



HEALTHCARE GIANT HARNESSES POWERFUL PRISYM^{LS} LABELING SOFTWARE TO MEET STRICT FDA REGULATIONS

Baxter Pharmaceutical Solutions of Bloomington, Indiana has standardized on PRISYM [Medica](#) software for compliant production and supply chain labeling management.

Maintaining their lead in contract manufacturing for global drug manufacturers is vital to Baxter BioPharma Solutions. Their confidence in the benefits that PRISYM^{LS} labeling software adds to their all-round service is part of their competitive advantage strategy.

“It was critical that we had a labeling system that complied with the strict requirements of the FDA, especially 21CFR Part 11 rules,” explained Kevin Hawkins, Technical Analyst at Baxter.

“This was not only important to our customers who, along with the FDA and its corresponding European agencies, carry out audit observations from time to time.”

After evaluating a number of labeling software systems, Baxter selected PRISYM [Medica](#), which was the only one to offer this key feature, for integration into one production line-filling, labeling and packaging phials at the rate of around 2,000 per day. 5 phials are packed into a container and a label is applied to each phial and also each bubble-wrapped container.

Labels are designed in-house and, once the template is approved by their customer, the data is uploaded to their J.D. Edwards (SAP) database. Labels carry the usual data including product name; batch number; expiration date; storage details etc. and are produced in a number of languages.

“Because of the nature of our business, security is an overriding requirement in our service delivery,” continued Kevin Hawkins. “PRISYM [Medica](#) allows us to limit access to the database, to limit the programs that can be opened by individuals and also to ensure that once approved nothing can be changed without our Quality Assurance people being involved. The extended hours Software Support Agreement is also an important benefit for 24/7 production.”

PRISYM [Medica](#)'s successful performance on the line gave Baxter confidence to harness its full traceability and tracking capabilities, especially, for use in their warehouse. The system allows

them to automate and track incoming customer inventory (raw material) at the loading dock. Label printing is triggered by hand-held terminals, which write a secure database entry containing the variable data and user ID which is accessed by PRISYM [Medica](#). All labels are printed on the warehouse floor on wireless printers and are applied immediately. This also enables close control over work in progress.

"PRISYM [Medica](#) has been an unqualified success, so much so that we are planning to roll it out to three other lines in the near future," concluded Kevin Hawkins.

PRISYM^{LS} is a global leader in validated FDA compliant bar code software, labeling and identification systems. With offices in the USA and UK as well as an extensive network of international partners worldwide, PRISYM^{LS} is able to provide bar code, labeling and RFID solutions on a global scale. The company boasts a comprehensive range of label design and printing software, including automated track and trace systems, consumables and 24 x 7 support staff.

PRISYM^{LS} is a division of PRISYM^{ID}. For further information please contact Martyn Kerluk at (704)-409-2351 or email info@prisymidinc.com. For additional descriptions, please visit www.prisymidinc.com