

# LIFE SCIENCES

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## Engineering & Automation, Project & Construction Management, Business & Operations Consulting Solutions Customized for Life Sciences

At EAD, we recognize the demands of the Life Sciences industry and tailor our services to meet the unique challenges faced by CDMOs, biotechs and pharma companies. EAD offers a comprehensive range of services to support clients throughout the entire product development life cycle, from the initial clinical trials to full-scale manufacturing. Our team of experts have specialized skill sets in the following areas:

**Efficiency and Automation:** Leveraging cutting-edge automation technologies, we optimize processes across ISO-regulated environments, including clean rooms, laboratories and throughout the pharma, biotech and biopharma commercial manufacturing process. Our solutions encompass asset management, controls, instrumentation and preventive maintenance systems tailored to each client's unique needs. By implementing efficient automation solutions, we drive productivity, reduce manual errors and streamline operations, resulting in increased throughput, cost savings and enhanced product quality.

**Project Management & Engineering Excellence:** Our team stays ahead of the latest trends and best practices. Our lead engineering staff are licensed professional engineers (PEs) with certifications in multiple US states. Many of our project management staff are certified project management professionals (PMPs). Several members of our team have also earned engineering specializations in hygienic and sustainable design.

**Innovative Design Solutions Engineering:** Our forward-thinking approach to facility/utility engineering, master planning, and feasibility assessments generates efficiencies in production, reduces costs and improves scalability. By aligning engineering design with the evolving needs of the Life Sciences industry, we deliver solutions that optimize space utilization, improve workflow efficiencies and facilitate future expansions or modifications. Our clients benefit from reduced operating costs, improved resource utilization, and increased flexibility to adapt to changing market demands, maximizing their competitive advantage in the industry.

**Compliance and Quality Assurance:** EAD offers a range of compliance services tailored to the specific needs of the Life Sciences industry. Our team excels at ensuring cGMP, QA/QC, and the highest regulatory compliance standards are met throughout the project life cycle. We deliver comprehensive compliance solutions, including thorough audits, meticulous documentation, and rigorous quality control. By prioritizing compliance, we mitigate risks and ensure that our clients meet industry standards and regulatory requirements, leading to enhanced credibility, reduced liability and operational excellence.

# EAD Core Competencies for Life Sciences

At EAD, we distinguish ourselves through our specialized expertise, ability to innovate, and deep understanding of the life sciences sector. Our team comprises seasoned technology leaders with experience in cGMP and FDA/EU consulting, single-use technologies, continuous manufacturing, modular design and Pharma 4.0 initiatives.

**Engineering & Project Management Services:** EAD excels in engineering and project management, ensuring projects are seamlessly executed and expectations are met. Our expertise in commissioning, qualification, and validation (CQV) allows us to contribute to and oversee every aspect of a project's life cycle, from feasibility assessments and procurement to the specification and installation of equipment. Our clients benefit from optimized workflows, minimized downtime, and accelerated time-to-market for their products, driving overall business success.

**Automation Services:** EAD specializes in leveraging cutting-edge automation technologies to optimize processes and enhance productivity in the Life Sciences industry. Our automation services ensure streamlined operations and improved efficiencies throughout the manufacturing process. We are vendor-agnostic and have expertise in Rockwell, ABB, Siemens, Emerson DeltaV and other platforms.

**Clean Room Design:** High-performing building management systems can efficiently control HVAC and lighting systems to help clients save energy, reduce building operating costs and keep occupants productive and comfortable. EAD is experienced in working in facilities with stringent hygienic standards and regulations and other classified areas with air handling units and pressure cascade controls in alignment with these standards. Using temporary BMS systems and HVAC solutions designed for clean rooms, we ensure clients' facilities are fully operational even while under construction, increasing profits and satisfying client demand.

