



# Prescription for Paperwork

## *CTG develops intranet-based document management system for pharmaceutical manufacturer*

### **Business Background**

In an industry where the rapid introduction of new and revised products is critical, a pharmaceutical manufacturer realized it needed to respond more rapidly to market-driven product changes and ensure consistent first-time quality. To achieve that goal, the company identified the need to improve documentation approval and distribution procedures so as to minimize the cycle time between a product change request and the first production batch. In addition, the firm's growth strategy called for the acquisition of new production facilities, each with its own business processes and document formats.

The development of a single, automated process for effectively managing production specifications, procedures, and vital support documentation was critical to the company's ability to achieve these goals. It asked CTG to help it implement such a process.

### **Business Objectives**

Regulatory management, manufacturing, packaging, and logistics all required immediate access to documents—specifications, directions, procedures, job-aides, and artwork—to meet the higher production volumes demanded by a growing multinational consumer base. The rapid proliferation of new products, as well as variations within product families, further complicated the control and dissemination of that crucial documentation.

The answer? A document management solution capable of meeting the needs of our client's international, multiproduct supply chain. The solution had to accommodate document creation, version control, and timely release to the production environment. It also had to be an easy-to-use system that would be readily available, auditable, and cost-effective.

### **The CTG Solution**

CTG business and technology experts worked with our client's Steering Committee, Core Development Team, and individual users to meet the document management challenge. The client team, supported by CTG analysts, reengineered supply chain document templates and workflows and implemented a technology solution—the Pharmaceutical Technical Specifications System (PTSS)—that provides immediate online access to documentation plus electronic routing for review and approval.

In developing the new system, business needs drove technology requirements. While documents have to be delivered to a production facility quickly, the appropriate security and approval processes must also be followed. Implementing online workflow and self-correcting, replicated remote-site storage schemes delivers rapid access. At the same time, consistent workflow processes for document creation, modification, approval, and release support regulatory compliance.



PTSS enables consistent, data-oriented documentation to be used in all the client's manufacturing sites. This common approach facilitates the exchange of information and allows products to be manufactured at multiple sites.

The technology solution supports an important business strategy—manufacturing flexibility. In the future, the company can consider bulk manufacturing at one site, with finished product being packaged at a second site. In addition, contract manufacturers can easily be supplied with the appropriate electronic documentation to add capacity efficiently as it is needed.

PTSS supplies online documentation for every production activity. When evaluating the impact of a change, users can identify all the product variations where a document is used to ensure that consistent specifications will prevail throughout the corporation. Whether it's procedural documentation or product specifications, the right information can be delivered when it's needed to keep the production process efficient, profitable, and regulatory-compliant.

A key feature of the system is the ability to link information across multiple sites while restricting access to each document to the appropriate personnel. This allows for consolidation and consequent reduction in the number of system documents and processes that need be maintained. Other benefits include reduced printing costs and a quick, consistent methodology for updating documentation across a wide geographical area.

## Business Benefits

The CTG solution is fast, inexpensive, and adaptable to any business environment. It offers:

- Immediate, worldwide access to current data via an easy-to-use interface
- Centralized document storage and management
- Easy access for updating and maintenance, with consistent version control for content and updates
- Controlled, adaptable, yet easily maintainable workflow, with fully 21-CFR-11-compliant change control
- Improved audit capabilities
- Rapid development time
- Low development and implementation costs
- Reduced documentation, printing, and data collection costs

CTG's use of the company intranet for document management control leverages the client's existing infrastructure to quickly and effectively communicate the most current information across a wide geographic location. The system's extensive capabilities, along with its consistent, intuitive interface, have resulted in easy validation, efficient rollout across multiple sites, and high acceptance at the plant and corporate levels.

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*Backed by 37 years' experience, CTG provides IT staffing, application management outsourcing, consulting, and software development and integration solutions to help Global 2000 clients focus on their core businesses and use IT as a competitive advantage to excel in their markets. CTG combines in-depth understanding of our clients' businesses with a full range of integrated services and proprietary ISO 9001:2000-certified service methodologies. Our 2,800 IT professionals based in an international network of offices in North America and Europe have a proven track record of delivering solutions that work.*

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