PROCESS DESIGN, ENGINEERING & CQV

Process Validation and Cleaning Validation Services

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.

Advent Engineering, a Trinity Consultants team, provides Process Validation (PV) and Cleaning Validation (CV) capabilities across the product/process spectrum (see figure below) during commercialization of new and follow-on drugs using development and small scale results to establish the GMP control strategy via risk assessments and updated specifications.

Our process understanding helps in developing protocols and reports that enable the control strategies for at scale mixing, filtration, hold times, cleaning, steaming, use-life parameters, and process conformance qualifications--delivering comparability and characterization results and providing a basis for ongoing process monitoring.

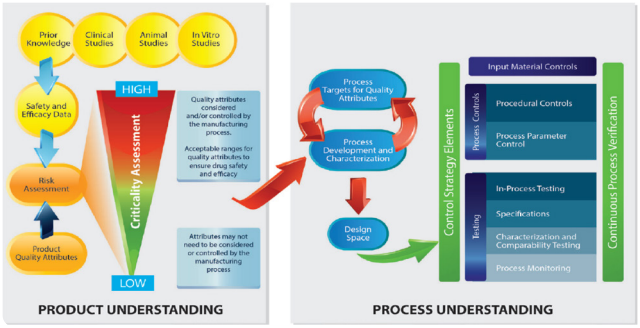
Process Supported

- Cell culture performance
- Purification performance
- Aseptic filling and lyophilization
- Sterile filtration
- Hold times
- Mixing
- CIP/SIP
- Small scale studies

Novel Modalities

Our process validation team has expertise with the following modalities:

- Monoclonal Antibodies
- Recombinant Proteins and Enzymes
- Viral Vector Based Gene Therapy
- CAR-T Cell Therapy
- mRNA Technology
- Antibody Drug Conjugates



Areas of Expertise - PV Process

- Validation master planning, reporting, and training
- PV technical project management
- QBD approach – establishment of CPPs & CQA
- Deviation handling and execution expectations
- Sample submission & analytical data management
- Change management and control
- Risk assessments, control strategies
- Technical Registrations document management

Process Validation Practices

- Data mining to establish PV criteria supported by process
- Statistical analysis of data to establish confidence intervals and design space for the process
- In-line mixing strategies for buffer and product stability testing
- Proactive troubleshooting and resolution on validation exceptions
- Cycle development for SIP, process, CV, mixing and recovery studies

CONTACT OUR TEAM!

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

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SCAN THE QR CODE TO LEARN MORE

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