



Quality Manager™

Quality Manager is an integrated business tool that helps companies effectively manage complex quality data and processes. Designed to leverage existing IT infrastructures, the system ensures that quality control becomes fundamental to all business processes, resulting in reduced wastage and increased profits.

In today's global marketplace, manufacturers are subject to greater competition and pressure for regulatory compliance than ever before. Companies need to not only create an operating infrastructure that improves efficiency and increases profit margins, they also need better access to information across the enterprise to smooth regulatory compliance, improve business processes and increase customer retention.

Improve your Efficiency

Quality Manager provides a comprehensive suite of functions designed to organize, simplify, automate, communicate and manage complex quality processes throughout your enterprise. It means you can improve operational efficiencies while maintaining regulatory compliance across the value chain, within the enterprise and beyond.

Quality Manager enables you to better respond to customers in instances of inquiry or complaint and it provides you with real-time visibility of product performance, improving the effectiveness of sales and marketing activity. By giving you seamless and transparent visibility of critical Quality Control and Quality Assurance processes, Quality Manager allows you to proactively monitor manufacturing variability, track product quality trends and manage non-conformance across the supply chain. Quality Manager will move your company one step closer to achieving Predictable Output.

Quality Manager Capabilities

Quality Manager offers a range of functions that enable you to consistently deliver high quality products and services while maintaining efficient and compliant production operations. The Regulations Management capabilities of Quality Manager enable enterprises to integrate FAA and FDA (including GxP and 21 CFR Part 11) requirements into the quality management process.

The Supplier Performance module ensures that raw materials for use in production are inspected at every stage of the value chain. The solution uses a sampling model that is based on individual supplier performance to reduce the number of inspections and associated costs.

KEY BENEFITS

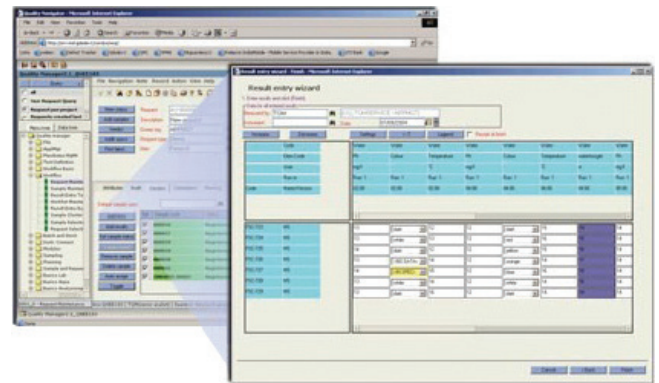
- *Reduce compliance risk by leveraging proven tools to meet FAA and FDA requirements and to ease computer system validation*
- *Improve product quality by proactively monitoring and managing key manufacturing processes and product specifications*
- *Improve customer retention by increasing your responsiveness, improving your reliability and consistently delivering high quality products*
- *Improve operational efficiency while maintaining regulatory compliance across your value chain*
- *Reduce wastage by better using your resources*

The Inspection Management module uses an intuitive browser-based, graphical user-interface to support and handle inspections and result entry triggered within batch oriented production and ongoing monitoring for continuous processing and environmental management.

The Non-Conformance Management module gives you an accessible overview of all processes related to the production of any inferior products. It continuously monitors key corporate data, including suppliers, specification of materials and equipment used, and the people and processes involved in producing any faulty products.

Main Capabilities

- **Regulations management**
Ensures compliance with key FAA and FDA (including GxP and 21 CFR Part 11) regulations
- **Supplier monitoring and management**
Organizes and tracks Supplier Audits, Supplier Certifications and Quality Ratings
- **Inspection management**
Supports Receiving Inspections, Work-in-Progress Inspections, Process Control Inspections, Storage Inspections, Finished Goods Inspections and Field Inspections
- **Instrument management**
Facilitates automatic connections, calibration, recording and maintenance of instruments and test equipment integrated with production
- **Version control**
Data includes Specifications, Test definitions and all other Standard Operating Procedures
- **Non-conformance management**
Functionality includes Reason Codes, Disposition Routings and Advice, Approval Routings, Corrective and Preventive Actions, Pareto Charts and Non Conformance Reports

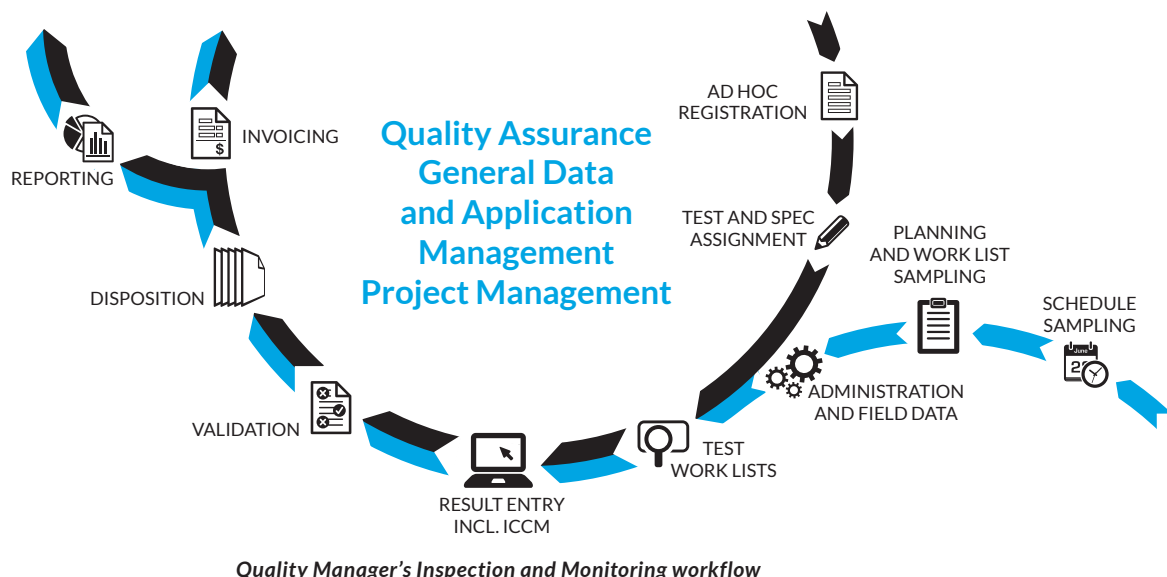


Quick and easy access to Inspections and Results

- **Quality-focused reporting and indicators**
Automatic alerts of unexpected trends to prompt preventive action and ability to generate ad hoc reports, trend analysis, views-at-a-glance and KPIs, depending on detail required
- **Flexible attributes**
Object attributes can be tailored and defined in a runtime, flexible and unlimited structure

Quality Manager, the integrated quality management solution

Quality Manager addresses all aspects of enterprise quality management, from non-conformance management to supplier management, inspection management and LIMS. The solution is highly process-centric and can be adapted to the very specific quality management needs of any company, whether in the discrete manufacturing or the process manufacturing sector. Quality Manager supports continuous business innovation and can improve efficiency, compliance and profitability at every stage of the manufacturing process.



Quality Manager's Inspection and Monitoring workflow

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