LIFE SCIENCES

Consulting Services for Pharma, Biopharma & Healthcare

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.

Complex Clinical Facility Design and Operations

Trinity's team supports the design and operation of complex facilities including healthcare, clinical, and research operations. The team includes engineers, space planners, regulatory compliance and Good Manufacturing Practice/Good Tissue Practice (GMP/GTP) subject matter experts, construction QA/QC specialists, testing and validation technicians, board-certified sterile compounding pharmacists, and facility operations supplemental standard operating procedure (SOP) developers and trainers. Facility type and program expertise include:

- Research and containment laboratories
- CDC and USDA select agent programs
- Vivariums
- Cleanrooms
- Clinical trial scale through commercial GMP and GTP programs
- Compounding sterile pharmacies

Trinity's clinical professionals have extensive experience in the field of GMP/GTP cleanroom design, construction, commissioning, qualification, and operations. The team addresses the engineering and administrative controls of the facilities that support the manufacturing of products as well as the science and process details of the products themselves. The team provides extensive support on critical issues such as USP <797>, <800>, and 503 A & B, pharmacy compounding SOPs, drug delivery, current GMP (cGMP), cGMP for cord blood, and hazardous drug exposure and risk management. Our services and areas of support include:

- HD exposure assessment and risk management
- Manufacturing risk analysis
- Market studies
- Facility & program GAP analysis
- Consolidation studies
- Programming and basis of design
- Design services
- Systems & equipment IQ/OQ

- Continuous quality control
- Commissioning
- ISO cleanroom certification
- SOP development & training
- Compliance plan set
- As-built documentation
- Modular/mobile swing space
- Multi-site program management
- Training
- GMP engineering controls

Healthcare Facility Design and Operations

Our healthcare team enhances the commissioning process at hospitals by evaluating what is working and what is not, identifying reasons of non-conformance, and providing a clear path to resolution. All efforts are focused on how to add value to the team, rather than standing on the sidelines and recording events. We work with operations staff and contractors to address issues that are critical success factors to the operators including maintainability, infection control, system flexibility, and quality. We use a Fishbone Diagram to help identify and resolve underlying root causes of an undesired condition rather than chasing symptoms and patching problems.

We provide in-house construction resources and knowledge of Lean Construction techniques, enabling us to identify the optimal times to integrate commissioning into the construction process. Services and areas of support for healthcare operators include:

- Design intent
- Commissioning
- Building forensics
- Risk assessments

- Systems optimization response
- Fault analysis
- Training of O&M staff
- Transitional operations
- SOP development & training
- USP <797> compliance
- USP <800> compliance
- TJC inspection support
- Infection control support

Gold Standard Support for Pharmacy Compounding

Trinity's team has extensive experience in the field of GMP/USP cleanroom design, construction, commissioning, qualification, quality assurance, and pharmacy operations. We support the engineering and administrative controls of facilities that house the compounding or manufacturing of sterile injectable and non-sterile/topical products (such as hand sanitizers) as well as the science and process details of the products themselves. We provide extensive support on critical issues such as USP <797>, <800>, and 503 A & B, environmental monitoring, pharmacy compounding and cGMP manufacturing SOPs, drug delivery, current GMP (cGMP), and hazardous drug exposure and risk management. Our services and areas of support include:

- HD exposure assessment and risk management
- Full-service facility design & program regulatory gap analysis to assess compliance with cGMP, USP <797>, <800>, <823>/<825>
- Consolidation studies
- Systems & equipment IQ/OQ
- Continuous quality control
- Commissioning
- Environmental monitoring program management and design
- ISO cleanroom certification
- SOP development & training, and compliance plan set
- Regulatory agency/association response support
- Manufacturing risk analysis
- Market studies
- Publication of design guide documents for cleanroom construction project

Process Engineering for Pharma/ Biopharma Manufacturing

Trinity's Process Engineering team has highly specialized experience in the commercialization of pharmaceutical/biopharmaceutical processes. We provide a wide array of engineering solutions supporting the entire product life cycle, including the following:

