, quality control labs, medical devices, enterprise systems, and combination products.

Automation Engineering

Our automation team comprises highly skilled biotechnology-focused process and building automation engineers who bring experience across a broad span of applications including technology strategy planning, distributed control systems, local controllers, historians, enterprise applications, and lifecycle engineering documentation.

For more information, please contact us at info@adventeng.com or 919.313.7234.

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