



## CASE STUDY

# CLINICAL DIAGNOSTICS SYSTEMS

## MANUFACTURING OUTSOURCED, VALIDATED & PRODUCT LAUNCHED, IN ONLY 9 MONTHS, DURING DESIGN COMPLETION

A tier one medical diagnostics company needed to outsource manufacturing of three clinical diagnostics systems. To meet their market launch date, the project had to start before the designs were finalized. In only 9 months, Sanmina validated production and shipped the first systems.

### GOAL:

A tier one medical diagnostics company needed to outsource the new product introduction (pre-FDA clearance) and manufacturing for three newly designed clinical diagnostic systems used in hematology and immunoassay analysis.

### CHALLENGE:

Market launch was planned in 9 months. Production needed to ramp up to deliver 15 systems per day, during design completion. Thousands of engineering change orders were anticipated. More than 3,000 components, 200 cables and 40 sub-assemblies had to be integrated into the systems during a complex build and test process that lasted over 100 hours per system.

### WHY SANMINA:

During an intensive two day workshop the customer evaluated Sanmina's capabilities in a range of areas including supply chain management, engineering, manufacturing, test, validation and regulatory compliance. They were impressed with the robust processes and the strength of the organization. The deep involvement and commitment from senior and executive management convinced them that Sanmina could successfully complete the project.

*"Although introducing new products and technologies within 9 months was a significant challenge, we were committed to make it happen".*  
Yong-wah Chua, VP Operations, Sanmina, Singapore.



## APPROACH:

Sanmina deployed an experienced cross-functional team with local and global resources representing engineering, quality, supply chain, operations and customer program management.

- The team followed a well-established new product introduction process.
- Sanmina corporate subject matter experts were positioned on-site for the duration of the project.
- Over 7,000 quotes were analyzed. The supply chain team visited suppliers, established new relationships and purchased components at competitive prices.
- Sanmina engineers were co-located with the customer's designers to provide DFX input and to design the manufacturing process.
- 6,000 incoming quality inspection plans were developed. 14,000 lots were inspected within the prototype phase.
- Robots were installed to deliver components to work stations on the production floor.
- The production process was simulated to verify efficient operation.
- Instead of cell build, a more efficient conveyor-based production line was designed to accommodate the highest volume systems. 60,000 square feet of production space was prepared for ramp-up.
- Sanmina validation engineers developed a Master Validation Plan for all equipment using Installation Qualification, Operational Qualification and Performance Qualification protocols.
- An electronic Device History Record (eDHR) was customized for each instrument.
- 150 engineers, technicians and operators were trained and certified over a period of six months.
- Technicians were trained to functionally test the complete system including robotics and refrigeration.
- Immunoassay and hematology tests were conducted using reagents.
- Hematology instruments were also tested using artificial blood.

## RESULTS:

- **The systems were launched on time.**
- **Zero system returns from the field.**
- **The Sanmina facility successfully passed an FDA inspection with zero 483s.**
- **The customer presented Sanmina with Significant Achievement awards for the first three years of production.**



## ABOUT SANMINA

Sanmina Corporation is a Fortune 500 company and a leading global provider of integrated manufacturing solutions, components, products, repair, logistics and after-market services. Recognized as a technology leader, Sanmina provides end-to-end manufacturing solutions, delivering superior quality and support to Original Equipment Manufacturers (OEMs) primarily in the communications networks, cloud solutions, medical, defense and aerospace, industrial and automotive segments. Sanmina has facilities strategically located in key regions throughout the world. More information regarding the company is available at <http://www.sanmina.com>.

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