Veeva

WHITE PAPER

Managing Quality Globally

A Practical Guide to Aligning Processes and Content for Greater Collaboration, Easier Governance, and Risk Management

Introduction

Life sciences companies often operate globally whether conducting clinical trials across several countries, or manufacturing and distributing products in multiple regions. Even organizations that start with a limited geographic footprint may eventually depend on the worldwide ecosystem to enter new markets, externalize operations, or make acquisitions.

Global enterprises offer many opportunities, but also pose some challenges. Maintaining global quality oversight and end-to-end control of the value chain, while addressing local market requirements is extremely difficult. Organizations often use multiple systems and processes to manage these functions. These fragmented or regional processes can impede growth and agility, and more importantly, adversely affect quality.

Lack of process alignment can have considerable impact on the business:

- **Limited oversight** – Limited operational oversight on quality metrics, status, and risk. Visibility is only achievable with significant manual effort that is error prone and leads to delays.
- **Lack of agility** – Time consuming quality decisions in product release and investigation activities exacerbate the bottleneck in the overall supply chain.
- **Difficult to collaborate** – Inconsistent local procedures and point IT solutions makes global collaboration across regions or departments difficult and inefficient.
- **Significant operational inefficiencies** – Many hours spent managing and updating documents, as organizations maintain several distinct repositories of regulated documents. For example, when defining and implementing a corrective and preventive action (CAPA) for quality issues, teams spend days or weeks finding and compiling the affected documents and processes.

Streamlining processes and content enable companies to better collaborate across organizations and gain visibility on quality for faster decision-making. This paper provides practical recommendations for implementing a global quality alignment initiative based on the successful harmonization experiences of life sciences companies.

Aligning Quality Processes and Content

It is important to introduce a global governance model to define ownership and common standards. Alignment of processes, nomenclature and content hierarchies are also critical components of the model. Key steps in this process, often called harmonization, include:

- **Standardizing** – Defining and agreeing on terminology, content taxonomy, document templates, and core processes common across different areas of the business.
- **Implementing a single source of truth** – Eliminating, consolidating, and streamlining inconsistent or redundant processes and documents, settling on a single source of truth and a global set of processes
- **Collaborating with key parties** – Sharing information securely and easily across the organization, and with external partners and regulators/auditors.

Gaining Visibility into Quality, Compliance, and Risk

The stakes are high when it comes to quality in regulated industries, especially in life sciences. Inconsistent quality controls in different regions, or gaps in visibility due to fragmented systems, can have serious consequences. Conversely, making a commitment to harmonize processes can increase quality and compliance, and longer-term, result in less regulatory scrutiny.

The FDA, in collaboration with the industry, is developing a quality metric program for risk-based inspections. Standardizing on quality metrics facilitates sharing of information using a common language, and will help regulators separate manufacturing sites with poor performance from those that continuously improve quality. Sites that can clearly demonstrate consistently high quality to regulatory authorities will likely reap the reward of less frequent or faster inspections. Maintaining control and visibility of quality worldwide will also reduce the risk of regulatory actions including warning letters and plant shutdowns.

Staying One Step Ahead

Most of the quality metrics that regulatory authorities are proposing are downstream metrics, lagging indicators that measures outcome. However, this hindsight view is not sufficient to prevent lapses in quality.

Gaining visibility into leading indicators can help predict future outcomes—preventing errors and identifying bottlenecks before the impact becomes significant. Document lifecycle metrics, such as how much time it takes to review and approve a change to a critical standard operating procedure (SOP) and train on it, can warn organizations of future quality discrepancies and compliance risk. Harmonizing the process, allows companies to gain global visibility and compare adoption and performance across regions. Leading life sciences companies are harmonizing as well as combining data with content review processes to track for example, which contract manufacturer (CMO)—on average—takes the longest to address discrepancies during the batch record review process, or compare the number of discrepancies across CMO's. When processes are fragmented, it is hard to see the big picture. Harmonizing metrics and the management of information enable companies to more readily uncover potential issues and areas of risk, and address them proactively.

