

The Missing Piece of Effective Change Management

Developing the Right Resources
and Structure



VERISTA

Contents

Documenting Change Can Lead to Increased Risk	3
Benefits of a Centralized Change Management Structure.....	4
Improve Efficiencies and Quality.....	4
Technical Resources Optimize Processes.....	5
Challenges of Implementing a Centralized Model.....	6
Conclusions.....	7

Documenting Change Can Lead to Increased Risk

In all regulated industries, an essential element of change management is documenting process changes in order to prevent unintended consequences to product quality and patient safety. Appropriate personnel within the organization and quality control specialists must document and approve modifications in production procedures and process controls in order to ensure a properly regulated transition between states. To be done effectively, the documentation and audit process should be clear, and ultimately result in a reduced number of audit findings.

While many companies enforce that proper resources are available to review and approve documents, oftentimes not as much planning goes into the execution of the change writing itself. Documentation can be relegated to Subject Matter Experts (SMEs) who are disconnected from the change management process or are unfamiliar with documentation practices. This increase of variability between change documentation can quickly lead to gaps in information and increase the risk of audit findings.

A typical change management process is depicted in Figure 1 below. Dedicated resources are designated throughout the four phases with the aim of improving the success of change management initiatives within an organization. A change manager, in this context, is an individual or group who follows this process to organize and document the change and its corresponding impact.

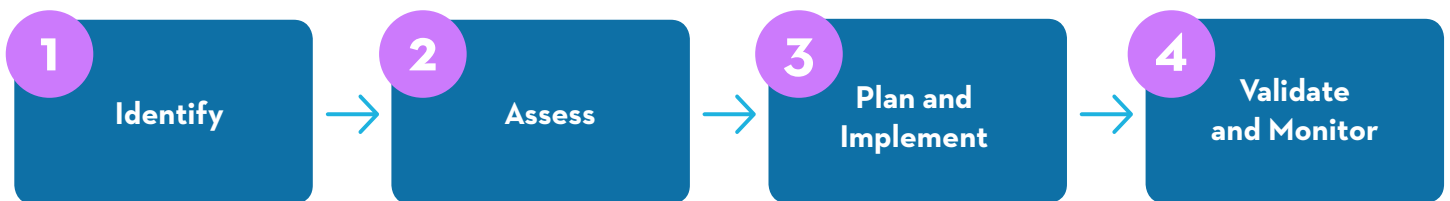


Figure 1: The Change Management Process

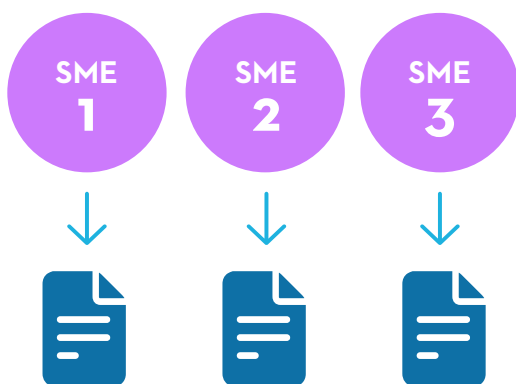


Figure 2: Localized Change Management Structure

In cases where the change management process is relegated to multiple SMEs across different functions (i.e., engineering, information technology, regulatory, logistics, or warehousing), the SMEs must seek out information from other groups as well as their own to assess the full impact of a change (Figure 2). Knowledge is often kept at the team level resulting in more time and effort for each SME to complete a single change control document. In addition, documentation practices often vary from group to group, increasing variability and a higher risk of audit findings.

Benefits of a Centralized Change Management Structure

To overcome these challenges, centralizing the change management function establishes a better and more formalized documentation process (Figure 3). This ensures more consistent and meaningful records. In addition, designating technical resources who are skilled at writing and understand change management provide additional process optimization benefits.

