QUMAS Whitepaper Series: Streamlining and Accelerating Change Control In Today's Complex Life Sciences Organizations.
Executive Summary
In today's highly regulated life sciences environment, organizations face a myriad of regulations and regulators, affecting all aspects of the enterprise. One area coming under increased regulatory scrutiny is change control: the ability to manage deviations to established policies and procedures in a way that is efficient, timely and compliant.

This paper examines why it is absolutely vital for organizations to take a comprehensive, closed-loop approach to automating change management, spanning all areas of the organization and extending throughout the product lifecycle. The key attributes of an effective solution are described including:

- A single point of visibility and control for the enterprise
- Flexible configuration to meet unique country, department, and site needs
- Robust integration with key business and product lifecycle systems
- A closed loop approach to monitoring and validating change control
- Automated workflow processes that streamline the completion of change management tasks.

This overview is followed by a discussion of the core technology components, human expertise and best practices that are required to deliver these capabilities.

Big Challenges Require Innovative Solutions
Change control is collaborative, iterative and labor-intensive. For any specific change event, multiple users are required to follow a prescribed set of tasks and processes, which need to be carried out in a defined sequence and are subject to multiple stages of review and approval. It's very easy to lose track of where you are in the process, what actions need to be completed next, who owns them, and when they are due. Yet the consequences of such lapses – for example, missed compliance deadlines or steep regulatory penalties – can be very costly.

A comprehensive change control solution will address this challenge by delivering automated workflow processes that drive the full and timely completion of change control tasks in an efficient and cost-effective way. In turn, an organization is in a much better position to enhance compliance health across the enterprise, streamline processes and cycle times for managing change, and reduce solution total cost of ownership (TCO).

The Challenge: Effectively managing change
The essence of compliance is to “Say what you’ll do,” by developing clear policies and procedures for running your organization and then to “Do what you say” by following and enforcing them in day-to-day operations. Yet, in complex environments, there inevitably will be deviations – both planned and unplanned – from the prescribed ways of doing things. Changes can occur for all kinds of reasons, including introducing new equipment and process improvements, consolidating facilities to achieve cost efficiencies, or developing new methods based on scientific discovery.
However valid or compelling the reason for a change, it must be recognized that changing a process, a piece of equipment, or a document can have unforeseen and undesirable consequences, potentially resulting in non-compliance, increased operational costs, and/or legal liability. In fact, like the ripples in a pond, a change can reverberate throughout the entire organization. For example, the seemingly straightforward act of adding a piece of equipment to the factory floor has implications far beyond the manufacturing group. Invariably, there is software that must be evaluated by IT and Quality. Employees must be trained to support the equipment. Fluid outputs need to be analyzed by Environmental Health and Safety. Finance wants to know the details of the purchase. Legal is involved in the contract review, and Accounting must calculate when the equipment will reach end of life and be retired.

**Change control defined**
A robust and compliant change control mechanism allows an organization to greatly reduce the risks and costs of such far-reaching changes. At its most basic, a change control system provides a prescribed sets of documents – including policies, procedures and protocols – that tell the organization exactly how to manage changes, from inception to closure. It puts methods in place to assess the full impact of a proposed change beforehand, to monitor and enforce prescribed change procedures across the organization, and to report up through the management chain.

**Today’s reality: Change management “silos”**
Due to the inherent complexity of life sciences environments most now handle it in a very siloed manner. It is common for different sites, departments and lines of business to employ disparate change control systems and methodologies. As many as 80 percent of these systems are paper-based. Others are partially automated, with data captured in Excel spreadsheets. Yet others are fully automated. There is little or no integration between or among all these change control systems and only limited integration with key business systems that touch on change control such as ERP, contact management, and content management.

As a result of these shortcomings, senior management lacks a true enterprise view of change control. There is poor or inconsistent enforcement of change control processes. Furthermore, a fragmented change control regimen makes it difficult, costly and time-consuming to track performance or measure progress against plans.

