



PRISYM^{LS} DELIVERS A SECURE SOLUTION FOR SPECIALS CLINICAL MANUFACTURING

PRISYM [Medica](#) software ensures efficiency and regulatory compliance for pharmaceutical labeling and clinical trials

When Specials Clinical Manufacturing required a validated label printing system which would satisfy the specific requirements of the Medicines Healthcare Regional Authority (MHRA) and the Food & Drug Agency (FDA), they found the specialist PRISYM [Medica](#) software with PRISYM [ClinTrial](#) module from PRISYM^{LS} was by far the best solution on the market. Now installed at Specials Clinical Manufacturing's state-of-the-art facility in Northumberland, this software is being used to print labels for patient packs and maintain secure record-keeping for clinical trials.

Because Specials Clinical Manufacturing performs clinical trials and drug labeling, security and regulatory compliance is of paramount importance. PRISYM^{LS}, however, was able to provide a validated system to comply with 21 CFR Part 11 rules regarding electronic records and signatures. The system manages the printing of patient data, treatment codes, study centre, stratification group and patient visits, while still ensuring all data is kept secure and traceable.

Specials Clinical Manufacturing provides a wide range of manufacturing development and packing services for the clinical trials market. Elaine Mackie, Packaging Manager at Specials Clinical Manufacturing, comments: "Initially, there was no suitable system in place for printing labels, especially labels for randomised studies and projects. We knew, however, what level of quality we required and the PRISYM^{LS} system not only delivered, but exceeded our expectations."

Elaine continues: "Unlike PRISYM^{LS}, many of the other systems we considered did not provide the correct level of service and security, which is an especially important factor in our industry. Plus, the PRISYM [Medica](#) software is user-friendly and has a very useful reminder mechanism."

PRISYM [Medica](#) label design and production software is specifically developed to meet the FDA's current compliance requirements, in particular, 21 CFR Part 11. Available as a client/server-based application or as a single workstation version, the software uses high

levels of security and data encryption to ensure systems integrity and regulatory compliance at all times. It is able to record critical activities and electronically links them to individual users, along with time and date stamping.

PRISYM [Medica](#) provides a totally secure environment for label design, approval, automatic gathering of variable data and label printing. It is developed, tested and documented in accordance with strict FDA and GAMP (Good Automated Manufacturing Practice) guidelines and supplied with full life cycle documentation. Plus, the system can be integrated with many other software packages, including ERP and MRP systems.

The PRISYM^{LS} team has over 20 years experience in delivering high quality labelling and auto-identification solutions to companies in a wide range of industries. With offices in the UK and USA as well as an extensive network of international partners worldwide, the company is able to provide barcode, labelling, RFID and print solutions on a global scale. The company boasts a comprehensive range of software and consumables; from intuitive label design and print to automated track and trace systems.

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