LIFE SCIENCES

Integrated Capabilities Driving Innovation

Trinity Consultants | LIFE SCIENCES

Trinity Consultants is a leading global environmental consulting firm that brings 50 years of experience providing services and solutions in the Life Sciences, EHS Regulatory Compliance, Built Environment, 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.

WHO WE ARE

Trinity Consultants | Life Sciences brings together world-class expertise from across the pharmaceutical, biotechnology, and healthcare continuum. We're an integrated team of engineers, scientists, pharmacists, toxicologists, epidemiologists, industrial hygienists, and automation experts, all working together to support the advancement of therapies and the environments in which they're developed.

Our teams are embedded across the full product lifecycle, from early-stage research and development (R&D) and clinical trials to full-scale commercialization and day-to-day facility operations. Whether it's making workplaces safer, scaling novel modalities, trending and analyzing data, or navigating complex regulatory terrain, we provide guidance that's both scientifically rigorous and grounded in real-world pragmatism.

We operate globally and engage locally, bringing sharp regulatory insight and deep industry expertise to every project. Our myriad capabilities are delivered through three seamlessly integrated practice areas: **Process, Engineering and Compliance; Automation and Digital Solutions; and Risk Science and Safety.**

PROCESS, ENGINEERING AND COMPLIANCE

In this practice area, our focus is on the process and systems that connect life science from concept to commercialization. Whether it's designing a new GMP manufacturing or compounding facility, or upgrading an existing process; our teams translate complex problems into practical, compliant solutions. This practice is comprised of expert teams from legacy companies **Advent Engineering and WorkingBuildings.**

Life Sciences Engineering

Our **Advent Engineering** team is known for its ability to bridge science and engineering. We help biopharmaceutical clients move therapies from concept to commercialization, bringing deep expertise in process development, facility design, process system design, Commissioning, Qualification, and Validation (CQV), and compliance. Our work often supports companies developing various modalities – from therapies such as gene and cell therapy, including mRNA platforms, to mature therapies such as OSD and biologics, to unique therapies like Plant-Medicinal pharmaceuticals, as well as other emerging modalities where standard solutions don't yet exist.

We provide end-to-end support across the project lifecycle, with a strong focus on process knowledge, regulatory fluency, and project management. From early process design and scale-up to equipment selection, facility design, and CQV, we help clients execute confidently at every stage. Our understanding of regulations from various nations, including FDA and Europe, as well as 21 CFR 210, 211, and FD&C 503A/503B for pharmacies, makes us a valuable partner in emerging drug product delivery.

Whether advising on single-use technologies, optimizing process flow, or customizing automation platforms, we focus on building and equipment systems that are both compliant and practical. We bring expertise in simulation and modeling platforms like CFD, PMD,

and SuperPro/ SchedulePRODesigner, helping clients visualize, design, and improve performance before implementation, a key differentiator in complex or high-stakes environments.

Furthermore, we provide integrated Chemistry, Manufacturing, and Controls (CMC) services to the life science industry, supporting products from development through commercialization. Our expertise spans process and analytical development, formulation, manufacturing science, quality control, and regulatory CMC strategy—ensuring efficient, compliant, and scalable pathways to market.

Clients rely on us not just for technical skills, but because we serve as trusted partners, deeply embedded in the process and committed to shared success.

Healthcare

Our **WorkingBuildings** team are experts in commissioning and operations for healthcare and pharmacy environments and specialize in spaces where sterility, safety, and regulatory clarity are non-negotiable. Clients include hospital systems, research labs, sterile compounding pharmacies, and other high-risk environments.

Our healthcare team brings a unique blend of architectural insight, mechanical expertise, and regulatory fluency to projects involving USP <795>, <797> and <800>, cleanroom certification, and modular facility development. We also offer construction QA/QC, transitional operations support, and standard operating procedure (SOP) development to ensure that facilities not only meet the letter of the law but function effectively for those who work in them.

Our healthcare experts are often brought in early to shape facility strategy and stay engaged through commissioning and post-occupancy phases, helping clients navigate inspections, accreditation, and daily operations. We are known for our ability to interpret regulatory intent and serve as a liaison between clients and relevant authorities. The team stays ahead of evolving guidelines to ensure that facility designs meet both current and anticipated expectations.

