CASE STUDY

CLINICAL DIAGNOSTICS SYSTEMS

CONCURRENT DESIGN COMPLETION, PRODUCTION PROCESS VALIDATION AND LAUNCH IN ONLY 9 MONTHS

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:

As part of a new generation of innovative products, the instruments had to be launched to the market at the same time. New product introduction and production validation needed to ramp up to deliver 15 systems per day, while the design being was finalized. 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 manufacturing and test process that lasted over 100 hours per instrument.

WHY SANMINA:

Sanmina participated in a two day workshop that allowed the customer to evaluate its extensive supply chain management capabilities, manufacturing operations, test processes and systems for ensuring quality, validation and regulatory compliance. Sanmina's competence at integrating and testing multiple complex technologies including motion control, pneumatics, robotics, fluidics, dispensing, pumps, chemistry, electronics and mechanical systems also made a strong impression.

As part of the comprehensive evaluation, Sanmina experts participated in a live question and answer session to address a wide range of customer questions. The customer appreciated the deep involvement and commitment of executive and senior management on the project.

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 robust and 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 deployed to the customer's R&D lab to provide manufacturing and test input and to establish 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 their point of use on the production floor.
- The production process was simulated to verify efficient operation.
- Instead of a cell-based manufacturing approach, a more efficient conveyor-based progressive production line was designed to accommodate the highest volume systems. 60,000 square feet of production space was prepared for ramp-up.
- A team of Sanmina validation engineers developed a Master Validation Plan for all equipment. They documented and executed validation protocols for Installation Qualification, Operational Qualification and Performance Qualification.
- 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 execute functional tests that verified complete system functionality including robotics and refrigeration.
- Lab analysis tests for immunoassay, hematology and antibodies were conducted using human blood and re-agents.
- Fluidic systems were tested for precision dispensing and aspiration of 10 microliters at a time with an accuracy of one percent.

RESULTS:

- All three clinical diagnostics systems were launched on time.
- 10,000 engineering change orders were managed during the first 18 months.
- There were zero system returns from the field.
- The Sanmina facility successfully passed an FDA inspection with zero 483s.
- Sanmina was honored 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.