Benefits of a centralized change management team:

- ✓ Standardized documentation practices
- ✓ Improved skillsets due to increased frequency
- ✓ Continual process improvement
- ✓ Centralized impact assessment
- ✓ Long-term knowledge retention

Additional benefits of employing technical resources:

- ✓ Right-size documentation detail
- ✓ Assessment cycle time reduction
- ✓ Built-in project management

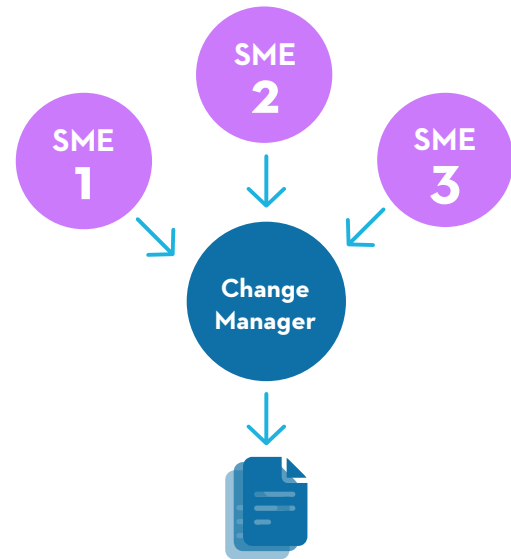


Figure 3: Centralized Change Management Structure

Improve Efficiencies and Quality

Writing, like any organizational or technical discipline, is a process, yet some organizations overlook the details of how to implement proper and effective documentation practices. Company-wide guidelines for how to document activities are often kept high level. While this allows freedom of interpretation and flexibility at a local level, it can lead to groups or individuals developing their own specific styles and interpretations, resulting in large variations from document to document.

Good documentation practices are the foundation of successful change management. By shifting the documentation practices to a centralized individual or group (Figure 3), they can establish a more unified, comprehensive and detailed approach. If an auditor cannot follow or understand the document in front of them, the company is required to further investigate the issue which results in time taken away from the work they need to do. Establishing clear standards for how all documents should be written reduces variability and provides clarity and structure to auditors. If a shortfall is identified during an audit, preventative measures can be identified and immediately applied to all new documentation so there is not a repeat offense.

A centralized function improves documentation output by providing individuals the opportunity to develop their skills because they are overseeing a large number of changes. Since team members repeat these activities, it creates an environment where documentation becomes second nature, allowing them to push the limits of their skillset. This transforms writing from an infrequent and labor intensive process to an everyday, easy task. With this increase in efficiency, fewer managers can be utilized to write more change documents in a shorter amount of time. For area SMEs, documentation activities are often a small and unrelated part of their duties. They may handle only a few changes spread over a long period of time, which requires continual retraining as they relearn processes. These activities do not add direct value to understanding their core work responsibilities, resulting in wasted time and effort. By shifting these activities to a centralized structure, SMEs are able to focus their efforts on their own job function, only providing assessments to change managers in a direct, value-added part of their work responsibilities. Centralizing the writing function increases the number of change control documents any one person sees and allows them to develop and build expertise in that area while identifying patterns and trends.

The ability to identify patterns and trends is one of the most significant benefits to a centralized change management model. Since change managers oversee all four phases of the process (Figure 1), they can quickly establish standard business activities and develop templates to simplify and error-proof their work. For example, the Assess Phase becomes routine and the areas of impact are easier to determine. A critical part of the Plan and Implement Phase is obtaining approval by area managers, yet it can be difficult when changes are different than their current processes. Identifying routine activities and establishing standard practices enables approvers to focus on the unique challenges of the change control, creating a more robust and impactful approval process.

Formalizing the change management process and establishing templates and guidelines for change managers to work from benefits long-term knowledge and skill retention. Where area SMEs tend to work independently, the development and improvement of the documentation process provides a good framework for new change managers to gain the experience and knowledge they need to quickly begin implementing effective change control documents. Instead of each individual needing to gain practical experience in the skill before seeing the benefits, basic and routine training can be used to onboard new members and ensure the same quality standards are met. This means that a change in personnel does not leave a business open to increased risk of audit findings and will maintain high documentation quality.

Technical Resources Optimize Processes

While centralizing the change management process improves the efficiency of documentation, allocating technical resources is essential to optimizing it. Organizations should select change managers with technical experience for these roles in order to tap into the full potential of a centralized change management system.

During the Assess Phase (Figure 1), area SMEs often have conflicting information and outlooks. When a writer does not understand the area of impact, one of two things can occur. Either the writer leaves out crucial information because they do not understand the impact, or they add every detail to the change control regardless of whether it is relevant or not. Both scenarios leave the change document open to increased scrutiny from regulatory auditors. Successful documentation includes all pertinent activities while still remaining on topic and focused. A change manager with technical expertise can more easily assess what information is relevant to a change control and ensure that all critical details are documented while preventing the scope of the change to creep beyond its required limits.

