TRACEABILITY AND LIFECYCLE MANAGEMENT
Your strategy to take the high ground

- Real-time status visibility of your products
- Reliable intelligence drives focused improvement
- Traceability linked with quality data
THE QUALITY LIFECYCLE

The Quality Lifecycle is a corporate strategy that is focused on aligning product development, process improvement and technology adoption with key business objectives.

Obviously, the earlier in the cycle quality control is implemented, the more actual product quality it generates and the more money it saves. Ideally, quality is injected from the very beginning, during the planning and product design phases. As a practical matter, it should at a minimum provide a bridge from engineering to manufacturing, feed forward to warranty and service, and provide a closed loop back for traceability and compliance purposes.

The ASI DATAMYTE Traceability and Lifecycle Management Solution is the infrastructure that supports this strategy and drives it forward.

The ASI DATAMYTE Traceability and Lifecycle Management Solution pulls together information from a broad base, including:

- planning input
- prototyping results
- measurement data collected from plant floor
- PLCs and CMMs
- PPAPs, FMEAs, APQP and control plans
- engineering change procedures
- document and revision control
- supplier quality metrics
- inspection plans and reports
- nonconformance input
- corrective actions
- calibration and equipment management
- SPC and data collection
- audit management
- compliance reporting

Leveraging the integration strengths of the ASI DATAMYTE solution, companies can build a historical, operationally predictable roadmap for business management and improvement that disparate application islands or silos will never be able to provide. Managing quality from an enterprise view, companies exploit the synergies of advances interconnected manufacturing processes and greatly improve the odds for mitigating risk of quality in manufacturing, assembly and laboratory issues from all angles.

TRACEABILITY

Traceability and Quality Lifecycle Management go hand-in-hand. Traceability and compliance requirements force manufacturers to analyze, validate and document everything about a product. They also mandate scrutiny of all processes associated with a product's production, from design and prototyping to assembly, test, delivery, and post-market monitoring – all of the areas covered proactively in a Quality Lifecycle Management initiative. Implement Quality Lifecycle Management correctly and the proper groundwork is laid to close the loop and ensure bullet-proof traceability.

ASI DATAMYTE’s QDA software manages the Quality Lifecycle and Traceability. It eliminates warranty claims and recalls by capturing defect-producing processes with real-time reports on the machines, parts, stations, shifts and operators involved – before the product is shipped. The software captures data via labels, bar codes, VINs, lot, serial and batch numbers, and deploys it to interdependent manufacturing and assembly operations. The system can identify single component parts or group them as needed to accurately identify and trace subassemblies or finished products.

Companies that take a proactive approach to traceability experience fewer product recalls and reduced product failure rates.

Product and process-related quality data can be tracked and combined to produce essential analyses and meaningful reports. This ability to ingrate quality data with traceability data is a unique component of the ASI's quality solution. For example, an auto VIN can be linked to the engine VIN, all of the vehicle's component parts, torque audit results, gap and seal tests, defect reports and the entire quality history associated with all these elements.
ISO 9000 mandates a comprehensive set of quality standards and practices for quality management systems, including monitoring, auditing, documentation, traceability and procedures for dealing with non-conformances. AS 9100 from the International Aerospace Quality Group adds, among other things, the need for consistency in verification methodology. Medical Device Reporting (MDR) requires FDA notification based on customers’ complaints of device malfunction, and product-linked injury and/or death. The TREAD Act does the same in the auto sector, but raises the stakes a notch by declaring intentional nonconformance a criminal act. The FDAs Safe Medical Devices Act carries the mandate upstream, requiring post-market device tracking and monitoring to the user level.

Digging for lot numbers, incoming inspection numbers and characteristic values manually is time consuming and inexact. The uncertainty of it all puts a company at risk. ISO cites the inability to retrieve documentation and information for compliance purposes as the number 1 reason for non-conformances.

▶QDA provides automated integration to a level of granularity that gives you a firm grip on an immensely complex process. The Process Data Tracking feature executes immediate traces, sifting through part masters, supplier data, SPC control charts, test reports, error logs, capability studies and failure analyses. The result is rapid error identification and root cause analysis. The number and severity of non-conformances, recalls and complaints are greatly reduced. For those that couldn’t be avoided, the level of responsiveness is raised, empowering resolution with confidence.

ENTERPRISE-WIDE

The ASI DATAMYTE Traceability and Lifecycle Management Solution has all the tools needed to allow you to leverage the strengths of the Internet. A portal provides access to quality professionals and other company personnel globally. This overcomes the slow and error-prone nature of conventional collaboration methods. The approach facilitates global communication and focused decision making, and further reduces time to market. Companies can organizer and share common business processes and product information with design, product development, planning, engineering, manufacturing and suppliers around the world. The solution complements ERP efforts with additional content and input from quality systems. The quality system becomes the information center, empowering rapid and focused traces to critical batch data, more efficient callback management and improved customer satisfaction.

The ▶QDA report structure provides a common meeting point for all data, forms, regulatory guidelines and other information. An intuitive editor allows for customized report generation and interaction with standard Microsoft applications. Relationships between interdependent documents, standards and processes are presented clearly, making it easy for the user to track and analyze product data related to all processes.
ASI DATAMYTE's Traceability and Lifecycle Management Solution drives focused management decision making by integrating quality data and analyses from all angles. Traceability backed up with solid data improved first time quality, reduces defects, rework and warranty claims.

**Major solution benefits and key features:**
- Real-time status visibility of your products
- Sound intelligence drives focused improvement
- Traceability linked with quality data
- Limit your recalls in size and cost
- Keep your product liability under control
- Integration into Quality Management System
- Central point of control
- Managing tool integrity, qualification and certification
- ERP/MES integration