



SOFTWARE SOLUTIONS & SERVICES

Avoid Errors, Reduce Risk, Increase Performance, & Stay Compliant With a Manufacturing Operations Management Approach



Control Associates will work with you to understand your manufacturing business goals, identify opportunities, develop a business case, and take a phased approach to implementation that is focused on ROI. We have the expertise to maintain your manufacturing operations systems in a secure, current, and optimized state to extract maximum value from your investment.

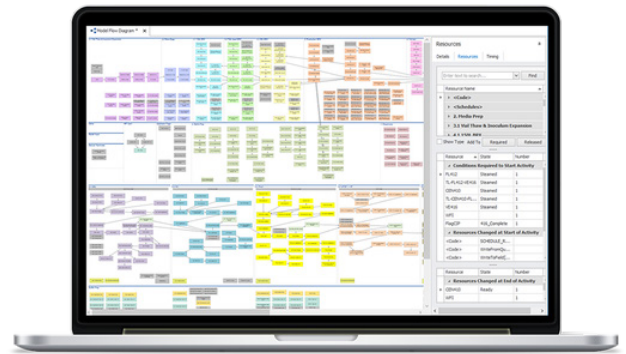
Are You Operating in the Past?

- **Do you still rely on labor intensive paper-based manual processes?**
Potential human errors represent a significant compliance risk. Control Associates can help automate your processes, reduce deviations, and increase overall operational efficiency.
- **Do you have islands of data that are trapped?**
Control Associates can help you aggregate, contextualize, visualize, and analyze your OT data to enable timely, informed decisions.
- **Do you have the ability to dynamically adjust to production changes and disruptions—thereby maximizing throughput?**
Control Associates can develop a model of your manufacturing process, update it in real-time using actual production data, and identify opportunities for improvement.

SUPPORTING SERVICES & SOLUTIONS

Gain Control and Visibility With Manufacturing Execution Systems (MES)

Control Associates can help you with everything from performing a business case analysis and developing requirements, to the design and implementation of an MES solution focused on delivering quantifiable benefits. Our solution can help you reduce human errors, improve compliance, eliminate labor intensive paper processes, and integrate data from various manufacturing systems.



Visualize Constraints & De-Bottleneck With Real-Time Modeling & Scheduling

Control Associates can implement a solution that leverages real-time data from your manufacturing systems allowing you to visualize your facility's constraints, debottleneck the process, optimize your production schedule, adjust production schedules, perform dynamic maintenance planning, and understand the implications of any change in the manufacturing process. The model itself produces an optimal scheduling overview and capacity analysis.

Ask us to see an example.





Support Your MES Investment

We are the experts when it comes to supporting your MES investment. Control Associates has the experience and expertise to assess the health of your system, optimize performance, and maintain your system in a compliant, cyber-secure, and supportable state. Control Associates offers an array of services and can tailor a plan to fit your needs and maximize the return on your MES investment. With decades of experience, no one else has this level of understanding and experience.



Turn Your Manufacturing Operations Data Into Gold

Optimize your operations and achieve your manufacturing goals. Our experts have the industry knowledge and experience to integrate your disparate data sources and enable data driven decisions. We can implement a scalable digital transformation strategy to integrate data from your OT systems—automation, operations management, laboratory results, & maintenance management—with your IT systems to create a common data management solution. Role-based visualization, analysis tools and reporting capabilities put the right information, at the right time, in front of the right decision makers.

