



LIFE SCIENCES

Break away from uncertainties in production.



engineering | systems integration | consulting

THE COMPLETE FORMULA FOR OPERATIONAL EXCELLENCE

MAVERICK Technologies understands the unique needs of life sciences companies. Few other industries require near-perfection for the survival of a company and the well-being of its end users.

To help you achieve your business goals in this demanding atmosphere where precision is the standard, MAVERICK acts as a partner. We provide the proven expertise for improving your process automation, systems and validation.

With MAVERICK's experience, global presence and business approach, you'll find the complete solutions and operational efficiencies that will help you realize the full potential of your business in an industry that holds perfection as the standard.

Working with you, MAVERICK acts as a true full-service partner. Our range of custom, scalable services differentiates us from the competition — and adds an unparalleled level of experience, convenience, value and service.

MAVERICK provides you with access to the systems and process expertise that drive the life sciences industry — from proven standards to the latest cutting-edge innovations. If it will work for your business, MAVERICK will help you define it, select it and implement it — thus driving business value through your enterprise.



MAVERICK's Focus on ROI

At MAVERICK, we understand that process automation improvement decisions need to be justified in terms of physical needs as well as bottom-line financial results. MAVERICK focuses on the positive use of return on investment (ROI) by reviewing the relationships among sales, expenses and investments, prioritizing cost efficiency and emphasizing operating asset efficiency. The table below represents a typical ROI our customers receive in the life sciences market.

Problem	Significant pattern of defects in a pharmaceutical packaging line.
Solution	Automated system that detects package defects and provides real-time data.
Measurable Result: <i>Materials</i>	Tracking and control system supports and monitors multiple tanks, reducing time spent manually transporting and weighing ingredients.
Measurable Result: <i>Labor</i>	More than 75 different juice recipes and more than 150 Clean-in-Place (CIP) recipes were defined and validated, and are now stored in the ISA-88 compliant Batch MES.
Measurable Result: <i>Productivity</i>	To eliminate bottlenecks, the system forwards data to prepare downstream processes with critical setup information.

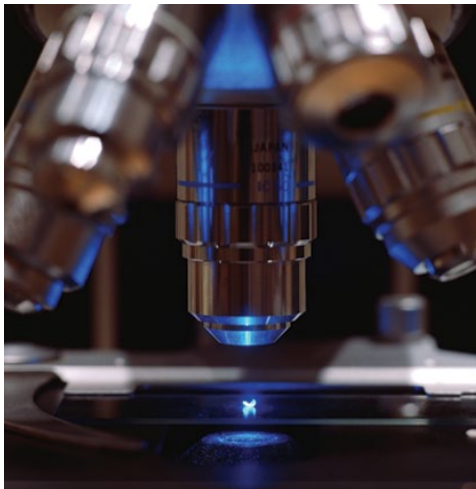
EXPERIENCE WHERE IT MATTERS



GAMP4-based Project Complete® and 21 CFR Part 11 Compliance

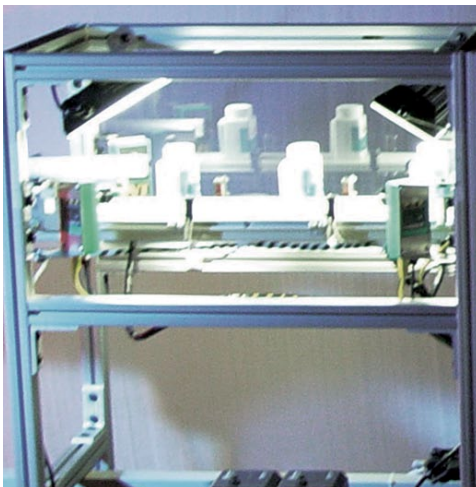
MAVERICK's GAMP4-compliant Project Complete methodology provides consistent, repeatable standards for meeting the critical objectives of the life sciences industry. Project Complete is designed for fast results and continuous improvement, with complete integration and validation for reliability, automation and business solutions. Our project management methodologies are based on proven PMI standards and efficiency tools to reduce project costs and compress project schedules.

MAVERICK's solutions are designed to comply with 21 CFR Part 11 requirements. Capabilities include developing guidance documents, computerized systems inventory, gap analysis, risk assessment and remediation plans. MAVERICK's services are structured to ensure strict compliance of formal regulations.



Process Analytical Technology (PAT) Support

PAT is a valuable framework for regulatory and quality improvement. When implemented properly, it can greatly improve design, analysis and manufacturing control capabilities for life sciences companies. MAVERICK's expertise with this advanced methodology ensures a smooth integration with your in-place systems and processes, and will help you identify opportunities for developing new tools and improving quality levels. PAT integrates process, platform and information technology experience to identify critical control points of **product safety, efficacy, identity, purity and potency**. MAVERICK understands your process, your monitoring and control systems, and your data. We can support your team to bring the benefits of PAT to your facilities.



