With Optos, collaboration was paramount. Sanmina engineering teams were on site at Optos, collaborating on product improvements and product launch. Without this intensive effort, meeting stringent deadlines like those for Daytona would be impossible.

THE OPTOS STORY

Shortly after the successful launch of a new medical-imaging system, Sanmina received a message from the product manager at Optos, the company that had chosen Sanmina for system manufacturing.

“It’s remarkable to think back to where we were just six months ago,” he wrote. “Indeed, it’s just over 15 months since we started to engage with one another and in that relatively short time we have succeeded in bringing an extremely complex product to market. The stories we have already been receiving from our customers show the impact our product has already had on patients’ health, in some cases even detecting life-threatening conditions on the very first Optomap image.”

One of those stories began when a New York man noticed that he wasn’t feeling well and that he was having trouble seeing out of one eye, symptoms that led him to visit an eye clinic. The ophthalmologist who examined the patient used a new piece of imaging equipment, the Optos Daytona, that had just been installed. Something appeared to be wrong, but it did not seem to be a routine eye problem. It was something else, but it was not obvious. It was clear that further investigation was warranted. The patient visited a cardiologist, who was equally uncertain, but a CT scan was ordered. That scan showed a brain aneurysm in its early stages, detected soon enough in this case to be treated.

What had started as a seemingly small problem with a man’s vision had led to an emergency intervention that may have saved a life. The impetus for that medical intervention was an image produced by a laser-powered imaging system able to see the retina in ways that no other system could.

THE OPPORTUNITY

The eye is the only part of the body in which it is possible to obtain a direct view of arteries, veins and nerves without resorting to surgery. For that reason, the ophthalmoscope has been a standard tool for diagnosis since its development in 1851.

By visualizing the retina, a clinician can find early warning signs of a host of systemic diseases – diabetes, cancer, cardiovascular disease, aneurisms and others – in addition to detecting those problems specific to the eye itself.

The standard ophthalmoscope, for all its utility, has its limitations. It cannot provide a view of the entire retina. A variety of instruments are available to provide more complete views and, while expanding on the ophthalmoscope’s range, devices like digital ophthalmoscopes have their own limitations. They allow a view of only 90 to 100 degrees and they deliver two-dimensional images.

Given the potential of improved retinal visualization, the opportunity presented by a device that surpasses those limitations.
THE CHALLENGE
Optos had developed a device, Daytona, which offered practitioners vastly enhanced capabilities. Instead of a camera, Daytona used low-power lasers. In a single capture, Daytona provides a view of more than 200 degrees in three dimensions.

The value of such an advanced mode of imaging is clear, and Optos was anxious to bring the technology forward, hoping to bring its new design to market within six months. Challenges included:

- **Six months is a remarkably tight timeline in any industry**, but it presents special difficulties in the context of medical manufacturing. Meeting this timeline demanded experience.
- **Daytona was a new product**. As with any new product, change management is a central manufacturing challenge.
- **Optos had an additional deadline**: It wanted to unveil Daytona at an upcoming trade show, and that meant working according to a production schedule that existing manufacturing partners could not meet.

WHY SANMINA?
Optos turned to Sanmina for Daytona:

- **Sanmina is the world’s largest manufacturer of complex imaging systems**, and has over 20 years of experience in medical manufacturing.
- **Sanmina has the credentials**. There are 21 medical facilities — the highest number of medically certified facilities in the industry.
- **Sanmina exceeds compliance expectations**. All of Sanmina’s facilities have attained 13485-2003 certification, with nine being FDA registered.
- **Sanmina’s capabilities are not limited to any one stage of the manufacturing process**. Lifecycle management is a core strength, and Sanmina has the capacity to manage everything from design and development to service and repair.

THE APPROACH
Sanmina’s work for Optos began with a phone call. Optos had concerns about its current manufacturer. The following week, Sanmina staff met with Optos in Scotland, where Optos is headquartered.

Sanmina’s representatives included a transfer engineer with 22 years of experience. Sanmina did an on-the-spot tear-down of the new Optos device, explaining how the product would be built, what controls would be in place and what pricing Optos could anticipate. The presentation explained how Sanmina intended to drive costs down.

- **Manufacturing Systems**. Sanmina has robust systems in place, developed for medical product manufacturing over a period of 15 years. Sanmina’s production software is FDA Part-11 compliant. Sanmina’s documentation system holds all product documentation, manufacturing instructions and processes. These systems are consistently deployed in Sanmina’s medical facilities all over the world.
- **Design Optimization.** Sanmina offered Optos design support, providing VAVE (value add, value engineering) to help reduce costs.
- **Documentation Control.** Sanmina provided early engagement in design and product engineering, including documentation-control, all managed for Optos by Sanmina.
- **Supply Chain.** Sanmina managed all materials. As a result, Optos could take advantage of Sanmina’s global reach and 30 years of experience in supply chain management.

Sanmina is distinguished by a commitment and approach that emphasizes collaboration. With Optos, collaboration was paramount. Sanmina engineering teams were on site at Optos, collaborating on product improvements and product launch.

**RESULTS**

In the end, every one of those deadlines was met. When Optos needed to go from bill of materials to tested board assembly in five days, Sanmina accomplished this, and did the same for the many revisions released as Daytona approached final clinical approval.

Sanmina took the standard Optos testing procedures and made them more robust. Improving the original assembly instructions was essential, along with making them faster and less costly. Moreover, it created manufacturing instructions according to best practices, and provided them back for incorporation into the Optos design history file.

Optos was able to benefit from Sanmina’s deep technical competence and years of experience. With Daytona a reality, the world will benefit from a medical device that is a step beyond existing options, and Sanmina is proud to have helped make this happen.

“With Sanmina’s help we met and even exceed our output expectations. That we did so is a testament to the focus, diligence and teamwork between both our companies.”

Optos New Product Manager

---

**ABOUT SANMINA**

Sanmina makes some of the most complex and innovative optical, electronic and mechanical products in the world. Recognized as a technology leader, Sanmina provides end-to-end design, manufacturing and logistics solutions, delivering superior quality and support to Original Equipment Manufacturers (OEMs) primarily in the communications networks, computing and storage, medical, defense and aerospace, industrial and semiconductor, multimedia, automotive and clean technology sectors.