Key Considerations

There are several key considerations that impact global harmonization initiatives:

Balancing global and local needs

Harmonization requires a global perspective, finding opportunities for consolidation, and reaching an agreement. Balancing local preferences or requirements with global needs can be challenging. Look for ways to establish standard processes with attributes that you can customize or configure for local demand. For example, in Europe the batch documentation, supporting the certification and release process, will likely include an additional 'qualified person' (QP) review step to comply with the European Directive 2001/83/EC.

Providing adequate detail

There is a greater risk of non-compliance with more specificity of instructions. Prescriptive SOPs are often used to mitigate risk from insufficient training. Conversely, the more a procedure is generalized, the easier for a user to meet SOP compliance but variances may have adverse effects on quality. Knowing how the content is used and past performance, if available, will help determine adequate detail for success.

Understanding trade-offs

The pursuit of perfection—such as waiting for industry-standard terminology, or getting agreement on a detailed specification document by every single user—can stall projects and impact cost. Decide which trade-offs are needed while still meeting objectives. With modern cloud technology, prototypes can easily be configured, allowing users to visualize and test new processes—minimizing risk.

Common Pitfalls

The most common mistakes in quality harmonization initiatives are:

- **Insuffieient upfront involvement from stakeholders**
  Initiative driven by only IT or technologists can be a harder sell and have lower adoption.
- **Lack of high-level commitment to objectives and process**
  If the team cannot reach agreement, executive management needs to keep things moving forward.
- **Inadequate communications**
  Invest time and effort in communicating and getting buy-in on the new approach or adoption will suffer.
- **Complex or cumbersome technology**
  Leverage modern applications to facilitate harmonization efforts.

How Technology Supports Harmonization and Governance

Modern cloud solutions built for life sciences allow global and easy access, while supporting strict security and regulatory requirements. These applications have an advanced security model that grants specific privileges—defining what employees and partners can do or see in the system. For example, partners can only upload and see their content, or only certain employees in the QA group can review and accept a batch record for a particular product. Detailed audit trails track all activities at the document and binder (folder) level, including capturing electronic signatures. Companies can easily extend quality processes to partners to accelerate compliance with business and regulated requirements, and facilitate harmonization across internal and external environments.

Harmonization with an effective technology solution simplifies user workflows and facilitates governance. For example, nomenclature rules or accepted values can be built into the application, and advanced solutions can automatically route documents based on a combination of rules such as document type and region.

Next-generation solutions are designed to address multiple areas:

Easier regulated document management

- Support for a common, shared set of document workflows and lifecycles, so the business can work from a single version of the truth
- Common attribute sets with field standardization and global rules for pick list values
- Enhanced global and local document searches that allow for hierarchical search within document structure (related SOPs, for example)

Support global processes with local customization

- Easy configuration of local values
- Multi-language support for user interface, attribute labels, attribute values, document overlays, etc.

Simplify administration and validation

- Streamlined maintenance
- Accelerated validation: Performed IQ/OQ; PQ ready
- Validation support
- Ongoing application support

Promote ease of use

- Intuitive interfaces designed to mimic popular consumer websites
- Ability to prepopulate pull-down attribute menus for easier navigation and consistent data entry
- Integration with training platforms

Enable better governance

- Global visibility and reporting
- Robust audit trail
- Support compliance with 21 CFR Part 11 and EU Annex 11
- Streamlined “read and understood” workflows and reports

Allow global access with flexible security

- Easy accessibility by all parts of the organization, at any time, on any device
- Secure, managed access by external partners
- Restricted view-only access to specific documents for auditors/regulators

User Engagement for Global Buy-in

Inertia, regional preferences, siloed departments and insufficient communication often impede efforts to align content and processes. It is important to gain buy-in from key users or groups, typically requiring an extensive design process with a lengthy user requirement specification document. Recent advances in technology enable agile solutions for rapid prototyping and time to production. Users can see how new processes work in an exploratory environment, making it easier to gather feedback and discuss recommendations as a group. Configurations are quickly and easily modified based on information gained from users seeing and trying the application—accelerating the design and evaluation process, and improving the chances of success.

Done effectively, process and content harmonization pays for itself in operational efficiency, risk reduction, and improved governance and business agility. As the business grows, well-designed and harmonized processes continue to scale and provide value. Life sciences organizations that do not take a global approach will find quality in conflict with business agility and efficiency, and experience unexpected and unmanaged compliance risk.

