



Scaling Lifesaving Organ Delivery

RoviSys and Critical Manufacturing Deliver an MES Foundation for a Next-Generation Transplant Device Manufacturer

A proven partnership advances the future of organ transport & transplant.

For two decades, a leading medical device manufacturer has been transforming what it means to wait for a life saving organ. Its Organ Care System (OCS™), the only FDA-approved technology in the United States for warm perfusion and preservation of donor lungs, hearts, and livers, keeps organs alive, functioning, and assessable during transport rather than packed on ice in a race against time. The manufacturer produces both disposable organ-holding modules assembled in clean room environments and the portable consoles that power them.

The impact has been significant: more usable donor organs, improved patient outcomes, and transplant centers that have expanded transplant volumes two to three times over.

To support this mission, the company built dedicated fleet of aircraft and a 24/7 logistics command center capable of mobilizing organ retrieval and delivery missions anywhere in the country at a moment's notice.

To protect their momentum, support growth, and prepare for the future, the manufacturer invested in a Critical Manufacturing MES foundation, and partnered with RoviSys to modernize its production operations. The objective was clear: move beyond a manual, paper-driven manufacturing environment and implement a scalable digital manufacturing foundation capable of supporting the next generation of life-saving medical technology.

The Challenge

Scaling a Mission That Can't Slow Down

Leadership recognized that scaling production would require more than incremental improvements. To support aggressive growth targets, ongoing regulatory submissions, and increasing product complexity, the organization needed a modern digital manufacturing foundation capable of delivering greater operational visibility, traceability, and scalability without disrupting active production.

Additionally, the company needed a partner capable of rapid response with proven MES solutions and on-site support.

Key drivers:

- Approximately 10× projected growth across lung, heart, and liver platforms
- The need to transition beyond paper-based manufacturing processes
- Increased regulatory and validation requirements for new organ module platforms
- Greater visibility into scrap, quality, production performance, material flow, and workforce deployment
- Faster access to detailed manufacturing data
- Implementation timelines that required uninterrupted production operations

RoviSys

Strategic alliance with Critical Manufacturing powers digital transformation, advanced traceability, and real-time operational insight.

To protect their momentum and prepare for what's next, this manufacturer invested in a digital manufacturing foundation and chose a partner who could deliver it without slowing down production.

RoviSys was introduced to the manufacturer through Critical Manufacturing, a strategic partner with an MES platform that is purpose-built for complex, regulated production environments. Initial C-level introductions quickly became deep technical sessions, and the connection was clear. An ideal platform combined with RoviSys integration expertise would accelerate and improve the company's operations and support its growth goals.

Three things set the partnership apart:

1. Deep discovery before configuration

RoviSys began with a detailed assessment of manufacturing operations, growth targets, and future product roadmap. The objective was not simply to digitize existing processes, but to design an MES foundation capable of supporting 10x growth, new product lines, and increasing production complexity without rework.

2. Platform discipline

RoviSys maximized the use of native Critical Manufacturing MES functionality rather than writing custom code. The result was a scalable, maintainable platform that can evolve alongside new products and meet validation and regulatory requirements, while reducing long-term complexity and integrator support

3. Coordinated delivery and presence

Throughout the 12-month project, RoviSys maintained a dedicated on-site team of engineers and project managers to keep the project moving. A true commitment built on long hours, through holidays, and engagement beyond system launch to provide continued support, and operational stability.

The Solution

A Robust MES That Orchestrates

RoviSys implemented Critical Manufacturing's MES as the operational backbone of the facility, replacing manual production processes with end-to-end digital work instructions for both disposable organ-holding modules and portable consoles. The implementation transformed an entire way of working, delivering a scalable digital solution.

The MES is now the orchestrating layer rather than a passive logger, aligning scheduling, execution, quality, and inventory to support the company's long-term growth vision.

Digital work instructions and standardized processes

The MES delivers step-by-step digital work instructions at every workstation, capturing procedures, checks, and required data consistently across every shift. By replacing paper tracking and reducing reliance on tribal knowledge, the system helps ensure operational consistency as production and workforce demands continue to scale.

Integrated workforce and task management

The MES integrates directly with a workforce management system, using real-time role and qualification data to ensure the right employees are assigned to the right tasks automatically. This replaced ad-hoc supervisor coordination with structured, rule-based task management, improving compliance, consistency, and operational efficiency.

End-to-end traceability

RoviSys integrated Critical Manufacturing MES with the company's QAD ERP to create granular, bi-directional visibility between inventory systems and the shop floor. The solution tracks which material lots feed specific builds, how materials are staged and consumed, and how inventory is replenished throughout production. The result is a complete, auditable traceability path from raw material to finished medical device, supporting the quality, compliance, and accountability required in a highly regulated manufacturing environment.

Digital nonconformance and quality workflows

Quality and nonconformance workflows are now fully managed within the MES, allowing operators to log issues, route reviews, and track corrective actions in a single digital system. Combined with detailed lot traceability and standardized work instructions, the solution provides a strong quality data foundation to support rapid response, continuous improvement, regulatory requirements, and long-term confidence in the manufacturer's life-saving technology.



The Result

Production Maintained, Scalable Growth Unlocked

The project delivered both immediate operational stability and a long-term foundation for growth. Most importantly, the MES transition occurred without disrupting production. Within weeks of launch, the manufacturer matched and slightly exceeded previous output, increasing from approximately 115 to 117 modules per week while operating entirely on the new system.

- **Scalable architecture:** The MES foundation was designed to support planned 10x production growth and expansion into additional organ platforms without major rework.
- **Regulatory-ready data:** Digital nonconformance workflows, lot-level traceability, and standardized processes provide the control and documentation required in FDA-regulated medical device manufacturing.
- **Real-time operational visibility:** Scrap rates, material usage, and production performance are now accessible electronically in real time, enabling faster and more informed decisions.
- **Streamlined operations:** ERP and workforce integrations created a connected digital environment that reduced manual coordination and improved operational efficiency.
- **Built for independence:** RoviSys trained internal engineering and R&D teams to manage and expand the MES environment, reducing long-term reliance on the integrator.

Building What's Next

Partnering With RoviSys

This manufacturer operates with a clear sense of urgency because every device shipped represents the possibility of a life saved. RoviSys helped ensure the manufacturing systems supporting that mission could scale with demand, maintain compliance, and support long-term growth without slowing production.

The RoviSys approach remains consistent:

- **Start with understanding.** Deep operational discovery translates manufacturing processes, compliance requirements, and growth goals into a scalable MES strategy.
- **Stay on-platform.** Solutions are designed within the native MES framework whenever possible, creating systems that are maintainable, validatable, and easier for customers to own and expand over time.
- **Stay engaged.** RoviSys remains involved through go-live and beyond with continued engineering, support, and operational partnership because MES is not simply a project delivery, it is a long-term operational foundation.

When manufacturing growth begins outpacing existing systems, RoviSys partners with organizations to build the operational foundation needed to move forward with confidence.



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