

CASE STUDY:
Optovue



OVERVIEW

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



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SNAPSHOT

INDUSTRY:
Medical Device

ENVIRONMENT:
Oracle E-Business Suite
Release 12.1.1

APPLICATIONS:
• Inventory Management
• Purchasing

GOALS ACHIEVED

- 1 Generates FDA-compliant UDI barcode labels for packaging and products.
- 2 Improves inventory accuracy from 99% to “near perfect”.
- 3 Automates pick lists for kitting processes on work orders.
- 4 Performs cycle counts quickly and accurately with mobile barcode scanners.
- 5 Increases the efficiency of PO receiving.

“ 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

THE CHALLENGE

In 2015, Optovue 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. “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,” explained Dana Barth, Materials and Facilities Manager.

Barth is responsible for the execution of the company’s ERP system, stores shipping, receiving, material planning, NPI sourcing and CM purchasing, and facilities management.

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."

“ The ease of use of RFgen helps to naturally produce a more accurate inventory by allowing our employees to key in fewer numbers. RFgen is an invaluable tool. ”

- Dana Barth,
Materials and Facilities Manager
Optovue

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

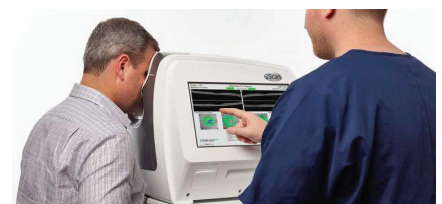
After the FDA imposed the UDI requirement, many foreign governments decided to improve labeling for medical equipment. As a global business, Optovue

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 required labels to be affixed to the product directly.

"It is designed so that after equipment or a part is unwrapped, 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 OPTOVUE

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 poster portions of the eye. Optovue distributes its products in 160 countries across the globe.