

SOLUMINA for Medical Devices

Solumina® is a suite of Manufacturing, Quality, Maintenance and Repair software solutions designed to manage the complex requirements of highly regulated environments.

Reduce Cost of Regulatory Compliance

- Provide complete electronic Device History Record (eDHR) documentation and parts genealogy
- Enable cradle-to-grave traceability with full audit trail of work processes
- Eliminate manual DHR with automatic electronic signatures, work instructions, drawings, test results, non-conformances, deviations, scrap and rework
- Implement strict audit process management guidelines for ISO 13485, ISO 9001, FDA 21 CFR Part 11, 21 CFR 820 and 2011/65/EU standards

Improve Quality, Reduce Scrap and Rework

- Reduce manual input errors by auto-populating all the order information when a non-conformance is generated
- Reduce compliance and quality issues with process control techniques for first time quality
- Leverage Six Sigma strategies and quality metrics to identify and remove root causes of defects and rework
- Identify quality issues sooner by monitoring quality at the supplier, reducing cost of quality, scrap and rework

Reduce Process and Product Variability

- Assure operators meet training and certification qualifications, tools are properly calibrated, and the latest process documentation and instructions are used
- Embedded in-process data collection and analysis alerts operators of inconsistencies
- Provide enhanced work instructions in areas where process improvement is needed

Shorten Cycle Times

- Seamless integration and coordination with engineering (CAD, PLM) and ERP systems streamlines production flow
- Production control data supports tracking and display of order statuses, scheduled start and stop times and crew assignments allowing for real-time adjustments

Improve Product Warranty Recall

- Identify affected products by lot, serial, customer, or work order, reducing cost and time involved in manual paper processes
- Full 8D closed loop corrective action (CAPA) process helps identify, contain, and fix product and quality problems

Increase Operators' Productive Time

- Ensure assigned jobs are free of constraints and ready to start
- Shorten guidance and learning times with easy-to-follow interactive electronic work instructions
- Display up-to-date information for operators including the latest drawings, specifications, and parts, as well as any conditions holding up the job with time-delay tracking
- Operators spend more time doing the job they are trained to do and less time looking for documents

Reduce Indirect Labor Costs

- Remove waste caused by routing paper documents throughout operations and the supply chain
- Streamline validation and collaboration among engineering, quality and manufacturing with eDHRs
- Deploy engineering changes to Bill of Material (BOM's) and work instructions to the shop floor in real-time, ensuring the latest versions are always used



About iBASEt

iBASEt is a leading provider of software solutions to complex, highly regulated industries like Medical Devices, Aerospace and Defense, Nuclear, Industrial Equipment, Electronics, and Shipbuilding. iBASEt's Solumina software streamlines and integrates Manufacturing Execution System and Operations Management (MES/MOM), Maintenance, Repair and Overhaul (MRO) and Enterprise Quality Management System (EQMS) for operations and Supplier Quality Management.