Another benefit of having a technical resource as part of the change management process is the ability for the change manager to more accurately assess impact. Before area SMEs are included, a change manager can take a change from the Identify Phase (Figure 1) and pre-determine much of the impact before the Assess Phase. This reduces the cycle time once area SMEs are incorporated into the process to ensure all impact is captured. A change manager with technical experience will be able to guide the assessment process to understand how parts of the system fit together and help each area SME better assess their own impact. Even in the Plan and Implement Phase, change managers are able to help the identified parties understand and complete tasks as they complete their change control, ensuring that work is completed correctly and on time.

In this way, a change manager becomes a central point of reference that can help manage the project from start to finish. This allows an organization to add the function of project scheduling and metrics tracking to the change management area. Change managers can analyze average times to complete activities and incorporate that into the documentation for their plan, providing a more accurate time to implement and help identify areas of continuous improvement. This is often looked at favorably by auditors, as it is a good indication of a controlled change strategy.

Challenges of Implementing a Centralized Model

The biggest challenge in implementing a centralized model for change management is making sure that the appropriate resources are allocated. Depending on the quantity of changes in a given organization, not having enough change managers available could cause an individual to be spread too thinly across too many change activities. Anytime their activities become rushed, errors can occur and cause documentation, or worse, compliance issues. This negates any benefits a centralized structure provides, as these errors will slow the process and potentially leave the organization open to audit findings as work is not completed or documented accurately.

There are several general risks in implementing a centralized function, including relevancy and bureaucracy. If change managers are in charge of several areas that have little or no overlapping impact, they can end up managing and training on information that is not directly relevant to their function. If spread thin enough, this creates a risk of poor documentation or confusion between areas of expertise.

Additionally, groups that are large and have too many areas to consider can quickly become bogged down with excessive bureaucracy which results in complicated verbiage and templates that do not actually simplify the documentation process. To combat an excessively large centralized system, it may be beneficial to split one large, centralized group into a few smaller groups focused on these areas of unique impacts as depicted in Figure 4. General documentation practices can still be shared between individual change management units while maintaining autonomy.

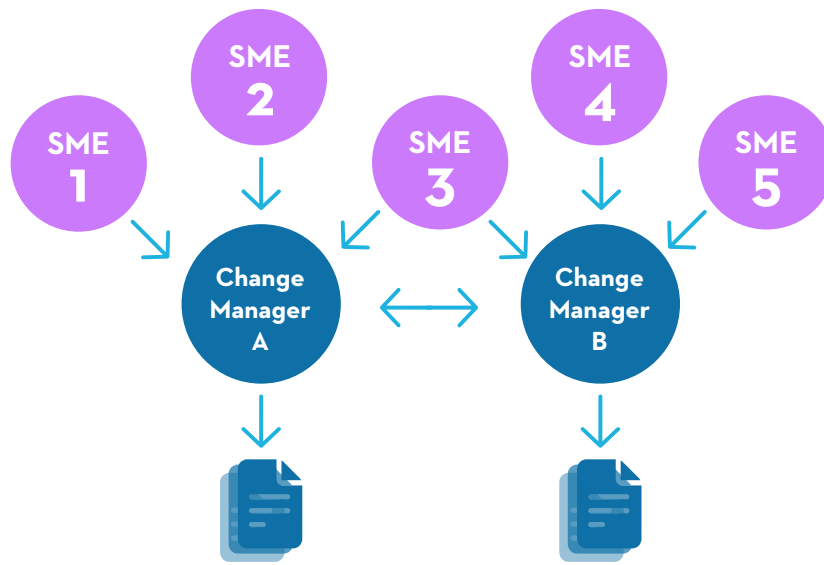


Figure 4: Semi-centralized Change Management Structure

Conclusions

- ✓ Establishing a centralized structure for change management provides numerous benefits to the quality of change documentation.
- ✓ Hiring change managers with technical experience simplifies and expedites the change management process.
- ✓ When a fully centralized change management structure is not possible to implement, a semi-centralized model can still provide an organization with the same benefits.

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