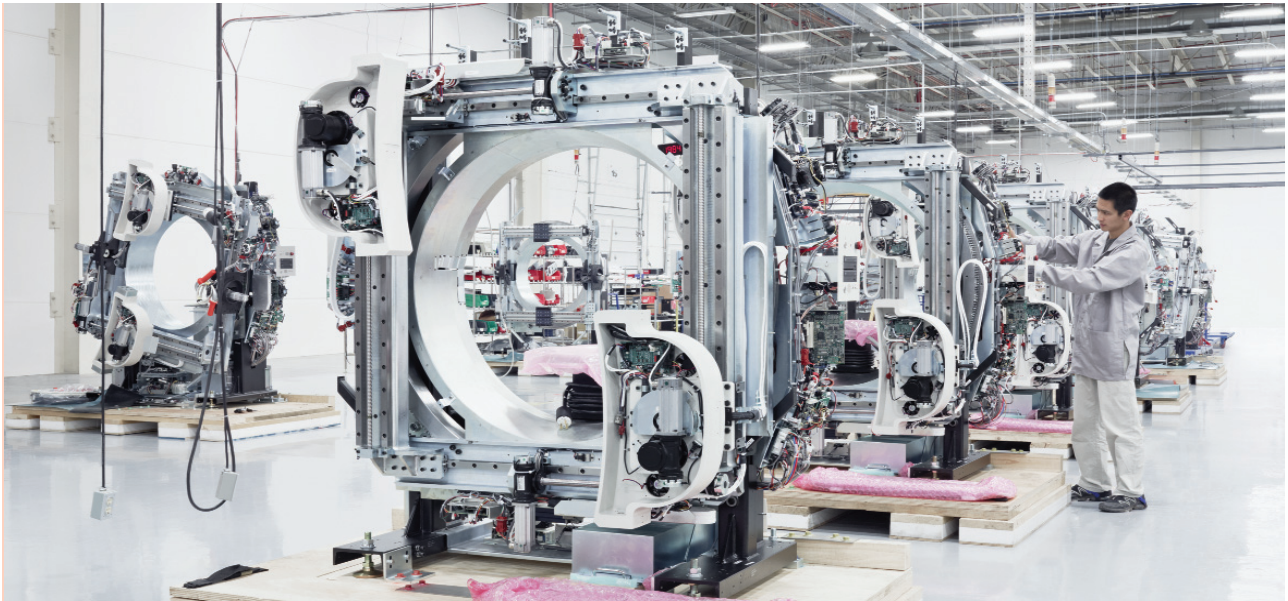


The Latest Solutions for the Medical Device Industry

Sanmina-SCI supplies to the international medical device industry, as well as for the communications, industrial and automotive industries. The medical equipment industry is highly regulated to ensure that safety standards are met.



Nuclear Medicine Systems Manufacturing

Having been in operation in Cork for nearly 30 years, Sanmina-SCI offers its customers the latest solutions in contract design, manufacture and test for the local and international medical device industry. Seamus Grady, Senior Vice President Medical Division at Sanmina-SCI explains that the level of service is second to none at the company which builds a broad range of medical products.

How long has Sanmina-SCI's Fermoy facility been in operation and what do you produce?

We've been part of the Fermoy community for near-

"We are proud to collaborate with our customers to bring beneficial new healthcare products to the market"

ly 30 years building some of the world's most complex and mission critical products. We offer our customers the latest solutions in contract design, manufacture and test for the local and international medical device industry, as well as for the communications, industrial and automotive industries, among others.

What sorts of medical devices do you make?

We build a broad range of both finished medical products, as well as PCBA's and sub assemblies. We focus on complex system builds for products such as ventilators, blood analyzers, cholesterol monitors, blood glucose monitors, oxymetry

systems, and defibrillators. We are proud to collaborate with our customers to bring beneficial new healthcare products to market. Our streamlined design and engineering processes facilitate whatever complex medical device a customer envisions.

Are there any special issues when manufacturing medical devices and equipment?

As you might imagine, the medical equipment industry is highly regulated to ensure that safety standards are met. All aspects of design, manufacturing and test are governed by the requirements of the FDA's Quality System Regulation (QSR). Compliance requires



Optos Daytona - A revelation in Eyecare

strict discipline and training to these requirements. The Fermoy plant is FDA registered, and our ISO13485 certified manufacturing systems are bolstered by "Six Sigma" programs and critical self-evaluation. Sanmina-SCI's global medical manufacturing footprint has 20 plants and one design center that are ISO13485. Our standardized Quality Management System (QMS) has undergone eight FDA audits in the last nine years with excellent results. Partnering with Sanmina-SCI allows our customers to leverage the offerings and scale of a global Tier-1 technology company with the individual dedication and attention to detail of a local engineering and manufacturing staff that focus on a customer's design, component and quick-turn manufacturing needs.

What trends are you noticing in the medical manufacturing sector?

We see an increase in US firms looking to launch products in Europe requiring the CE Mark, signifying European Compliance. This approach provides a history of product efficacy for easier FDA compliance at a later

"We assign a complete project team with expertise in engineering, test and supply chain, providing customers with the resources necessary to get a product to market on time and on budget"



Seamus Grady, Senior Vice President Medical Division

stage. This region has a history of compliance due to the large pharmaceutical industry located here, which is helping spur the growth of the medical device business. Because of this compliance, we are seeing an increased willingness from OEM's to outsource the manufacturing of FDA class III products, including implantable products where historically there was great reluctance to do so.

What would you say is unique about your operation at Fermoy?

Early involvement with our customers, where we provide Design For Manufacture (DFM) analysis and fast prototyping and NPI capability is a real differentiator for us. The level of service is second to none in Fermoy where the New Product Introduction (NPI) department has over ten years experience in bringing medical devices to market on time.

Can you give an example of a New Product Introduction for the medical market?

In a recent case, Optos, a leading provider of eyecare devices, required a very short turnaround time to introduce a new product, Daytona, which provides an unequalled 200° view of the retina in a single capture through its patented Virtual Point(tm) technology.

Optos needed a very tight five-day turn from bill of materials release to tested printed circuit board assemblies. It was achieved not only once, but for each revision release to the recent final clinical unit. We started building early designs in June 2011, and in August 2011, Optos received 510(k) clearance from the US Food

and Drug Administration (FDA) to market Daytona.

Daytona was formally announced in October 2011 and scheduled to be released by Optos in Q1, 2012. During March, the promised release date, Daytona was delivered to the market with Sanmina-SCI Fermoy providing metalwork, cables and circuit boards in modular tested format, which enabled Optos to complete final configuration and test in Dunfermline, Scotland.

What are some of the challenges associated with producing medical equipment?

In addition to normal manufacturing controls, medical products require extra testing, process validation, component traceability, and sound documentation practices. The tests are highly complex and we employ the most stringent manufacturing protocols in designing and producing medical test systems. In accordance with FDA regulations, design history file (DHF) databases are created for all functional testers to store test records, calibration and component traceability. A results database is also installed to capture automatic reporting of the device history record (DHR) from the shop floor data collection (SFDC) system.

We also provide guidance on component selection and innovative technical solutions for micropackaging and complex functional test. Plus, we assign a complete project team with expertise in engineering, test and supply chain, providing customers with the resources necessary to get a product to market on time and on budget.