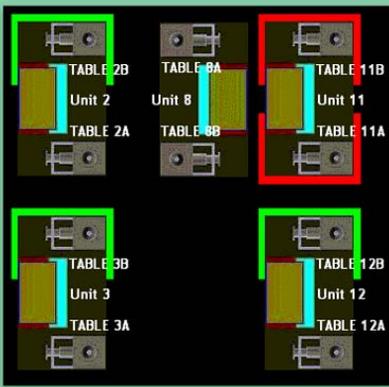




Automated Control Concepts, INC.  
**Smart solutions.**

Driving process improvement by transitioning to paperless: ACC creates manufacturing intelligence strategy that ties together multiple data sources to deliver regulatory and real-time operations reports



**Large screens located above the factory floor display production information with each piece of equipment color coded to signify status of operations.**

### THE STARTING POINT

A leading medical manufacturer serving the growing demographic of aging baby boomers needed to rapidly expand production capacity to keep up with growing demand. With limited space in its facility to add new lines, the company needed to focus on improving cycle time and yield. To improve cycle times, company leaders wanted to gather more data about its process to establish ideal operating parameters. To address yield while operating under tight regulations and reporting requirements, the company needed to reduce or eliminate losses and shipment delays caused by reporting or quality issues.

### THE PROBLEM

The need for rapid expansion of production capacity within tight regulations and with limited facility space

### ACC'S SMART SOLUTION

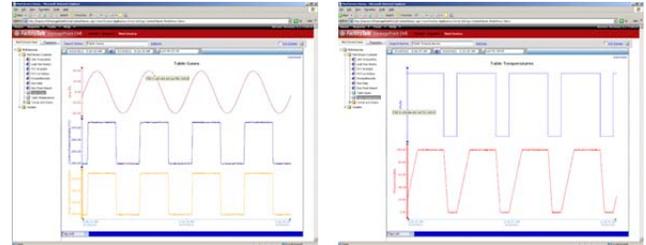
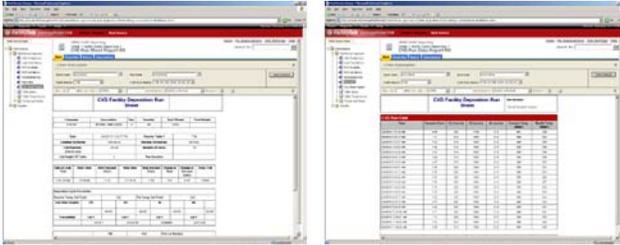
Upgrades were made to production control and reporting systems to add capacity, improve quality, and simplify reporting. ACC worked with the device manufacturer to develop a manufacturing intelligence strategy that eases the collection of data necessary to generate the FDA-required Device History Record for each lot and unit they produce. In addition, electronically available data has helped the customer gain visibility and traceability, driving process improvements. As part of this approach, ACC designed an information system based on the FactoryTalk software suite from Rockwell Automation and ACC's own proprietary software, processRecords®.

- ACC provided system design, configuration, implementation, and project management paired with industry expertise to convert a weighty paper process to a more nimble paperless one.
- Compliance and quality have been enhanced by leveraging solutions like FactoryTalk® software to gather data from control system to automate FDA reporting and enable process improvements, and ACC processRecords software to manage workflow and generate electronic Device History Records (eDHR).
- Productivity has increased by 20% over the previous system with the addition of automated alerts and reduced training time.
- Visibility into the production process has improved, empowering operators with role-based data and control.



# CASE STUDY: MEDICAL DEVICE

Let's take a closer look at the details of the project.



## SECURITY AND COMMUNICATIONS WITH FACTORYTALK

The FactoryTalk suite provides a standard platform for security and communications – with each application gathering data directly from the manufacturing and testing control system. The system can be easily expanded to incorporate data from additional machines, lines or areas of production, as necessary.

Specifically, FactoryTalk Historian software collects and archives historical and real-time manufacturing and testing data from third-party applications. To visualize the runtime data, ACC deployed FactoryTalk View software. Built-in write and security capabilities in FactoryTalk View software allowed the company to gather signatures verifying metrics gathered by the control system needed for compliance reasons. Authorized users simply provide an electronic signature directly through their control screen.

Production data gathered by the FactoryTalk applications is automatically gathered by the processRecords software and combined with manual entries required for FDA compliance. The software then automatically and securely compiles an electronic device history record for each medical device that tracks development.

The system also produces reports used throughout the day by the manufacturing and testing team to compare lot metrics to previous results to ensure quality. FactoryTalk VantagePoint EMI software aggregates information from all other FactoryTalk and processRecords applications and produces real-time dashboards and reports with unique situational and historical context for different users.

## BETTER DATA AND COMMUNICATION DRIVE PROCESS IMPROVEMENT

The analytics provided by the system have empowered the production team to bring process improvement recommendations to business management. Because their guidance is rooted in real metrics, production staff has taken a greater role in directing research and development (R&D) activities. For example, input from the production team has already caused the R&D team to hold-off on purchasing a new furnace system while they narrow down optimal furnace requirements with the manufacturing intelligence data and analysis provided by the new system.

Since the initial installation, the company has extended the manufacturing intelligence strategy from production to its extensive testing process. It's also worked with ACC to install large LCD screens though out the plant floor to help managers clearly see the status of operations across the plant, where physical visibility is limited. Alarms and inconsistencies are clear and immediately noticeable, so if action is required, managers can quickly pull up the same screen through their local human-machine interface (HMI) to enact a change or optimize a process.

With actions taken based on manufacturing intelligence, the device manufacturer has tightened up the heat and run-time tolerances in its furnaces. Use of the new system has helped operators attain five percent increase in equipment efficiency through better equipment utilization. In addition, enforced workflow provided by the software's proactive alerts has increased productivity by 20 percent, while plant floor staffing has remained the same.



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