

CASE STUDY:

PRISYM ID'S INNOVATIVE SOLUTION BRINGS FDA COMPLIANT LABELING CAPABILITY TO **CARDINAL HEALTH**



Cardinal Health is an \$87 billion global manufacturer and distributor of medical and surgical supplies and technologies. Cardinal boasts a healthcare customer base that covers five continents and includes hospitals, medical centers, retail and mail-order pharmacies and clinics.

To match Cardinal Health's requirements, PRISYM ID offered two purpose designed off the shelf products, which meant no customization. This means the project costs were quantifiable and didn't spiral and the new system can be easily upgraded in the future.



THE CHALLENGE

To accommodate the needs of new customers in North America Cardinal Health needed to upgrade their labeling systems to meet the stringent FDA regulations. Cardinal also wanted to extend their branding to secondary labels in order to promote their products more effectively in the marketplace.

KEY OBJECTIVES:

- Meet FDA 21 CFR Part 11 requirements
- Supplied with full life cycle documentation
- Supplied with supporting GMP compliance
- Extend Cardinal branding to secondary labeling
- Validation of the complete solution once in situ
- Reduce user inputs and ensure data integrity
- A WYSIWYG (what you see is what you get) print preview was required as an aid in the label design stage and as a last check before printing.
- Initiate label printing from Oracle and utilise existing system
- Printing of the first label must start in less than 3 seconds.
- Flexible, highly featured label design capability
- Install of the new system needed to be complete at the first site within 3 months
- Overall improve labeling efficiency
- The new labeling systems were to be installed at two UK manufacturing sites, Brentwood and Romford in Essex.

THE SOLUTION

PRISYM ID's dedicated life sciences team responded to Cardinal Health's User Requirement Specification (URS) with a detailed proposal to install a solution based on PRISYM labelling solution, the world's only purpose designed labeling software for FDA 21 CFR Part 11 compliant applications. In addition a DataWatch module, also developed by PRISYM ID would be used to link the labeling system with the existing Oracle Business Suite 11i. The proposal included validation of the complete solution once in situ.

BENEFITS FOR OUR CLIENT

- PRISYM ID's experienced project team completed installation of the new system just two months from placement of the order.
- Interfaced with Oracle Business Suite 11i which automatically populated up to 20 key fields in the labels to reduce user input and ensure data integrity
- Branded Secondary labels which promoted their products more efficiently in the market place
- Commands from Oracle were accepted by the system and started printing the first label in under 3 seconds
- Cost were quantifiable as there was no customization required due to being an off the shelf product
- The new system can be easily upgraded in the future