Five Steps to Aligning Quality

Step One: Define Objectives and Goals

Harmonization projects typically occur after quality management systems (QMS) have grown organically in different regions or departments. Moving to a global and harmonized environment is also complicated by externalized business functions, as partners have their own systems and procedures. Harmonization does not necessarily mean replacing local systems with a single global application—just alignment of processes, procedure, and nomenclature. However, adopting a new solution that accommodates most or all the business requirements is likely easier than integrating, maintaining, and validating multiple systems.

Lack of agreement from the top is one of the most common causes for projects to fail. Getting stakeholder buy-in for objectives and goals helps resolve potential conflicts and serves as a compass for making trade-offs or difficult decisions. For example, if your objective is to gain quality oversight and accelerate quality decisions, the first priority is to give all process participants—internal and external—access to the same information, enabling real-time reporting and visibility into the single source of truth. Even regulatory authorities are showing a greater propensity for alignment, collaborating and sharing information among agencies.

Common quality objectives and harmonization benefits include:

- **Reducing compliance risk** – When processes are globally aligned, companies gain better control into quality and compliance risk across the business addressing problems faster and proactively.
- **Improving quality and operational efficiency** – As businesses grow, quality processes usually become cumbersome. Optimizing quality content and simplifying workflows reduces operational redundancy and training overhead, and often increases process adherence.
- **Technology savings** – Companies that have grown through acquisition frequently maintain and validate multiple systems to support regulated documents and processes. Consolidation frees IT time and budget.
- **Business agility** – Quickly respond to business, market, and regulatory needs such as making informed decisions or applying operational changes under effective global change control. When processes are aligned and streamlined, it is easier to gain visibility, respond, and make operational adjustments.

Linking global quality initiatives to meaningful and measurable business objectives makes it easier to understand and gauge performance. Identify the core processes and associated systems and content to harmonize. Ensuring there are realistic and achievable short-term as well as long-term goals helps demonstrate success and assure continued buy-in.

Step Two: Bring the Right People Together

Quality is a global responsibility and impacts many areas. Build a team based on the goals and target processes, including stakeholders from:

- Business units that are involved with the process and documents
- Quality and compliance team
- Information technology team

Make sure that different geographic regions participate, particularly if there are language and cultural differences. It can be difficult to gain global acceptance for change if people feel their concerns have not been heard. Teams can mitigate this risk by bringing the team together in-person. Invest in workshops—sharing your objectives and setting expectations for participation and collaboration. Communicate the broader vision of how global alignment of content and workflows will solve common problems, make their job easier, and help achieve the company quality goal.

Committing time to let people work on the project, and schedule in-person one-on-one or group meetings to gather feedback on proposals will also help ensure success.

Many companies involve a neutral, third party representative such as a consultant to facilitate the harmonization process. Without a personal stake in how new processes are defined, a neutral party can more easily ask difficult questions or settle disagreements.

Step Three: Create the Global Process Framework

When harmonizing quality, it is important to assess supporting processes and quality documentation such as policies, guidelines, and procedures. Determine which quality processes should be aligned or shared globally. For each relevant process—discuss the supporting organizational structures, process names, attributes, and metrics. You can start from current operations, or work from a template based on common industry practices.

Create a framework that balances global standardization and consolidation with local customization. Avoiding excessive complexity in the global process structure also improves user adoption. The overall framework and workflows should align with the business and be easily understood by internal stakeholders, partners, and regulators or auditors. For example, batch release processes and workflows in Europe may differ from other areas due to EU specifications, requiring additional steps and controls. In this case, you may need to create local workflows that feed more general, global processes.

Step Four: Define Document Structure, Terminology, and Attributes

Once the team has identified the processes, create and define the content structure to support it.

- **Build content and metadata inventory** – Identify the content, content templates, and attributes that support the process framework.
- **Create document nomenclature and taxonomy** – Define document terminology and structures. For example, what is the difference between SOP and work instruction? How many document types do you have, or how many do you need?
- **Institute a global document numbering system** – Decide on versioning, numbering conventions, and time stamps. These attributes may be manually defined, or built into the application currently storing and managing the documents. Determine if you need to maintain legacy numbers or historical pointers for documents migrated to a new system.

