

Managing Projects for Regulatory Compliance

by Allan McNaughton

Standards and regulations exist for a reason. They set a minimum level of quality and ensure accountability is present in crucial business processes. Even if regulatory compliance is not required by government agencies, competitive pressures may warrant the adoption of industry standard quality programs. Meeting these challenges is not optional — it is often required for business survival.

No aspect of a business remains untouched. Sweeping rulings such as Sarbanes-Oxley can send managers searching for better ways to manage business processes. Widely accepted quality standards such as ISO 9000:2000 lead to similar challenges as old systems fall by the wayside. Furthermore, businesses that participate in the intensely regulated health care industry face even greater challenges as they must also abide by stringent rulings of the Food and Drug Administration (FDA).

Process Management

Project managers have long relied on tools to help them do their jobs, but have lacked effective solutions for process management. A typical project management cycle involves a “one time pass” through a task list to prepare effort estimates and resource assignments. Project management tools are designed to handle the scheduling and interdependencies of these tasks.

While project management tools help managers plan business activities, they do not ensure business processes are followed. Organizations have generally relied on documenting processes, establishing

principles and rules, and then requiring their people to follow these guidelines. If the business environment never changed, this approach would be sufficient because a process could be set up to meet compliance requirements and then be left to run.

In today’s fast moving business environment it is likely that processes will be constantly changing due to factors both within and outside of an organization’s control. This can challenge the organization as manually implemented processes are difficult to update. Effectively managing and tracking ever changing processes is a large part of what standards and regulations bodies require.

Effective Tools

Attempts to streamline the management of business processes have resulted in a proliferation of custom applications, each designed to guide people through processes they may not fully understand. Although these applications may solve the problem at hand, they lack the flexibility to be applied quickly and easily to new situations. Instead of expensive one-off solutions, organizations should seek more adaptable tools that

can aid in the automation of business processes and provide the rigorous change management that standards and regulations often require.

When searching for tools to better manage business processes one should look for the following qualities:

- Can manage and track any business process.
- Provides insight into the activities and documents that support a process.
- Maintains accurate historical records of who changed what and when.
- Fulfills even the most rigorous audit trail requirements.
- Limits record access to only those users that should have it.
- Can be deployed on multiple platforms to expedite adoption.
- Integrates with other systems to maximize the value of the information collected.

Fulfilling these requirements is simple using Seapine Software’s Seapine CM. The suite consists of TestTrack Pro, a tool that can manage and track the activities of any business process, and Surround SCM, a product that integrates with TestTrack Pro to manage and track changes to the documents that support a process.

The uses for TestTrack Pro and Surround SCM are virtually unlimited. Managers can track changes to policies and procedures. Business analysts can track the authoring,

review and approval phases of requirements documents. IT can manage change requests and project plans. And, of course, developers and testers can manage specifications, product issues and software releases. Seapine CM not only helps organizations better manage business processes, it also aids regulatory and standards compliance.

Built for the Task

Tools for managing and tracking business processes do little good if they are not used. Seapine CM offers just the right mix of features with the simplicity to entice even the most recalcitrant user to participate in process improvement efforts.

Process Neutral

Organizations can easily customize Seapine CM to support their unique business processes. TestTrack Pro's powerful workflow engine easily tracks the states, events, and transitions of any business process. The complexity of a workflow is dependent on the complexity of the business process itself. Simple processes may only require a few steps while more complex processes may include assignments of a single task to multiple team members and require additional sign off steps.

The flexibility offered by Seapine CM gives organizations the ability to implement most any workflow, including those that require additional levels of management

authorization for changes and approvals (e.g., Sarbanes-Oxley).

TestTrack Pro can be further customized to support a business process by renaming field labels to match process terminology or collecting additional data fields that are unique to the process. For example, a medical devices company seeking FDA 510K certification could rename the Custom Fields tab to Compliance Details and use it to track compliance-related issues. Additional process-specific fields can be added as needs change.

When properly employed Seapine CM strengthens business processes by ensuring no activity is left untracked. Implementation activities can be driven using issues in TestTrack Pro. Supporting documents can be version managed in Surround. With these tools, issues that used to fall through the cracks are now assigned to team members who are responsible for moving them through the workflow.

Information Access

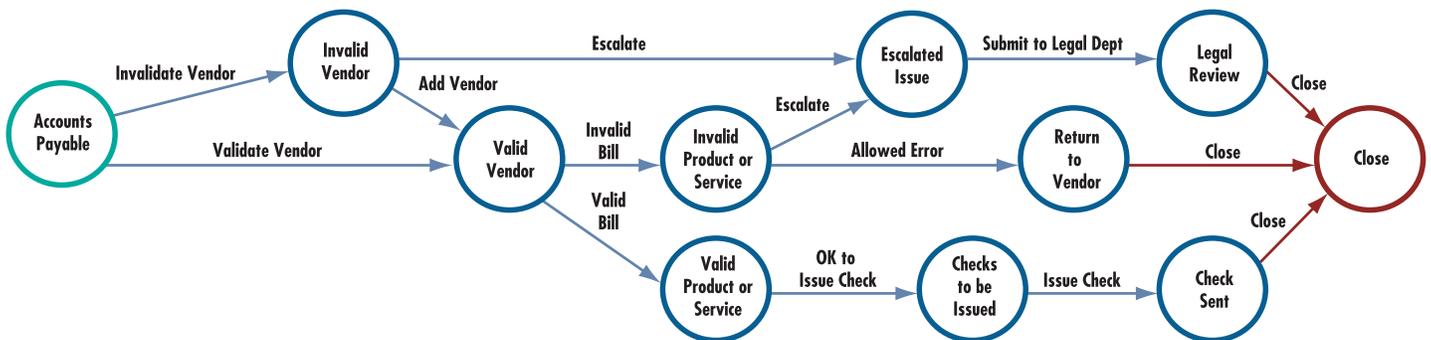
Managers will find Seapine CM quickly becomes a veritable storehouse of valuable information. As Seapine CM manages business process issues and their supporting documents, a detailed historical record of how a process unfolded is automatically created. Seapine CM makes searching through these records for crucial information virtually effortless.