We excel at bridging the gap between technical design and operational reality, translating complex code requirements into facilities that work. When facilities underperform or fail inspection, our team is often brought in to diagnose the root cause, whether it's improper pressurization, airflow disruption, or operational breakdowns. The team's forensic approach helps clients recover faster and avoid repeat issues. We also employ state-of-the-art technologies such as Computational Fluid Dynamics, which plays a vital role in designing safer, healthier, and more efficient healthcare environments.

Clients choose our healthcare team because we turn critical environments into high-performing ones. Our deep understanding of facility systems, regulatory frameworks, and user needs makes us a trusted partner from concept to occupancy.

DIGITAL SOLUTIONS

This practice area focuses on building the digital and automation infrastructure life sciences organizations need to operate efficiently and compliantly. From control systems to data integration, our team helps connect technology with process, performance, and regulatory readiness. This practice is comprised of expert teams from legacy acquisition **Aztec Technologies.**

Our Automation and Digital Solutions team specializes in automation and digital enablement. We help life sciences clients implement, upgrade, and validate complex control systems and data infrastructure. From instrumentation selection to system integration and data visualization, we ensure that automation solutions are intelligent, compliant, and built to scale.

Our automation team's engineers are fluent in platform migrations, PLC/DCS programming, and smart system configuration. The in-house UL-certified Panel Shop adds a unique layer of value, allowing us to fabricate and deliver custom control panels under strict quality controls.

Our digital solutions team provides expert services for AVEVA PI integration, MES support, data modeling, and digital transformation projects. We help clients build and manage data lakes, unifying fragmented information across systems to support real-time analytics, regulatory reporting, and long-term operational insight. Our work also often supports Industry 4.0 initiatives, transforming siloed data into actionable insights, enabling predictive maintenance, and improving visibility across operations.

Clients choose us when they need reliable, tech-forward solutions to modern automation challenges. Whether delivering a turnkey control system or helping transform data into strategy, our automation and digital solutions team brings a sharp digital edge to Trinity Consultants Life Sciences.

RISK SCIENCE AND SAFETY SOLUTIONS

This practice area is comprised of teams from our legacy companies: **SafeBridge Consultants, Safety Partners, WorkingBuildings,** and **Benchmark Risk Group**, all industry leaders in their fields.

Together, we enable safe, compliant, and efficient pharmaceutical and biotech operations. From worker health to regulatory clarity, our teams focus on assessing and minimizing risk while strengthening safety culture and program quality.

Potent Compound Safety

Our Pharmaceutical Toxicology team is globally recognized as the gold standard in potent compound safety. We develop occupational exposure limits (OELs), create containment strategies, and verify controls through real-world testing and monitoring. Offering the SafeBridge Potent Compound Safety Triangle® of solutions, we are the only consultancy that provides Toxicology, Industrial Hygiene, and Industrial Hygiene Analytical Chemistry (as well as hazard communications support) enabling clients to assess, analyze, and manage the risks associated with highly potent compounds, ensuring safe handling practices in R&D, pilot plant, scale-up, and manufacturing environments.

Our industrial hygiene (IH) team works with clients to identify, evaluate, and control occupational health hazards. We review and prioritize risks, perform exposure monitoring, and verify control performance through containment performance assessments. Our team provides potent compound facility, equipment, and process design feedback during renovation or construction projects, and we evaluate programs and develop hygiene and potent compound procedures. Our IH team routinely provides hands-on and classroom training to reinforce safe potent compound principles and work practices.

Potent Compound Services also includes a dedicated analytical IH laboratory. Our state-of-the-art laboratory continuously invests in advanced equipment and applies evolving analytical techniques to ensure that testing remains cutting-edge, defensible, and aligned with the complex needs of modern pharmaceutical environments.

Our Potent Compound Safety hazard communications and toxicology teams also provide expert guidance on hazard communication, developing accurate and effective safety data sheets, labeling, and classification systems for drug substances and drug products. This regulatory and toxicology support is essential to responsible product development and risk management across a broad range of life sciences and adjacent industries.

The **SafeBridge Potent Compound Safety Certification®** is a mark of excellence recognized across the industry. It demonstrates that a facility not only understands the risks of potent compounds but has implemented effective programs to control them. The team also delivers highly respected training programs, including the popular Potent Compound Safety Boot Camp®, to help teams internalize the science and practical steps required to operate safely. Finally, the SafeBridge® Global Potent Compound Congress & Expo® brings together the brightest minds in pharmaceutical potent compound safety and an unwavering focus on science. This premier annual conference showcases cutting-edge innovations in drug discovery, developments in potent compound safety, and challenges and solutions in R&D and manufacturing for highly potent APIs and therapeutic products.

