



Compliance Support

A multinational medical device business turns to SDI Global Services to improve its compliance documentation.

CUSTOMER PROFILE

Fortune 100 medical device company with customer contact centers worldwide

THE CHALLENGE

The company needed to consistently meet FDA and other regulatory requirements for document and information control, validation and verification

THE APPROACH

Develop information products that would transform the company's customer information and reduce the likelihood of rejection by regulatory entities.

THE SOLUTION

Provide a synchronized, single-source system to produce consistent and compatible information across all deliverables.

THE RESULTS

The single-source content management system allowed consistent information products to be developed for multiple uses, such as documentation, marketing communications and eLearning.

BACKGROUND

Our Client engaged SDI Global Services to assess their current methods for producing product documentation and associated training materials. This environment consisted of two different departments (Documentation and Training) which acted independently to create, manage and deliver critical information and instructional products which needed to also be submitted for regulatory review and approval.

While collaborating in regard to their development activities, each department used authoring tools, databases and delivery methods which were highly prone to error and misinterpretation, causing rejection and delay by regulatory agencies.

SOLUTION

SDI GS consultants recommended an approach which would provide more effective control over information at a granular level by employing a DITA XML topic mapping and management publishing system. This type of system enabled "single source" management of information at the topic level. This increased the reusability of topic elements, allowing customer documentation and training materials to be created from a "common source", in accordance with best practices for usability, efficiency and the economies of reuse.

RESULTS & BENEFITS

- Provided customers with the information and training they need to get up and running quickly and use the product effectively
- Enhanced the client's brand, by presenting a common look- and-feel and by positioning client as a company that is easy to do business with
- Eliminated the need for the client's technical support functions to create their own product documentation
- Provided consistency and completeness among the product documents and the training materials
- Significant reduction in redundancy, costs and development time
- Increased accuracy across all products and subsequent upgraded versions

PROJECT HIGHLIGHTS

- Reduced the likelihood of regulatory rejection and delay to market
- Reduced their customers' dependence on technical support
- Service personnel could now develop product documentation and information products using a single source content management system
- Produced the following documentation and training products:
 - Quick reference guides
 - System operations manuals
 - Getting started guides
 - End-user and administration guides
 - Web-based training (WBT)
 - Mobile learning (M-Learning)
 - Marketing video ads and Event Posters

Client feedback

"This methodology reduced the time our team took to complete the original documentation and especially shortened update time when the product was changed. "

"By implementing a defined workflow process, the projects experienced a significant reduction in redundancy, costs and development time. "