TestTrack Pro's customizable filters allow users to sift through thousands of issues to find only those that meet their criteria. These results can be fed into TestTrack Pro's reporting engine, which sorts the data as required and generates either summary or detailed reports. Users can also examine the historical details of an issue to see what state the issue is in and how it got there. To further simplify information retrieval, issues in TestTrack Pro can be directly linked with their supporting documents in Surround.

In addition to pulling information from Seapine CM, users can also have it pushed directly to their email inbox. TestTrack Pro contains a robust email notification system that lets users receive updates when certain conditions occur. For example, the project manager may want notifications when new issues arrive. Users may also find it helpful to receive email updates when issues are assigned to them or when issues they filed progress through the workflow. Likewise, users can receive email notifications when changes are made to documents that are under the control of Surround.

Compliance Ready

Seapine CM streamlines compliance efforts by providing the detailed historical records that regulations and standards require. This information gives auditors the ability to walk back in time and enables them to understand the subtle implementation



Sample workflow diagram

Summary	Vendor	Description	Severity	Priority	Type	Status
Snow removal service	Johnny's Landscaping	\$ 1,250 - 1/23/2004 Removal	Level 2	Regular	Routine Maintenance	Valid Product or Service, not assigned
Special accounting services	ABC Accounting	\$2,334.50 fee for special accounting consultation	Level 1	Heat Treat	Regular Fees	Accounts Payable, not assigned
Weekly cleaning	William's Cleaning Service	\$585 weekly cleaning week ending 1/12/2004	Level 3	Regular	Regular Fees	Valid Vendor, not assigned

Robust reporting system

details of a business process. For especially demanding regulations, such as FDA ruling 21 CFR Part 11, Seapine CM's audit trails conveniently capture the who, what, and how of issues and documents that have changed.

With Seapine CM's accurate historical records there is no doubt about which user was responsible for making a change. Each time an issue or document is updated identifying user information and the time of modification are attached. TestTrack Pro also supports electronic signatures, which can be used to ensure users sign off on each change to an issue. When an issue is created, modified or deleted the user is prompted to enter their credentials along with a reason for making the change. If the user's credentials are not validated by TestTrack Pro within a certain number of tries, the user is automatically logged out.

Numerous security layers control who uses Seapine CM and how they use it. No change can take place without a user successfully logging into TestTrack Pro or Surround using his unique user name and password. Once logged in, record security limits the issues and documents that are visible based on the security group to which the user belongs. Within the records that are visible to a group, command security restricts users to specific commands, and for TestTrack Pro, field security controls who can enter or edit issue field data.

IT Friendly

Seapine CM is easy to install and requires minimal administration. TestTrack Pro and Surround SCM each use a single server that can concurrently manage multiple issue databases and document repositories, respectively. Issues databases can be as simple or complex as requirements dictate. One database might be used to track compliance issues against a single product while another might be used to track the entire development process. Likewise, Surround's repositories can contain any number or size of supporting documents arranged in whatever hierarchy an organization desires.

Users can access TestTrack Pro through its Web interface or with a client application that runs on Windows, Solaris, Linux or Mac OS X. Surround users can access their document repositories through a similar multi-platform client, or by taking advantage of Surround's integration with leading IDEs (integrated development environments).

Seapine CM works well with other systems. TestTrack Pro offers a SOAP API that supports user-level TestTrack Pro operations such as running queries and adding, deleting or modifying issues. Say you want to implement a business process that escalates an issue's priority after 30 days of inactivity. Using the SOAP API, you can write a script to execute a TestTrack Pro

query, iterate through the results and update each record accordingly. Another way to leverage TestTrack Pro is to export its issue database as an XML document, which can be imported into another application.

Seamless two-way integration between Surround and TestTrack Pro lets users manage an issue's supporting documents from TestTrack Pro. It also integrates with other tools via a command line interface, so scripts and other applications have easy access to its change management capabilities.

Take Control

The challenge of achieving regulatory and standards compliance requires organizations to faithfully follow well thought-out business processes. Seapine CM provides a flexible and easy-to-use set of tools to ensure even the most complex processes are appropriately managed and tracked. Using this information organizations gain exceptional visibility into their business so they can ensure compliance requirements are properly addressed throughout a project's lifecycle.

About the Author

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