

## INSYS GROUP CASE STUDY: Pharma ERP Labeling



### INSYS Specialized Skillsets

Workflow Design

ERP Integration

Manufacturing Process  
Management

Quality Assurance

Regulatory Compliance

### Introduction

**No aspect of business today is subject to more governmental regulation** than the development, manufacture, approval, sale and marketing of pharmaceuticals.

Products that customers rely on for their well-being have to be right. At present, the pharmaceutical industry is experiencing declining profits because of increased competition from generic brands and errors within the manufacturing process. In order to improve this situation, many pharmaceutical companies are attempting to increase efficiency by optimizing their resources, controlling inventory and reducing waste and errors. Pharmaceutical companies generally rely on ERP software to help them meet the highest standards of efficiency, traceability and quality assurance.

### Business Challenges

**Recent changes in federal regulations require pharmaceutical companies to provide more granular product labeling.** Besides the benefit of simplified dosage instructions, improved product labeling may make it easier to identify manufacturing defects. Our client is a global pharmaceutical and consumer products company that was challenged to find a solution to reform package labeling world-wide. It wanted to address the new regulations as well as help with the identification of defects in product manufacturing.

### Solution

**INSYS Group was engaged to develop a workflow** that would integrate labeling software with an existing SAP system that could serialize the package coding and labeling scheme. This would let the company improve regulatory compliance and reduce risk by making it easier to identify manufacturing defects on a lot-number basis.

### Benefits

**The labeling workflow helped the company improve its compliance** with industry and government regulations, increase traceability and integrate quality control and product safety document management.

### **Why INSYS Group**

**INSYS Group's Pharma and Biotech practice develops workflows that result in the kind of thorough, complete documentation** that addresses the demands of both internal compliance specialists and regulators throughout the world.

On this engagement, the INSYS team included senior-level business and product manufacturing professionals with experience developing work flows related to assembly, tracking and documentation for product packaging, as well as integration with ERP and supply chain systems. Since initiating the project, INSYS Group has been engaged to provide additional workflow and integration services throughout the company's global marketplace.

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