

CASE STUDY
MEDICAL



Medical Device Manufacturer Lowers Costs, Improves Product

Outsourcing Increases Capacity By Streamlining Production

Outcome

Eight-fold increase in production rates, more robust quality assurance testing, improved yields, and improved product performance.

Challenge

The worldwide market for blood and blood products is growing at an annual rate of 4 to 5%. Ashland Specialty Ingredients' RAD-SURE device services this market by providing an easy-to-interpret indication of whether or not a unit of blood has been irradiated. Blood is irradiated to prevent transfusion-associated graft-vs-host disease (TA-GVHD), a potentially fatal complication of blood transfusion. As market demand grew, workflow bottlenecks required Ashland to closely monitor and manage the production schedule to ensure order fulfillment. The company turned to Web Industries to develop a manufacturing solution with greater capacity, improved quality assurance, and improved yields of high-value input materials.

Ashland chose Web because of our reputation for managing complex medical device programs. Our experience providing

CHALLENGES

- Increase RAD-SURE™ manufacturing capacity
- Increase yields from high-value materials
- Improve Quality Assurance
- Reduce workflow bottlenecks to ensure order fulfillment

SOLUTIONS

- Reconfigure product assembly to utilize one of our precision modular converting lines
- Source materials that are optimized for the new manufacturing process
- Develop in-line QA system
- Implement real-time production and supply chain management systems

RESULTS

- Eight-fold production increase
- Improved yields
- Reduced unit costs
- Increased capacity to handle surge and long-term volume increases
- Eliminated shortfalls and late deliveries

full supply assurance in manufacturing critical-to-patient devices and our strong quality systems gave Ashland confidence in our ability to support their programs. Working together with Ashland's development and manufacturing teams, we identified improvement opportunities in manufacturing methods, component materials, in-line quality inspection, and inventory and supply chain management.

Solutions

Web Industries' engineers approached the challenge of increasing the RAD-SURE production rate from several directions. Manufacturing was reconfigured to utilize one of our precision modular converting lines. This combines multiple web-based raw materials into discrete subassemblies, which are then combined with intermediate materials also processed by Web and precisely assembled into the finished medical device. This final assembly process involves a number of complex operations, including:

- Precision die-cutting and island placement
- Fixed-and variable-data printing using thermal and flexo processes
- In-line lamination, kiss cutting, and sheeting

Quality assurance was addressed through the development of several new systems. These include an in-line vision inspection system that checks 100% of the critical-to-safety features of every indicator, and a reject verification system to confirm that non-conforming indicators are correctly culled out. These systems automatically detect and segregate out-of-spec products and ensure that registration tolerances of up to of up to $\pm .005$ " are maintained during product assembly.

Web Industries profiled the RAD-SURE device and worked with Ashland to find component materials that were optimized for the new modular manufacturing process. This allowed both companies to exercise better control of the supply chain, accurately model costs throughout the length of the contract, and build in profitability over the entire product life cycle.



Real-time data monitoring and tighter supply chain controls combined to increase material traceability and supplier accountability, raising both quality levels and manufacturing efficiency for all versions of the RAD-SURE indicator. As an FDA registered medical device manufacturing facility, Web Industries is approved to ship finished devices directly to Ashland's customers.

Results

The first shipment of RAD-SURE devices manufactured by Web Industries was delivered to Ashland's distribution center in November 2011, where it was sent to medical facilities without additional assembly or inspection.

Partnership with Web Industries has allowed Ashland Specialty Ingredients to realize immediate and future benefits:

- Reduced unit costs
- Significant improvement to functional and aesthetic product parameters
- Increased capacity to cover both surge and long-term volume increases, eliminating late deliveries and shortfalls
- Using Web Industries as their contract manufacturer frees up internal resources and will allow Ashland to focus on new product innovation and developing new markets for RAD-SURE

The world's top medical companies trust our innovative engineering, converting, and manufacturing solutions to improve their products and protect their customers. Contact Web Industries at **+1 508.573.7979** or **sales@webindustries** to find out why.