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*An effective change management solution interfaces with key business systems in a robust, transparent and bi-directional manner, without requiring costly one-to-one integrations.*
The Vision: A single point of visibility, with multiple location oversight

A true enterprise solution provides the organization with a single point of visibility and control for change management across all countries, departments, and sites. At the highest level, it allows an organization to apply a common set of enterprise standards, rules and requirements built around compliance saying, “This is how we will manage change control. These are the people responsible for initiating, approving and closing events. This is how we’ll make certain all change control actions are routed to the appropriate individuals or escalated when required. This is how we will track and report change control activities for business management and compliance purposes.”

At the same time, what works in one country or department will not necessarily work elsewhere. For this reason, it is critical that a solution not be so rigid or restrictive that all rules and standards must be applied globally. Rather, there should be sufficient flexibility to configure and modify the system for individual countries and departments, on a factory-by-factory basis, or even down to individual roles within a factory.

Change management should be comprehensive

People often think of change control as pertaining only to manufacturing, but as discussed earlier, it touches all corners of the organization. Consistent with this reality, an enterprise solution must encompass all departments and systems affected by regulatory compliance. This universe may include:
- Pre-clinical and clinical
- Regulatory
- Manufacturing
- Sales, marketing, legal and accounting
- IT systems and networks (both hardware and software)
- Document control
- Facilities

Additionally, change control must be viewed as spanning the complete product lifecycle, from acquisition planning to retirement. Changes need to be proactively tracked and managed, starting well before a new piece of manufacturing equipment is installed, new software is deployed, a policy is rolled out, or a new supplier is brought on board. When a whole new facility is being planned, change control may need to be instituted years before construction begins. Subsequent modifications, updates and enhancements to all these elements are captured and monitored until the time a specific process element is retired, or even beyond, if compliance requires it.
Integration with key business systems is paramount
Life sciences organizations have invested heavily to create diverse “systems of record,” designed to serve as authoritative and up-to-date sources of data in key areas. These systems may include ERP, the employee directory, customer and vendor contact management, content management, product data management, finance and many more.

An important aspect of an effective change management solution is its ability to interface with these business systems in a robust, transparent and bi-directional manner without requiring costly one-to-one integrations. Instead, web services technology can be employed so that business systems continually update the change control system without requiring human intervention and, conversely, the change control system can update these same systems to reflect the latest change control activities. This capability helps ensure that change control processes move forward on a fully automated and compliant basis and that users across the organization always have a complete and current view of change management activities.

A closed loop system is essential for audit and compliance
The concept of a closed loop system is becoming more and more important to regulators and chief compliance officers. From a compliance perspective, it is no longer sufficient to simply define appropriate procedures for change control. An organization must also have automated methods to comprehensively monitor and audit all the change management activities related to a specific event, validate that the prescribed tasks were indeed completed and closed, and aggregate all the related change control data. This capability is critical for monitoring the compliance health of an organization at the local, departmental, enterprise and global level.
An effective change control system can greatly reduce the number of “false positives” an organization experiences in its CAPA process – completed events that have been closed but are incorrectly reported as open.

However, it is impossible to fully achieve with paper-based or partially automated systems. Change management activities are too numerous, complex and branching – and reach into too many areas of the organization – to systematically track all those activities to closure using manual methods or disparate systems.

What's required instead is a single resource for initiating change control tasks, monitoring the status of change control across the enterprise, and documenting all aspects of change control including tasks, processes, enforcement, correspondence, amendments and so forth.

**Automated workflow processes dramatically streamline change control**

A comprehensive change control solution delivers automated workflow processes that drive the full and timely completion of a myriad of change control tasks. Workflow management typically combines a forms-based application for capturing user inputs and automated workflow routing that delivers communications to the appropriate individuals. Reflecting best practices, the system should provide a great deal of what’s needed right out of the box while being highly configurable so workflows can be tailored and refined to meet the organization’s unique and evolving needs.

**Workflow management capabilities should allow an organization to:**

- Provide a mechanism for required stakeholders to offer their input on proposed and ongoing change events.
- Notify individuals of change control tasks they are responsible for completing, with due dates automatically calibrated based on when the notice was received.
- Send reminders when deadlines are approaching or have already passed.
- When a task is completed, automatically initiate the prescribed next steps, for example routing a revised document to all the appropriate reviewers.
- Issue flags and alerts when a potential problem is spotted.
- Escalate events requiring urgent action.

