



“When you are doing cycle counting, invoicing and sales order transactions, you need real-time data in Oracle. RFgen was the only vendor that offered that.”

DANA BARTH | MATERIALS AND FACILITIES MANAGER

Optovue

Global manufacturer of ophthalmic imaging equipment improves inventory accuracy and complies with FDA requirements using RFgen Mobile Foundations for Oracle E-Business Suite.

At a glance...

Industry
Medical Device

Application
Inventory Management
Purchasing

Environment
Oracle E-Business Suite
Release 12.1.1

The Challenge

Headquartered in Fremont, California, Optovue designs, manufactures and sells imaging systems for ophthalmology and optometry based on optical coherence tomography (OCT), which provides exquisitely detailed images of the anterior and posterior portions of the eye. Since introducing OCT technology to the ophthalmology market in 2006, Optovue continues to advance the technology, and has more than 11,000 systems installed worldwide. In 2014, AngioVue OCT Angiography Imaging was introduced as the world's first OCTA system capable of visualizing ocular blood vessels, which provides physicians with the ability to more closely manage debilitating diseases that lead to blindness such as diabetic retinopathy and acute macular degeneration. Optovue distributes its products in 160 countries across the globe.

Dana Barth is the Materials and Facilities Manager at Optovue. He is responsible for the execution of the company's ERP system, stores shipping, receiving, material planning, NPI sourcing and CM purchasing, and facilities management.

In 2015, Barth was facing a new compliance challenge: The FDA had implemented a regulation that required medical equipment manufacturers to label each medical device with a Unique Device Identifier (UDI). “Every medical device had to be specifically symbolized and barcoded for traceability, in case there was a recall,” he explained. “The FDA regulation defined where the packaging labels had to be placed, what type of barcode could be used, what the human readable interpretation of those barcodes would be, and the information barcodes had to contain including manufacturing

location, date code, serial number, and contact information for the facility. The FDA gave us a drop-dead date of August 2016 or our shipments would be frozen.”

Barth's challenge was to find an automated mobile data collection system that could handle barcode generation, read inventory transactions and interface with Optovue's Oracle E-Business Suite ERP system. “We created a cross functional team with members from Regulatory Affairs, Manufacturing Engineering, IT and Materials to ensure there would be compliance in all aspects of the implementation,” he said.

The Solution

There were two major requirements for the new solution. First, it had to integrate with Oracle E-Business Suite and be able to exchange information bi-directionally in real-time. Second, it would have to support a barcode labeling solution that could produce FDA-compliant UDI labels by the August 2016 deadline.

Barth first evaluated the Oracle Mobile Supply Chain Application (MSCA)—Oracle's built-in solution for barcoding, but it lacked the flexibility to meet Optovue's needs. “I did a lot of Internet data searching to find a real-time Oracle interface for these applications,” recalled Barth. “I found a few systems that were parallel databases and would update Oracle in a non-real-time mode. That just was not a direction I wanted to go. When you are doing cycle counting,

invoicing and sales order transactions, you need real-time data in Oracle. RFgen was the only vendor that offered that.”

RFgen Mobile Foundations for Oracle E-Business Suite is a suite of pre-written, pre-tested Oracle-validated data collection solutions that combine real-time Oracle workflows with barcode devices and roaming mobile applications. RFgen helps businesses drive greater efficiency with faster, automated mobile apps for inventory management, manufacturing, purchase order receiving, and more.

The Result

RFgen enabled Optovue to create UDI barcode labels in time to meet the FDA's 2016 deadline, thanks to RFgen's integrations with both Oracle and the BarTender® label printing solution. Using RFgen has helped Optovue to:

- Generate FDA-compliant UDI barcode labels for packaging and products.
- Improve inventory accuracy from 99% to “near perfect”.
- Automate pick lists for kitting processes on work orders.
- Perform cycle counts quickly and accurately with mobile barcode scanners.
- Increase the efficiency of PO Receiving.

Complete Compliance with FDA Labeling Requirements

RFgen features built-in integration capabilities to major enterprise barcode labeling solutions, including BarTender and Loftware Label Manager®. Optovue uses RFgen's integration with BarTender to populate barcode labels with their ERP data for full compliance with the FDA's UDI requirement.

RFgen can generate many types of custom barcode labels and RFID tags, or allows companies to simply scan pre-printed labels and attach product information to the unique identifiers. Optovue opted to use RFgen to print its own custom barcode labels. The RFgen interface to BarTender is seamless, so workers only interact with RFgen.

Using RFgen, Optovue met the deadline for FDA compliance with new UDI packaging labels. “We flew through with flying colors because we went through a very in-depth validation and verification process. Being FDA controlled, it is crucial that any change to our system, our processes or equipment be very well documented,” Barth said.

Extremely Accurate Inventory Control

Optovue uses RFgen to manage parts inventory as well as finished products. According to Barth, using RFgen has enabled his teams to improve upon inventory management that was already well-controlled. “RFgen has allowed me to move from a 99% accurate inventory to a near perfect inventory level. It is rare that we do an inventory adjustment since full implementation,” he said.

“We use RFgen to manage the receipt of incoming materials used to produce our product, both components and purchased assemblies from our contract manufacturer,” Barth continued. “We run a tight inventory control system as well as a FIFO system. We are able to accurately scan in the receiving and put away information, pull kits using the barcode labels, perform cycle counts and any adjustments, and transfer inventory from one location to another. And we also use RFgen for our shipment transactions as far as scanning what goes out the door and validating it against the UDI label.”

Easy to Learn and Use

The employees at Optovue had no trouble learning to use RFgen on their mobile devices. Barth said, “The ease of use of RFgen helps to naturally produce a more accurate inventory by allowing our employees to key in fewer numbers and instead scan barcodes. I am now in the process of reconfiguring our warehouse space for workflow improvement to reduce kitting time and production. RFgen is an invaluable tool.”

Ready to Tackle Future Compliance Challenges

After the FDA imposed the UDI requirement, many foreign governments decided to improve labeling for medical equipment. As a global business, Optovue must reconfigure many of its packaging labels again so that they will be compliant not only with FDA, but other regulatory bodies around the world.

There is also another FDA deadline looming. While the first phase of the regulation required labeling the packages the products ship in, the August 2018 deadline requires labels to be affixed to the product directly.

“It is designed so that after equipment or a part is unwrapped and installed and the packaging thrown away, people can still find out where it came from and when it was developed by a label on the product itself. I will be working with the RFgen team for that requirement,” said Barth.

Whatever new Oracle transaction or labeling requirements arise, Barth is confident the RFgen solution will help Optovue rise to meet the challenge. “I would definitely recommend RFgen. We would not have been able to ship product over the last ten months unless things worked correctly—RFgen made it possible.”

About RFgen Software

RFgen Software helps organizations reduce supply chain implementation costs and increase accuracy and efficiency with the industry's most reliable and flexible mobile data collection software and supply chain automation solutions.

Enabling you to increase productivity by providing your mobile workforce with real-time and on-demand access to enterprise data, RFgen's mobile data collection solutions easily connect Windows, Android and Apple iOS mobile devices like barcode scanners, tablets, handheld computers, voice recognition devices and more to your back office ERP systems and databases, including Oracle's JD Edwards, Oracle E-Business Suite, SAP, SAP Business One, Deltek Costpoint and more.

In business since 1983, RFgen is known in the manufacturing and distribution industries for its solid, high-quality products and high customer satisfaction ratings among its more than 2,800 customers. With a global reach and local touch, RFgen and its network of more than 140 certified solution partners can support your organization no matter where your operations are located around the world.

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