EH&S Services

Our **Safety Partners** team takes a hands-on approach to workplace health and safety. We embed directly with research and development organizations, building and maintaining Environmental, Health, and Safety (EHS) programs that align with local, state, and federal regulations. Our consultants work side-by-side with lab and facilities teams, ensuring day-to-day compliance, supporting incident investigations, and offering ongoing safety training and audits.

Our work spans initial and ongoing EHS permitting, licensing, biosafety, chemical hygiene, radiation safety, and routine support serving as organizations' in-house safety officers. And, as science has evolved, so has our scope. We increasingly support companies working in synthetic biology, gene therapy, mRNA platforms, and other emerging modalities, helping teams navigate unfamiliar EHS terrain and speeding innovation. With an eye on efficiency and transparency, we also guide clients through EHS management system adoption, digital reporting tools, and audit tracking platforms, bringing a tech-enabled edge to traditional safety programs.

Our Quality, Research, and Training (QRT) team drives consistency and quality by managing our internal knowledge base, providing internal QA/QC, and supporting our field/on-site consultants with expert guidance and the latest regulatory developments. Through Safety Partners University, a comprehensive internal proprietary onboarding program, and one-on-one support, QRT equips consultants with the tools, training, and technical insight they need to deliver high-quality client EHS programs. Our expertise is especially valuable in biotech hotspots, where local permitting and nuanced regulations demand both speed and accuracy.

Clients choose us because we deliver more than compliance. We help build a culture of safety that's sustainable, effective, and ready to grow with the organization.

Risk and Regulatory Services

Benchmark Risk Group anchors the new Risk and Regulatory Services practice. Adding to our existing expertise creates a service dedicated to the assessment and management of human and environmental health risks. Our risk and regulatory specialists have proven experience in epidemiology, toxicology and regulatory affairs and help clients evaluate the potential human and environmental health impacts of ingredients, products, and byproducts by focusing on chemical, physical, and biological exposures.

Risk and Regulatory Services partners with industrial and food & beverage clients, regulatory agencies, legal teams, and community organizations to provide data-driven, defensible solutions. Our expertise spans exposure assessment, toxicological evaluation, epidemiology, regulatory strategy, and risk assessment—helping clients quantify exposures, interpret scientific data, and determine safe levels for human health. Our team offers regulatory consulting, navigating requirements such as GRAS (FDA), Proposition 65 (California OEHHA), TSCA (EPA), and FIFRA (EPA). With an interdisciplinary team of toxicologists, industrial hygienists, epidemiologists, and exposure and risk scientists, the firm combines scientific rigor, transparency, and collaboration to deliver trusted results.

WHAT SETS US APART

Trinity Consultants Life Sciences brings together technical mastery, regulatory depth, and a shared commitment to improving public health. Across the entire life science division, our talented teams operate with several core principles:

- **Let Science Lead:** Everything we do starts with a clear understanding of the science: the properties of the compound, the goals of the process, and the nature of the risk. That foundation is what makes our guidance practical, relevant, and defensible.
- **Build Trust That Lasts:** We're collaborators by nature and we work best as an extension of our clients' teams. We listen closely, adapt quickly, and stay focused on what success looks like for them, not just for the project.
- **Think Across Disciplines:** Our teams bring together specialists from across safety, engineering, automation, toxicology, and compliance so we can look at challenges from every angle. This ensures that clients benefit from the full breadth of our capabilities.
- **Customize for Every Context:** We bring global insight, but we never lose sight of local realities. Whether it's a permitting issue in Cambridge or a validation strategy in Singapore, we tailor our approach accordingly.

WHO WE SERVE

Our clients span the spectrum of therapeutic innovation and delivery:

- Pharmaceutical and biopharmaceutical manufacturers
- Contract Manufacturing Organizations (CMOs)
- Contract Development and Manufacturing Organizations (CDMOs)
- Compounding and hospital pharmacies
- Academic and commercial research laboratories
- Healthcare systems and hospital networks
- Emerging biopharma companies (developers of emerging therapies including gene therapy, cell therapy, mRNA, and plant-based biologics)

Whether you're scaling your first therapy or managing a global portfolio, **Trinity Consultants Life Sciences** is here to help you move forward safely, effectively, and confidently.

CONTACT OUR TEAM!

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

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