



Trinity Consultants is a leading global environmental consulting firm that brings 50 years of experience providing services and solutions in the EHS Regulatory Compliance, Built Environment, Life Sciences, and Water & Ecology markets. Trinity has the technical expertise and acute industry knowledge to provide optimal solutions to highly complex pharmaceutical development, process, safety, and facility design challenges.

Process Development Solutions

Advent Engineering, a Trinity Consultants team, has years of expertise spanning the entire bioprocess, starting from host cell line generation to drug product formulation & filling. Our talented resources possess extensive experience in scaling up a bioprocess from lab-scale to a commercially viable manufacturing-scale and developing in-process controls method development and validation.

Upstream Process

- Conceptual design & modeling of process train from cell banking to harvest
- Host cell line development & cell culture development
- Media development & feeding strategy optimization for titer improvement
- HTST development for cell culture media
- Implementation of continuous cell culture systems based on perfusion
- Set up of harvesting/cell separation processes using filtration or centrifugation
- Scale-up and tech-transfer of the clinical to commercial scale process
- Identification & evaluation of critical process parameters (mixing, shear, and mass transfer)
- Oversight for contract manufacturing including deviation assessments

Downstream Process

- Conceptual design & modeling of Purification Process Train
- Design of chromatography skids capable of in-line dilution & real time chromatographic data analyses
- Buffer optimization and delivery
- Resin selection & optimization including static/dynamic binding studies
- Development of column packing procedures for compressible and incompressible resins



- Scale-up & tech-transfer of the bench scale process to large scale process
- Development of continuous chromatography based on expanded bed systems
- Identification & evaluation of critical process parameters for chromatography, TFF and bulk substances

Professional Registrations

Our Process Development team has subject matter experts who hold professional licenses and are members of multiple professional organizations. Advent Engineering's team members stay current with evolving modalities by participating in various webinars, contributing to journals, and providing technical seminars both internally and to our clients. Many of Advent Engineering's team members maintain leadership and active participation in ISPE, ASME-BPE, PDA, and many other industry related organizations.

Areas of Expertise

Advent Engineering's team of well diversified consultants enables us to provide vertically integrated solutions for our clients. Our consultants are from areas of chemical engineering, bioprocess engineering, pharmaceutical sciences, biochemistry and molecular biology. Our consultants have experience in process modeling, pilot process development, manufacturing sciences, and technology as well as commercial manufacturing of biologics.

- Process modeling for risk mitigation and feasibility analysis (e.g., Ansys CFX and Fluent)
- Process design & debottlenecking (e.g. SuperPro & SchedulePro)
- QbD and DoE based process development approach (e.g. JMP)
- Design space generation for various unit operations
- Process scale-up & tech-transfer

- Process scale-down for optimization & understanding of existing process
- Continuous Operations & Single-Use technology for bioprocessing
- Supporting regulatory CMC technical submissions for agency filings

Fill-Finish Process

- Integration of isolators for integrated fill line including decontamination cycle development/validation
- Design and transfer of freeze dried drug products using Design of Experiments
- Development of depyrogenation cycles for vials
- Evaluation of key lyophilization process parameters (ex. eutectic/collapse temperatures)
- Evaluation of pump-based and time pressure-based filling processes

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.

CONTACT OUR TEAM!

For more information about how we can help your organization, please contact us.

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