



# Medical Device

iBase-t Solutions Overview

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# Medical Device manufacturing in a regulated, competitive industry



## Key Benefits of Solumina

- **eDHR:** Electronic Device History Records are consolidated and automatically updated from design through production to ensure FDA regulations and standards are met.
- **Built-In Quality:** Quality management is embedded in Solumina, letting you hard-wire quality procedures into your production process.
- **Supply Chain Visibility:** Define, manage, communicate and verify product quality requirements, specifications, and inspection results with suppliers.
- **Full Traceability:** Gain control & visibility over lot and serial tracked parts for all materials, components, and subassemblies from cradle to grave.
- **Error Reduction:** Improve quality with standard work instruction illustrations, videos, slideshows, and built-in data collection.
- **Auditing & Reporting:** Meet reporting requirements easily and generate audits to ensure compliance with internal and external standards.
- **Electronic Signatures:** Meet FDA requirements and eliminate the need for paper oversight.
- **Compliance Scripts:** Standard software requirements, specifications, test cases and test result traceability are available.



## Challenges in the Medical Device Industry

The medical device industry combines the complexity of highly engineered products with a market where failures can be catastrophic. Manufacturers in this space are subject to some of the most stringent compliance regulations of any industry. FDA regulations such as 21 CFR Part 820 and 21 CFR Part 11, and international standards like ISO 13485, make rigorous and robust compliance procedures essential.

Producing such complex medical products is difficult enough, but companies also must cope with market pressure for cheaper, faster, and safer innovation. Shifting global supply chains and labor talent shortages make the challenges even greater.

## How Solumina Meets the Challenges

At the center of what makes any medical device manufacturer competitive is making quality and compliance the foundations of every sourcing, procurement, production and service process. The Solumina Manufacturing Operations Platform provides an integrated digital solution for quality and compliance across manufacturing operations to unify value chains with well-orchestrated processes.

Medical device manufacturers can build compliance into the production process with Solumina's Enterprise Quality Management System, which is embedded throughout the platform to monitor and enforce quality at every step. If a problem does occur, Solumina provides full traceability and genealogy for rapid root cause analysis and minimization of risk. Regulatory requirements and reporting are easily accommodated in Solumina, while business executives can access the real-time information they need, enhanced with iBase-t's Manufacturing Intelligence solution.



Production Process Verification (PPV) and First Article Inspection (FAI) with AS9102 forms are built into Solumina for both manufactured and purchased parts. Randomization based on Supplier DPPM and sampling logic based on AQL, severity switching rules, and MIL-STD-1916 inspection item classes are also built in. Add Solumina SQM (Supplier Quality Management) and Solumina MRO (Maintenance, Repair, and Overhaul), and you have a comprehensive digital solution to ensure quality, compliance, and efficiency in medical device manufacturing.

## The Solumina Platform for Medical Device Manufacturing

The Solumina platform by iBase-t enables medical device manufacturers to maintain quality and compliance while accelerating production and growing profits.

### Solumina Maintenance, Repair, and Overhaul (MRO)

In the medical device industry, compliance in maintenance is just as important as it is in manufacturing. Solumina MRO facilitates better visibility, traceability and efficiency during maintenance execution. It replaces paper-based processes with a centralized digital platform, reducing turnaround time and lowering hourly costs. It also establishes a complete historical record for future traceability.



### Solumina Supplier Quality Management (SQM)

Medical device suppliers have to meet the same high standards as the manufacturer. Solumina SQM provides the visibility into supplier performance that manufacturers need to monitor and improve quality. Track real-time supplier quality performance and history for all related processes and activities, including online verifications and characteristic data collection for inspection orders.

### Solumina Enterprise Quality Management System (EQMS)

Nowhere is quality more important than in medical device manufacturing. That's why EQMS is embedded across every part of the Solumina platform to enforce quality throughout all production and sustainment processes. Embedded quality control leads to more ownership of quality by production personnel, driving operational efficiency.

### Solumina Manufacturing Execution System (MES)

There is no room for error in medical device manufacturing. Solumina MES provides real-time control and tracking of all manufacturing operations, with digital work instructions that are always up to date with the latest engineering changes. This comprehensive digital platform reduces errors and accelerates production, while providing decision-makers with real-time information whenever and wherever needed.

## Designed for Digital Transformation

Solumina's microservices-based, cloud-native architecture is agnostic to source systems, enabling enhanced connectivity and integration. Through integration with ERP, PLM, and other enterprise systems, it provides a path for manufacturers to move smoothly from paperless operations to advanced digital manufacturing.



**“We’re impressed with iBase-t’s pre-configured solution, which has been instrumental in our digital transformation strategy. The complexity and cost of paper-based processes was just too high. iBase-t’s solution lets us quickly apply engineering changes and design updates during New Product Introduction, unlocking greater value to our customers.”**

JASON GUHSE, Associate Director of Information Systems, D&K Engineering

### About iBase-t

To learn more or book a demo  
visit [www.iBaset.com](http://www.iBaset.com)

iBase-t is a software company that simplifies how complex products are built and maintained. Founded in Southern California in 1986, iBase-t delivers solutions that ensure digital continuity across manufacturing, quality, and maintenance, repair, and overhaul (MRO) operations on a global scale.

iBase-t's Solumina Manufacturing Operations Platform is a cloud-native solution that drives innovation and improves operational performance for complex discrete manufacturers. iBase-t customers include Lockheed Martin, Northrop Grumman, Rolls Royce, Pratt & Whitney, and Textron.