- **Simplify content structure** – In defining the document structure, strike a balance between breadth and depth, and where possible consolidate and simplify the number of document types, It may be easier to get agreement on a new set of optimized document types rather than having everyone comply with one group's existing practices. In addition, you may be able to eliminate legacy complexity.

When creating document structures and attributes, consider the following best practices:

- Establish global and persistent document structures. Organizations often change over time so it is not recommended to embed your business' organizational structure into the document structure. For flexibility or to capture changing elements, leverage document attributes.
- Decide on the necessary document attributes to support the business processes and also allow for customization or localization.
- Define a global list of attributes that allow localized values. For example, lab and manufacturing equipment is likely to vary considerably between sites, requiring localized attribute values.
- Leverage attributes to capture specific business information, enabling reporting and better insight.

Agreeing on terminology and naming conventions is a critical part of harmonization, and one that can easily impede the globalization process. Define and record terminology for everything from document types to product and process names. With many businesses operating in multiple languages, having common definitions is essential for creating accurate and consistent translations.

Step Five: Streamline Processes and Content

Consolidating and aligning processes and content requires time, effort, and a spirit of compromise to align current content and document types to the optimized process and content framework. You may need to refine processes, content templates, attributes, and other decisions based on business realities.

Some areas of the business will be easier to tackle than others. For example, it will be easier to harmonize across multiple manufacturing sites that develop the same product versus facilities that manufacture multiple different products, as there will be a higher degree of variability.

Life sciences companies that have successfully harmonized quality processes and content recommend:

- Setting aside a period of time for commissioning the change. Leading life sciences companies define a "commissioning" phase as a period in which technologists and team members work alongside early adopters to better understand business processes and address problems.
- Working with a subset of processes in a validated sandbox environment. Starting small helps people focus, making it easier to talk about the new approach.
- Demonstrating early successes, then branching out. If you have defined your goals and can measure results, you'll get the buy-in to continue your work.
- Being patient. The larger the business and process environment, the longer the overall process.

When it comes to measuring your success, make sure you define metrics and processes clearly. One global company decided to track how long it took regional teams to approve quality content. When they looked at the results, they found a significant difference in approval times between two groups. Upon further research, they discovered that one group performed approvals and reviews offline before submitting content for approval, so their online approval times were much shorter and did not accurately reflect the true approval cycle time. By ensuring everyone is measuring the same things, you can accurately compare performance.

Summary

Harmonization is a time-consuming process, requiring a great deal of stakeholder buy-in to achieve success. However, there are significant advantages to taking on this transformation now. Regulatory agencies' approach to quality is evolving, and only demonstrating a state of control and compliance during inspections will no longer be sufficient. Inspectors are looking for evidence that companies have invested in continuous improvement of quality, and failure to do so may introduce additional compliance risk.

Streamlining quality processes and content greatly accelerates cycle times. Many downstream processes can benefit such as ensuring associated documentation for a batch record is reviewed and accepted quickly for faster product to market. Additionally, target states are achieved in a timely manner with an efficient change control process, minimizing compliance risks. Capturing relevant and meaningful data at each critical step of a process enables a feedback loop based on outcome to improve quality. And, standardized metrics facilitate efficient communication across departments, teams, and partners—allowing visibility into progress by all stakeholders. With greater insight and operational alignment, issues are addressed proactively allowing for example, reallocation of resources with minimal complications to areas of greatest need.

In addition to increasing quality, compliance and operational efficiencies, companies with a harmonized and global approach to managing quality will improve partnership success, easily integrate companies or sites post-acquisition, and more importantly can take advantage of emerging trends.

About Veeva Vault QualityDocs
Vault QualityDocs is a cloud-based document control application that provides superior ease-of-use, seamless collaboration with employees and partners, and automated workflows to accelerate review and approval cycles. Enforcing good documentation practices and driving greater user adoption, Vault QualityDocs enable customers to create better quality documentation, improve quality processes, and reduce compliance risk. For more information, visit **veeva.com/qualitydocs**.

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