Regardless of whether the change is being made to hardware, software, the manufacturing line or an SOP, an enterprise solution will provide all users with a common framework, consistent change control processes and a consistent user experience – with the result that change control is properly used and well understood within the organization.
Straightforward validation yields significant compliance savings
When enhancements are made to an existing change control system that was previously validated, the change often triggers the need to revalidate the system. This can be an enormously costly and time-consuming process – sometimes stretching over months and requiring the services of expensive application development resources. Revalidation is a hidden cost that a vendor is likely to downplay and a customer may not discover until it's too late to avoid. One common side effect is to delay needed enhancements to the change control environment because such enhancements simply aren't affordable relative to the benefits they confer. To avoid this conundrum, an organization should look for a platform that allows policies and processes to be easily changed by configuring the software rather than requiring it to be customized by a developer. Furthermore, software that is based on configuration makes it possible to deliver pre-defined validation scripts that can reduce validation times from months down to weeks or even days. Streamlining the validation process not only enables timely, cost-effective compliance, it also removes a significant barrier to continually and iteratively improving the change control environment to support evolving needs.

A User Scenario: “Closing the loop” by reporting changes to controlled documentation
One small example illustrates the value that comes from “closing the loop” in today’s highly complex change management environments.

In manufacturing plants that rely on a paper-based or partially automated change control system, it often happens that corrective and preventive actions (CAPAs) are initiated and completed but are not actually documented in the change control system as being “closed”. As a result, auditors looking at a plant’s open CAPAs may find dozens or even hundreds of deviations that appear to be open when, in fact, many of them should be marked as closed.

These unclosed CAPAs – which are the equivalent of a “false positive” in medicine – can create an erroneous impression that the manufacturer is not managing deviations in a timely way. They require staff members to scramble to document the events that have been closed, pulling people away from other duties. Furthermore, a failure to formally close CAPAs that have been completed can also lead to regulatory fines.

It is estimated that 80 percent of all CAPAs involve some kind of change to documentation – for example revisions to standard operating procedures (SOPs) – and failing to close the loop around document revision is one source of such false positives. Frequently, documentation is revised and approved and the new version is released within the document management system (DMS), yet that fact is not reported back to the change control environment. The result is that the sub-task of revising the documentation cannot be closed within the CAPA process; any sub-tasks that are dependent on the revised documentation cannot proceed; and the CAPA itself cannot be closed, even if all other required activities have actually been completed.

To achieve an encompassing vision for enterprise-wide change control, it is essential to have both the right technology and the right expertise in place. If either is missing, the potential for delays, missteps and failure is very high.
This common scenario can be eliminated by closing the loop between the change control environment and the DMS. With a robust interface in place, the two systems can “talk” to each other at critical junctures, without requiring human intervention. For example, once an SOP has been duly revised, reviewed and approved, the release of the new SOP version can trigger an automatic notification from the document management system to the change control system. This allows the document revision sub-task to be closed and the CAPA process to move ahead to subsequent steps, such as ensuring users are trained on the new procedure. When this one small capability is multiplied across hundreds or thousands of CAPAs a year, it is clear to see that significant time and dollar savings can be achieved by speeding up the change management process, reducing staff time spent following the “paper trail” for CAPAs, and allowing a greater percentage of CAPAs to be closed in a timely way.

Requirements: Putting the pieces together

A purpose-built and fully integrated platform is certainly one of the keys to effective change control. Core solution components should include:

- A robust workflow engine for automating change control processes
- A flexible and well-proven forms manager for capturing data on change control activities
- A data dictionary that allows data elements to be reused across multiple processes
- Interactive process instances that enable change control to transparently query and load current data from other business systems
- A highly configurable business rules engine for defining how the system will behave when alerts or flags are raised or user-defined thresholds are reached.

The system should provide a single, unified point of access for both the process workflows and controlled documents. The ability to interconnect disparate systems through mechanisms such as a Web services API enables systems to seamlessly communicate, thus facilitating lifecycle change control across the organization.