Our Customers Have Experienced Big Benefits by Implementing Modern MES Solutions

GENERIC PHARMA/CONTRACT MANUFACTURING ORGANIZATIONS: MES Implementation Drives Down Operational Costs, Decreases Time to Market, and Maintains Product Quality

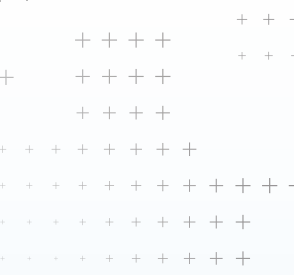
There are potential applications for MES in both formulation and packaging with the end goal of getting from tech transfer to production faster and with the appropriate documentation. Tracking SKUs can be a difficult task considering all the formulation types, dosage strengths, packaging, labeling, and language requirements. A strong MES solution can help with inventory and supply chain management, as well as other functional activities such as resource planning, scheduling, and managing overall equipment effectiveness. Additionally, MES can drive lean manufacturing; thereby reducing waste, re-work, and downtime.

Generics and CMOs dedicate their business to providing services such as drug development, manufacturing and packaging for pharmaceutical companies who need production scalability. A source of long development and production lead times for product lifecycle is from data—especially when manufacturers have islands of automation. An ISA 95 MES solution can help integrate all levels of manufacturing systems—instrumentation (L0-PLCs, DCS, BAS), SCADA systems (L2), LIMS (L3), and ERP (L4)—to collect, measure, and analyze data.

Managing the challenges of data integration for efficient manufacturing is one aspect of Generic and CMO business. The most impactful use case for an MES solution is compliance. In 2022, the second most Inspection/FDA 483 observation was FDA 21 CFR 211.192 Cite ID 2027—investigations of discrepancies and failures. By sufficiently collecting, measuring, and analyzing data with an ISA 88 MES solution, batch reporting can be completed sooner, but most importantly, to meet compliance. Put our decades of MES experience to work for your data integration, recipe authoring, and batch reporting needs—regardless of your platform.

**Here's the big deal:
When you're doing 5,000
production orders per
year, saving 2 hours per
order translates into
10,000 hours saved.**





BIG PHARMA MANUFACTURER: MES Enables Predictability and Reduces Inventory

It takes weeks or months to release a vaccine batch to the FDA for review. This big pharma customer previously had a complex batch record consisting of over 1,200 pages and taking over 30 days to complete. Every page had multiple opportunities for human error including incorrect entries, miscalculations, and executing steps out of order. Administrative controls as well as rigorous and time-consuming batch record reviews were required at the end of production to ensure product quality.



By implementing an electronic batch record in MES, this pharma manufacturer practically eliminated opportunities for error—enabling more predictable batch release cycle times, and ultimately reducing finished goods inventory.

CELL/GENE THERAPY COMPANY: MES Implementation Maintains Chain of Identity

With Cell/Gene Therapy, the treatment must be provided ‘vein to vein’ in a limited period of time—with the same rigorous controls as any other biologic. This manufacturer, not unlike others in this industry, also had additional process challenges to accommodate cell count variations in the starting material. In addition, this customer’s autologous process requires maintaining strict chain of identity across the supply chain with no room for error.



In Cell/Gene Therapy, the uniqueness of each batch requires it to be adjusted for every patient’s starting material. That’s where MES comes in: MES maintains control over a complex manual process; MES automatically tracks materials usage to an individual patient lot and maintains identity of the lot; and MES recipes help accommodate varied growth timelines for varying starting material.



Our Manufacturing Operations Management Solutions Address:

- **Weigh & Dispense / Material Management / Labeling**
- **Recipe Management**
- **Equipment Management**
- **Electronic Batch Records**
- **Product Release With Review by Exception**
- **OT Data Integration**
- **Operator Mobility**

About Control Associates

Control Associates is a provider of process control systems, valves, actuation, instrumentation, regulators, relief valves, asset reliability, systems integration, manufacturing execution systems, and data management solutions for industrial and commercial customers in the tri-state metropolitan New York, New Jersey, and Connecticut region. Our unique long-term partnership with Emerson and other leading manufacturers enables us to connect customers with innovative technology, engineering expertise, and 24/7 lifecycle support services to optimize the reliability, safety, profitability, and performance of their operations. Our 40,000 sq ft facility is 20 miles from Manhattan, offering local services and support.