Process Design

Our team provides design and engineering support for all biopharma engineering, and manufacturing projects, addressing pre-conceptual design, conceptual design, basic design, and detailed design. Our design teams include process subject matter experts with extensive professional credentials including chemical and mechanical professional engineering licenses, operational excellence, and leaders in ASME and ISPE. We support clients with process design engineering services including:

- Equipment design, sizing, specifications, and procurement
- Process skid design
- Design drawings (PFD, P&ID, GA, Piping) and schematics
- Instrumentation selection
- Scale-up and Scale-down
- Thermal/fluid dynamics analyses
- Fluid/flow simulation (CFD analysis)
- 3-D modeling (AutoCAD, SolidWorks)
- Process simulation/modeling (e.g. Superpro, SchedulePro)
- Process analytical technology
- Hydrodynamic characteristics
- Statistical analysis (MATLAB, JMP)

Process Development

We have extensive process development experience associated with supporting the cGMP manufacturing of bulk drug substances (BDS) for many clients, several of which have served as benchmarks for other development projects in our clients' respective pipelines. The team is particularly adept in process/product development related to Scale-Up and Commercialization. In these areas, we have supported rangefinding studies in cell culture, developed in-line buffer dilution systems, designed formulations for sterile processing, and created analytical methods for characterization and product release. We are knowledgeable about disposable component technologies and have implemented sterility assurance for high viscosity product intermediates.

- **Pharmaceutical Scale Up** – We develop solutions for process transfer from small to commercial scale. We review manufacturing processes and testing regimes to ensure that they meet GMP requirements during process implementation. From generating product requirements to establishing "best practices" for quality, we guide our clients to execute successful scale-up of manufacturing processes.

- **Pharmaceutical Commercialization** – We guide clients through FDA's New Drug Application (NDA) process, the precursor to full commercialization of the drug. We partner with you to provide the necessary NDA information to determine "...whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity," as required by FDA.

Process Automation

Our automation specialists support the entire pharmaceutical product manufacturing life cycle, from conceptual design through production. Our team comprises highly skilled biotechnology process and building automation engineers with experience ranging from facility and process automation to data and enterprise systems. Specifically, we provide automation support in the following areas:

- Technology strategy planning including feasibility planning and vendor/technology selection
- Installation and integration of Distributed Control Systems, SCADAs, stand-alone controllers, and historians
- Engineering lifecycle documentation including system URS, FS, HDS/SDS phase gate design review and design qualification/ risk assessment

Commissioning, Qualification & Validation (CQV)

Trinity's team provides CQV support for biopharma GMP manufacturing including facilities, utilities, equipment, automation, and analytical systems. We have extensive experience in the practical application of risk-based (ASTM E-2500) verification methods and subject matter expertise in all aspects and phases of the CQV lifecycle including:

- Validation master planning, protocols and test scripts/test forms
- Risk assessments including FMEA, PHA providing lifecycle control strategies
- Design verification to support design review, factory acceptance & site acceptance
- Process and cleaning validation with an QbD approach
- Cycle development and performance qualification (for CPP, CQA establishment)
- Analytical instrument qualification and method validation
- Requalification and revalidation including periodic review
- Technical registration document management
- Data integrity assessments
- Custom software (cloud-based) for change & deviation management for capital and site projects

Project Management

For the past 25 years, we have executed and supported projects through the application of integrated project management services and methodology supported and reflected by our experience and policies. Our project management team includes experienced project engineers that have the technical and leadership expertise to help clarify goals and requirements for complex projects and to effectively resolve issues that arise in order to keep the project on schedule and within budget.