**Safety:** With over 2,000,000 manhours without a recordable incident and counting, safety is built into our culture. Process safety is critical to ensuring OSHA compliance in the Life Sciences industry. Our safety services include Process Safety Management (PSM), Process Hazard Analyses (PHAs), Management of Change (MOC), and material and chemical compatibility reviews. We also provide Dust Hazard Analyses (DHAs), Lock-Out Tag-Out (LOTO) services, machine guarding and arc flash studies.

**Digitization and Documentation:** In no other industry is proper documentation as important as the Life Sciences. Document digitization improves information access, creates process and time efficiencies, and reduces labor costs. EAD can assist with developing electronic or both electronic and paper batch records for manufacturing processes. We also have experience developing

functional design and user requirement specification documents for pharmaceutical applications.

**Facility Design:** Designing facilities in compliance with cGMP regulations is essential for ensuring product quality and regulatory compliance in the Life Sciences industry. EAD specializes in facility engineering design services that prioritize regulatory compliance and operational efficiencies. We have expertise in sanitary, aseptic and hygienic design, purified water systems, waste solvent systems, aqueous waste and general clean utilities.



**Control Panels for GMP Environments:** Building control panels for GMP environments requires specialized expertise and attention to detail. EAD is one of the few engineering firms in the US with a fully in-house control panel fabrication shop. Our control panels undergo a rigorous review process to ensure compliance with UL, NEC and other electrical and industrial standards. We seamlessly take clients' projects from concept to completion, providing a control panel solution that meets all budget and schedule requirements.

**Embedded Services:** EAD provides embedded services and staff augmentation solutions to meet the specific needs of our Life Sciences industry clients. Our embedded services ensure that clients have access to skilled professionals who can seamlessly integrate with their teams to support and grow their businesses. EAD has logged over 1.2 million hours of embedded services since 2001.

**Biopharmaceutical Processing Expertise:** Our system design experience encompasses all stages of biopharmaceutical processing, from fermentation to packaging. We have experience in bioreactor and fermentation design, ensuring efficient separation and concentration techniques such as centrifugation, filtration, chromatography, ultrafiltration and evaporation. Our proficiency in these critical processes ensures the production of high-quality biologics while maximizing efficiency and yield throughout the manufacturing life cycle.

**Process Optimization:** Optimizing processes is essential for improving efficiencies and meeting quality standards in the Life Sciences industry. EAD offers process optimization services that help clients streamline their operations and achieve their goals more efficiently.

**Better Use of Data & Pharma 4.0:** Utilizing data and technology for better decision-making and efficiency is the key to success in the Life Sciences industry. EAD specializes in leveraging data and technology, including Pharma 4.0 initiatives, to drive innovation and improve operational efficiencies for our clients.

**Packaging Solutions:** EAD provides expertise in packaging solutions tailored for the Life Sciences industry, including consumer packaging, bottle/vial filling and intermediate bulk container packaging. We ensure that products are packaged efficiently and in compliance with industry standards.

**Start-up, Commissioning and Qualification Support:** Assisting with the start-up and qualification of equipment and facilities is essential for ensuring regulatory compliance and operational readiness. EAD provides comprehensive start-up, commissioning, and qualification support services to help clients achieve their goals efficiently and effectively.

**Validation Plans, Execution and Support:** Developing and executing validation plans is critical for ensuring product quality and regulatory compliance in the Life Sciences industry. EAD offers validation services, including validation plan development, change management and ongoing support to help clients meet regulatory requirements and maintain quality assurance throughout their operations.

As we reflect on the last 20+ years of service, we find ourselves humbled. Working together behind the scenes as an extension of our clients, we've made a lasting impact. We have built our reputation as an expert, a support system and as a part of our clients' families.

With multiple locations across the US and projects on 5 continents, we are actively engaged in the advancement and expansion of Fortune 500 companies around the world. Leveraging the relationships we've built and the lessons we've learned, we hope to engineer a lasting, brighter future for many years to come.



ENGINEERING & AUTOMATION  
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