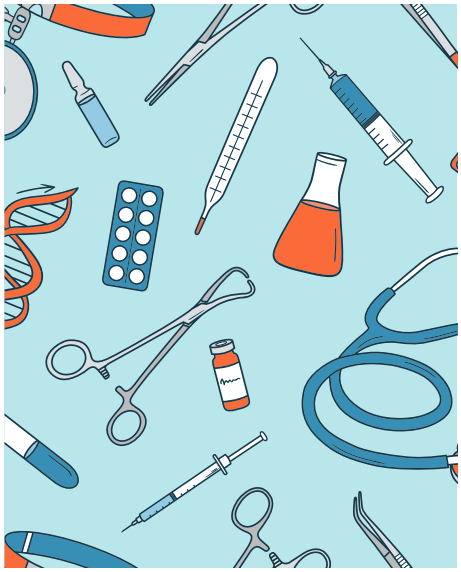
Implementing GS1/UDI Compliant Labels for a Medical Device Company

Business Goal

The client is an American manufacturer of surgical instruments. They wanted to adopt GS1/UDI standards, a system used to assign Unique Device Identification (UDI) numbers to medical devices within the healthcare supply chain. UDI compliance is a requirement for any medical device manufacturer hoping to sell their products in the U.S. market.



BUSINESS BENEFITS

- Achieved 99% accuracy with automated QC and label proofing
- 70% increase in productivity
- 38% savings through the managed services model
- Increased the efficiency and accuracy of deliverables
- Improved visibility into the ongoing process with project metrics

CHALLENGES

- Separate master template design and validation was required for each medical device class
- GS1 and UDI compliance had to meet FDA timelines for each class
- A standard process was required for error-free delivery of converted labels and barcodes
- Stringent quality checks were required prior to barcode implementation
- Support and update labeling documentation in PLM systems

SYNTEL'S SOLUTION

The client turned to Syntel to provide a complete solution for UDI assessment, implementation support, and conversion support. Syntel was involved in the effort from end to end, working with the customer to effectively plan the project activities in order to ensure optimum resource utilization and seamless coordination between teams. Syntel helped them:

- Conduct complete GS1/UDI impact and implementation assessment
- Ramp-up and ramp-down capacity throughout the project, using a shared services model
- Perform a thorough regulatory and risk assessment
- Ensure smooth change management, program planning and training
- Create and validate master templates for repetitive use
- Introduce checklists for design and proofing to reduce rework, track projects, and increase accuracy