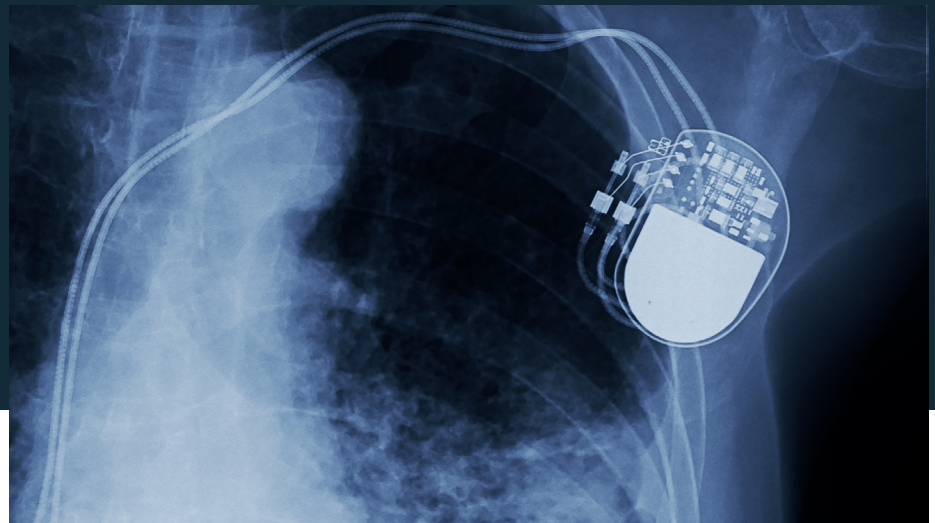**REGION**
Global

USE CASE
Medical Devices

COMPANY SIZE
Enterprise

Key Benefits

— Reduced the number of unique label formats

— Increased labeling accuracy and regulatory compliance

— Enabled secure handling of regulatory information throughout the company's ERP system

Medical device manufacturer works with BarTender® to streamline logistics, ensure compliance, and enhance security

BarTender's label design and printing software integrates with Oracle E-Business Suite to consolidate global ERP processes, satisfy FDA requirements, and significantly reduce unique label formats.

A multinational medical device manufacturer integrated Oracle E-Business Suite with BarTender label design and printing software from Seagull Scientific, resulting in streamlined supply chain processes and increased regulatory compliance and system security moisture, variations in temperature and rough handling throughout the supply chain.

Challenge

The medical device manufacturer operated a collection of disparate, unsupported ERP and labeling systems that were the result of a period of organic growth and M&A activity. While consolidating ERP processes through the deployment of Oracle E-Business Suite, the manufacturer reevaluated its labeling systems. Key business drivers included:

— moving from local, unsecured data storage to a Single Source of Truth for their master data;

— needing to comply with the US FDA's Unique Device Identifier (UDI) regulations for the labeling of medical devices; and

— reducing the total number of unique label formats serviced and maintained.

Approach

The new system integrates BarTender software with Oracle E-Business Suite.

Using Oracle as the source for master data, the system leverages native Oracle printing processes to pass XML to BarTender, which transforms the data into FDA-compliant labels. The new system includes optimized label templates, reusable label components, version control and a fully redundant architecture. BarTender was configured to also handle input from legacy systems, so production could continue uninterrupted during the transition to Oracle E-Business Suite.

Results

Pilot and initial rollout took place at one location, and were completed within one week. After the successful pilot, the manufacturer's Oracle-based, BarTender-driven labeling system was deployed to multiple data centers to manage the company's compliance labeling processes at its facilities worldwide.

The new labeling system dramatically reduced the number of unique label formats the company needed to maintain, increased labeling accuracy and regulatory compliance, and enabled secure handling of regulatory information throughout the company's ERP system.