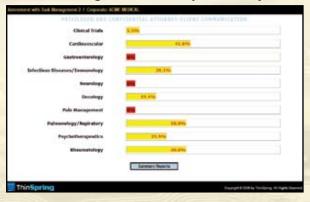


# XML Sage<sup>™</sup>

# Audit & Compliance Management in Regulated Industries

The path from product discovery to its actual delivery to the market is often long and costly, taking on an average of 15 years of research and development and requires a considerable investment before approval is obtained from the regulatory agency. In parallel to this process, the company is ramping up for both approved product production and that product's associated marketing campaign. The estimated cost for each day of delay in delivering a new product to market is in the millions.

## XML Sage Status Roll-up Summary



## **Key Features**

- Quality Systems and Process Management
- Product Lifecycle Management
- Tracking and management of costly Auditing and Validation activities
- Tracking of Clinical Trail activities, trail approval status, qualified sites and resources
- Product Information Labeling and Labeling Submissions Management
- Business Continuity Management

Hand-in-hand with this product development process are the intense business and regulatory compliance demands that must be adhered to, in order to mitigate any non-compliance conditions to help ensure the timely release to market for any new product, as well as, existing product lines.

# **Industry Challenges**

Every company in a regulated industry has the ultimate goal to produce a safe, reliable, and effective products. We at ThinSpring acknowledge that a certain level of reliance is placed on product and service providers that thoroughly understand the technical constraints and requirements of product development and release processes, including the designing, implementing, validating and sustaining of compliant support systems. Included in this challenge is the management of global quality initiatives that drive continual improvements throughout the enterprise.

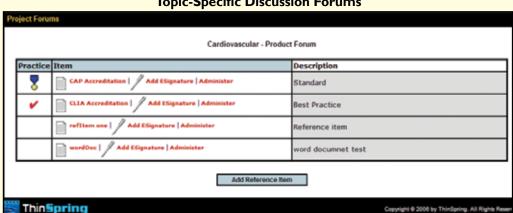


# **Solutions for Software Auditing and Regulatory Compliance**

At ThinSpring, we understand that compliance activities do not exist in a vacuum and that they can substantially impact your company's core business processes. To help your company meet these challenges ThinSpring has developed the fully-web based XML Sage™ Modular Software Application Suite that is deployed from a centralized location, but available to members of your company's multinational teams. This worldwide accessibility helps promote quality throughout the enterprise by allowing the management of multiple initiatives that can be continuously monitored and proactively improve the quality process.

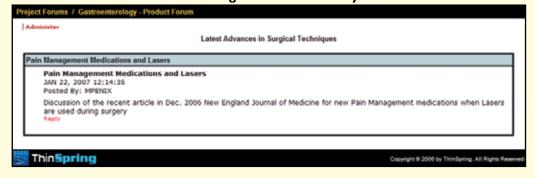
The XML Sage™ Modular Software Application Suite, is an XML based software product, developed to provide an information infrastructure that supports both your drive for operational excellence and your need for accurate, timely compliance to agency regulations or business process need. Flexibility and scalability are at the heart of any XML Sage™ modular solution. XML Sage meets stringent regulatory demands in a secure, role based, password encrypted web-based environment that provides a true enterprise approach to solutions for software auditing and regulatory compliance.

Easily configurable, the XML Sage™ Modular Software Application Suite provides business process solutions that are easily modified to incorporate your specific terminology, workflow, and business rules. As the dynamics of your industry changes, you'll be assured to know that, when and if you need it, the scalability of the Modular Software Application Suite will allow you to easily change your solution to meet the continually advancing requirements around the specialized business needs of your operational processes. Offering a complete collaborative environment, the XML Sage™ Modular Software Application Suite delivers a powerful, interactive knowledge sharing tool that supports open communication on a global level, allowing your multi-national team to exchange ideas, share valuable knowledge and address tasks or activities all accessible through their local browser.



**Topic-Specific Discussion Forums** 

#### XML Sage Reference Library



#### www.thinspring.com

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