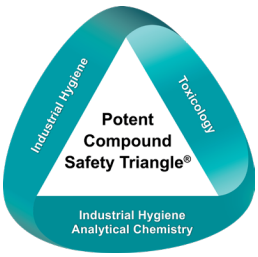
Our project managers develop plans and "road maps" to clearly define project objectives, goals, and timelines as well as key performance indicators (KPI) that provide real-time measurements of overall project success. Equally, we are highly focused on managing risk while achieving defined goals and objectives within the desired timeframe. Our project managers routinely support biopharma expansion projects such as the following:

- Manufacturing technology transfer from site to site
- Regulatory submission and compliance
- Product launch readiness and commercialization
- Supply chain and manufacturing optimization
- Quality assurance and quality control
- Business process improvement
- Capital expenditure planning and execution
- Product and technology development
- Project portfolio and resource planning
- Product and facility lifecycle management

Our expertise covers multiple modalities including small molecule, various recombinant DNA technologies, and allogeneic & personalized cell and gene therapies. Our engineers comprise industry leaders and innovators with experience in the application of numerical methods, such as computational fluid dynamics, in supporting our clients to better understand and optimize the compliant production of novel therapies.

Employee Protection Regarding Potent Compounds

Within the pharma/biopharma research and manufacturing, pharmacy operations, and healthcare delivery environments, Trinity's team is the premier resource for high level safety and health consulting regarding potent compounds. Founded in 1997, the team provides the Potent Compound Safety Triangle® of services including toxicology, industrial hygiene, and industrial hygiene analytical chemistry. Our team has extensive expertise in the recognition, evaluation, and control of potential worker exposure and product safety issues associated with the handling of potent and highly potent drug substances and drug products.



Toxicology Services

Trinity provides broad toxicological support regarding occupational exposure in the life science research and manufacturing environment, including:

- Risk assessment and communication
- Occupational exposure limit (OEL) development
- Occupational health categorization and banding

- Testing of products and key intermediates to assure employee and environmental protection and regulatory compliance
- Evaluating toxicity of chemicals and potential for health effects, pharmaceutical cleaning limits, personal injury litigation support, worker's compensation assistance, product safety, and Proposition 65 compliance
- Safety Data Sheets (SDSs) development of SDSs on active pharmaceutical ingredients, drug products, and key intermediates
- Establishment of health-based exposure limits (HBELs) for product contamination of drug products with other drug substances, process intermediates, residual solvents, and foreign substances
- Evaluation of acceptable limits for extractables & leachables
- Failure criteria for child-proof packaging (F-Values)

Industrial Hygiene

Our experienced industrial hygienists provide extensive industrial hygiene support for a wide range of facilities in the life sciences sector. Our expertise and support include the following:

- Containment performance assessments - ISPE (SMEPAC) assessments for pharmaceutical equipment using industry leading surrogate analytical methods
- Exposure assessment - identification of potential hazards, performance of field sampling surveys, coordination of sample analysis, and recommendation and validation of exposure controls
- Potent compound handling guidance
- Technical support for issues of concern regarding hazard communication, air monitoring, training, personal protective equipment, and product handling guidelines
- Engineering project review on potent compound containment issues

Industrial Hygiene Analytical Laboratory

Our laboratory team develops and modifies analytical methods to help our clients meet workplace air monitoring requirements. Our methods achieve high sensitivity and high recovery rate through the proper choice of filter media and extracting procedures as well as the optimization of air sampling parameters. Our methods are validated with respect to analytical detection limits, precision and accuracy. Data on the stability of compounds relative to airflow volume and storage conditions are contained in these methods. Our AIHA-accredited industrial hygiene analytical laboratory routinely processes samples that contain biologically active pharmaceuticals such as steroids, peptide hormones, and cytotoxic compounds, utilizing HPLC, RIA, and ELISA techniques.

Trinity Can Help

From assisting with the design of a university-based research facility to protecting staff who handle hazardous drugs in a hospital, Trinity Consultants can provide the right team, custom-matched to your needs. Our highly specialized professionals and proven track record enable us to provide the support you need to research new methodologies, bring new drugs to market, and protect workers from risks associated with life-saving, yet highly hazardous compounds.

Related Training

Trinity's Life Science experts provide frequent public and custom training on a wide range of related topics including the following:

- Potent Compound Safety Boot Camp for Environmental Health and Safety Professionals
- USP <800> Facility and Sampling Fundamentals
- CFD Modeling for Biopharma Facility Design and HVAC Optimization
- Practical Industrial Hygiene Statistics

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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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