

## Case Study

### **BIOSENSE WEBSTER, A DIVISION OF JOHNSON & JOHNSON**

- Highly Audited, Validated, and Regulated Environment
- Reduce Cycle Times to Reduce Inventory Levels
- Extensive Cross Training in Labor Intensive Operation

*"Improvements have been recognized everywhere: Inventory reductions, operator education, improved space utilization, and our equipment requirements based on the new plant layout."*

- Manuel Garcia  
Director of Manufacturing  
BioSense Webster, LLC



## **Business Objectives:**

The first useful deflectable tip catheter was pioneered by Will Webster more than three decades ago. Ever since then, the Webster name has been synonymous with industry-leading design and craftsmanship in diagnostic and therapeutic cardiac catheters. In 1993, revolutionary Biosense technology paved the way for important advancements in cardiac imaging. Combining these technology leaders as Biosense Webster, Inc. within the Johnson & Johnson family of companies has significantly enhanced both the science and the clinical application of electrophysiology.

Biosense Webster is positioned within the medical devices sector of Johnson & Johnson. The company has also become a world leader in software and hardware systems for three-dimensional cardiac mapping and navigation. Biosense Webster is recognized worldwide for its development of advanced cardiac catheter designs.

Headquartered in Diamond Bar, California Biosense performs 85 percent of its manufacturing in Juarez, Mexico. The Juarez, Mexico facility has become a prime producer for the Biosense Webster products. Operating for slightly over four years, today the plant produces and ships directly to hospitals in North America and South America or ships to distribution centers in San Diego for shipment overseas and rest of world.

## **The Business Challenges:**

Marketing and customer demand has required a significant increase in the quantity of stock keeping units, (SKUs), and features/options offered. This had put a strain on the existing facility's ability to react appropriately on lead times and inventory investment decisions. Market

demand from both customers and marketing has put strains on demand management and forecast accuracy levels that the plant must cope with.

Regulatory compliance, periodic audits, validations, and approvals from multiple governing agencies place a difficult demand in evaluating any dramatic changes to the operating environment. Regulatory documents typically arrive at the plant facility from California while the Device History Record (DHR) data is created and maintained at the plant.

In addition to the periodic audits from the regulatory agencies, Johnson & Johnson is ISO 9000 certified which brings an extra level of control that must be recorded, documented, and maintained during the transformation. This is a corporate mandate.

## **The FlowVision® Solution:**

Biosense Webster was not new to FlowVision®. Based on the excellent work they performed at the corporate facilities in California, it was a logical choice to extend their capabilities to the Juarez facility. However, the Mexican facility presented a significantly larger challenge on multiple fronts due to product mix, demand signals, plant layout, and labor-intensive operations.

It is the "hands-on" approach that FlowVision excels at. They educated us on what needed to be accomplished and they provided the tools and skills for our workforce to meet our goals" Said Manuel Garcia, Director of Manufacturing.

"More importantly, besides providing us with theory, they directly help with building the system and establishing the new production lines. They have exceptional knowledge transfer

capabilities and we were tied to their sides during the implementation. Not only do they know the integrated lean environment and how it should operate, they translated that knowledge directly to our product sets and have made us self-sufficient." Garcia added.

## Implementation:

Before Flow was implemented the plant layout had to be re-designed. The existing environment led to high queue and lead times and increased buffer levels at each major work center. The plant was re-aligned into three lines so that each line could leverage basic technology and platform components depending on the type of catheters. A constraint that had to be addressed was the need to support the forward and backward lot traceability from a regulatory perspective.

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Director of Manufacturing  
Biosense Webster*

The relocation of equipment was done over a long weekend. There was a slight build-up of inventory prior to the conversion as an insurance policy and extra care with respect to product and process quality during the conversion.

The production of catheters is labor intensive. This impacted the implementation at two levels: the first on the design layout, the second on educating lean principles. Since the plant was now aligned into similar production lines from cellular based production, plant

personnel were cross-trained on performing operations both upstream and downstream.

The Federal Drug Administration, (FDA), also played a role in the implementation. They had to approve the new plant layouts prior to them occurring. This extra level of care has paid off. Biosense Webster is now able to perform their Lean audits internally. They recommend that an audit be performed every six (6) months.

Lean audits, first done by FlowVision after implementation, are needed to review and balance the lines every 2-3 months. It is important for adapting the new parameters to reflect the changing product and demand fluctuations that occur. FlowVision transferred this knowledge and tools to the engineers and staff of Biosense Webster to make them self-sufficient.

## Results:

After implementing Lean, multiple goals have been achieved. Inventory was reduced substantially even though product mix continues to grow. "Improvements have been recognized everywhere," said Garcia. "We have made tremendous gains in educating our operators, improving space utilization within our facilities, and have a much better grasp on our equipment requirements based on the new plant layout."

In addition, the bottom line:

- Reduced our inventory by 25%
- Lead-time was reduced by 50%
- Successful regulated audits

So what is next for Biosense Webster? Extending the Lean environment to the California finished goods facility and main suppliers in the US. The journey to Lean is continuous.

## **ABOUT FLOWVISION**

FlowVision is the leader in lean and flow manufacturing consulting that provides real world experience in lead-time reduction and supply chain management, resulting in significant financial benefits.

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