Manufacturing Execution Systems (MES)

MAVERICK's MES integration team will enable your enterprise to manage, implement, report on and respond to all production activities of your plant. MAVERICK streamlines your supply chain to get higher-quality product to customers more efficiently and implements 21 CFR Part 11 compliant MES solutions that maintain electronic records for batch release, device history and Corrective Action / Preventive Action (CAPA). MES provides forward and backward Genealogy, to meet and respond to FDA compliance issues. Tracking WIP and inventory consumption, responding in real-time to Engineering Change Notices (ECN) and integration with laboratory information management systems (LIMS) and ERP systems creates a seamless flow of information that empowers your team to make informed decisions resulting in higher asset utilization, plant harmonization and ROI.

A COMPLETE SET OF OFFERINGS

Regulatory Compliance

- GAMP4 / PMI-based lifecycle approach
- Functional specifications and user requirements
- DCS / PLC / HMI / MES / ERP implementation
- FAT / SAT / IOQ protocol development
- Operator / administrator manuals, SOPs and training
- Technical support and preventive maintenance

Eliminate production delays and fully comply with FDA requirements. Our unique approach, expertise and experience combine validation and system integration with a focus on project management.

Process Analytical Technology (PAT)

- Process understanding, controls and monitoring
- Broad range of control systems experience
- Process data storage, analysis and reporting

Leverage a GAMP4 / PMI-based lifecycle approach, which provides quality by design, to interpret current standards.

21 CFR Part 11 Compliance

- Client guidance documents
- Computerized system inventory
- Gap analysis and risk assessment
- Remediation planning and execution

Interpret current standards and incorporate best practices to provide guidance in not only your current systems, but also in the implementation of new systems to meet full compliance.

Preventive Maintenance and Contingency Planning

- DFMEA and PFMEA systems
- Computerized maintenance management systems (CMMS)
- Preventive maintenance software
- Maintenance process and system optimization
- Predictive analysis and control systems

Reduce maintenance costs by optimizing maintenance time through the utilization of planned outages — rather than disruptive, unscheduled downtime — and by monitoring data integration in real time, between plant floor, IT and CMMS.

Inspection and Identification

- Vision inspection systems
- RFID and barcode inspection

MAVERICK's vertically integrated technology teams provide a seamless joining of process control, information technology and inspection systems.

Data Collection, Analysis and Recording

- Downtime tracking
- Key performance indicators (KPIs)
- Automatic data logging and trending systems
- Web-based access and display
- Automated paging / e-mail

Process, display, analyze and distribute the infinite amount of data generated by your systems in an efficient and cost-effective manner. Improve overall operations through "plant floor-to-boardroom" systems integration.

Engineering and Integration

- Continuous and batch control
- Programming / configuration (HMIs, SCADAs, PLCs, DCSs)
- Instrumentation / electrical / mechanical design and CAD
- Instrumentation and control hardware / software
- Robotics
- Documentation, testing, training and validation

Being platform-independent allows MAVERICK to determine and apply the best solution for both your immediate and long-term needs and avoid implementing technology simply for the sake of implementing technology.

Complete Business Solutions and Operational Consulting

- CRM and ERP systems including Microsoft Dynamics™ AX
- Supply / demand chain software and EPSs
- Throughput analysis and asset utilization systems
- Lean manufacturing
- Enterprise systems strategy and architecture
- Business process definition, mapping and design

Utilizing enterprise-wide software systems will allow you to view all aspects of your operation in one place, effectively solving supply and demand chain issues. This in turn will increase customer satisfaction, reduce inventory costs and allow you to have faster reaction time in future situations.

BREAK AWAY

THE GREATEST RISK MAY BE STANDING STILL

MAVERICK Technologies is a global engineering, systems integration and operational consulting firm. We deliver innovative solutions for a wide range of manufacturing and process clients, leveraging our extensive network of skilled employees deployed from locations around the world.

Our talented staff is dedicated to helping our clients break away from the business inefficiencies they face. We deliver profitability improvement — individually in plant automation, performance management and business systems, and holistically by integrating knowledge across the enterprise.



Visit www.mavtechglobal.com/locations for all of MAVERICK's domestic and international locations.



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DOES YOUR FACILITY DEMONSTRATE **ABSOLUTE COMPLIANCE?**

In the life sciences industry — which includes pharmaceuticals, biotechnology and medical devices — compliance has become more than just a manufacturing goal. It's an absolute necessity. Marketplace competition demands it. Government regulations require it. And your customers rely on it.

At MAVERICK, we understand the intense and unforgiving nature of your manufacturing environment. We know that consistent delivery of the safest and most effective products is the key to success — and even survival.

Our focus on absolute compliance helps you thrive in this demanding field. MAVERICK combines experience and expertise to go beyond consulting — giving you the tools and the knowledge for continuous improvement. In the demanding life sciences industry, our solutions provide a significant bottom-line advantage, including streamlining your validation process, reducing your cost of goods sold, assessing risk to exponentially increase quality and improving your time to market, to take your business efficiency to the next level.