Ensuring fast, affordable scalability

In addition to these elements, an enterprise class solution will be scalable and web based. It can be deployed to support anywhere from a handful of users to tens of thousands, using the same system and code. When new processes are introduced, they can be validated in a matter of hours – not days or weeks, as some systems require. In today’s virtual world, where responsibilities are often distributed among different entities, the system manage change collaboratively across multiple sites, divisions and geographies – even involving multiple companies.

By implementing a consolidated approach to change control, life sciences organizations are in a strong position to enforce consistency, eliminate duplication of effort and gain complete visibility across all changes.
Providing simple yet flexible reporting
To provide immediate insight to management, a change control solution should offer simplified reporting right out of the box, with a series of built-in reports that reflect change control best practices. Straightforward tools enable visualization of data via charts and graphs. Equally important, the system must accommodate the varied reporting needs of different types of life sciences companies. Some organizations will have more of a discovery focus while others have a manufacturing focus; the requirements of a device company will differ from those of a pharmaceuticals maker or a biotech firm. A highly configurable system allows users to “have a conversation with the data,” tailoring reports for different industry segments or departmental needs, and exploring various scenarios in an iterative fashion.

Building in flexibility
It can’t be stated too often that a change control solution must be flexible and configurable. As an organization grows and changes and new regulations emerge, the system must be adaptable to these and other unforeseeable developments. The organization should not have to purchase additional software modules from the vendor, engage in costly development projects, or go through the lengthy and costly process of revalidating the solution.

Implementing best practices through professional services
Because change control touches so many corners of a business, it is imperative to have the right expertise in place. The vendor’s professional services team should demonstrate a deep understanding of change control and compliance in life sciences and have experience mapping and configuring solutions for real-world settings. Proven methods must be in place to perform a gap analysis, thoroughly but rapidly evaluating the current “as is” regimen and defining the desired “to be” state.
Beyond these capabilities, the solution provider must also have a track record for facilitating cross-functional collaboration. One of their key tasks is to bring together stakeholders from disparate “islands of control” – at the corporate, regional, departmental and local level – and build consensus and alignment around how to move towards the desired end state. This collaborative approach helps ensure a workable balance between the high-level need for disciplined compliance with policies and procedures, the local autonomy individual groups require to perform their work on a day-to-day basis, and the need for stakeholders to feel ownership in a solution if it is to achieve wide acceptance. At a more granular level, extensive workflow mapping provides a blueprint for how the solution software will be configured to deliver the defined capabilities. Depending on the complexity of the environment, mapping may be done on a single-site or a multi-site basis. Once the initial configuration is completed and the solution deployed, a committed vendor will often stay on the scene and further fine-tune the system to ensure the client derives maximum benefit.

The Payoff: Enhanced visibility, control and compliance
Organizations that implement an effective, enterprise-wide change control solution can count on achieving far-reaching benefits. The guidance of an expert team can help the organization harness and align change management capabilities to support both strategic and operational goals. With a consolidated approach to change control, organizations can enforce consistency, eliminate duplication of effort, and efficiently manage, monitor and audit change activities across the organization and throughout the product lifecycle. The end results include enhanced compliance health for the enterprise, reduced cycle times and increased operational efficiencies for managing change, and reduced total cost of ownership (TCO).
About QUMAS
QUMAS is the leader in Enterprise Governance, Risk and Compliance (GRC) with more than 250 customer deployments and over a decade of experience helping companies in highly regulated industries provide a proactive regulatory defense. QUMAS solutions for life sciences are designed to achieve compliance with industry and government standards for 21 CFR Part 11, cGxP, Quality, R&D, Regulatory Affairs and Clinical Operations. QUMAS is successfully enabling global life science organizations to proactively manage regulated content and processes thereby reducing costs and improving quality.

QUMAS provides highly configurable applications, ready for validation and deployment within regulated environments. Based on open systems platforms, QUMAS technology integrates seamlessly with existing corporate database, applications, operating systems and hardware from most major vendors.