Veeva

Standardizing Content Management Across the Life Sciences Industry

The Veeva Quality Content Reference Model

Historically, implementing an electronic document management system involved lengthy and complex requirements definition, custom configuration, and significant validation efforts. Most of this was due to lack of standardized best practices and industry-focused innovation.

As a result, life sciences companies made significant investments in deploying, maintaining, and updating their document management systems. End users found these legacy systems difficult to use and less reliable, so they adopted web-based collaboration tools like SharePoint and file shares to manage and share GxP documents. These workarounds increased compliance risk and resulted in operational silos.

Veeva took an innovative approach to software deployment and delivery to speed system implementation and drive consistency across customers by:

- Connecting clinical, regulatory, quality, and safety applications on a common cloud platform
- Delivering built-in best practices as part of business applications
- Providing continuous innovation through three scheduled releases per year

Veeva's best practice-based approach has helped life sciences companies consolidate GxP and corporate governance content in Veeva Vault QualityDocs, a modern content management application.

Today, more than three hundred customers worldwide are leveraging industry best practices delivered as part of Vault QualityDocs to improve quality and compliance across the global supply chain.

To drive further standardization across the life sciences industry, Veeva is publishing those best practices in a quality content reference model. The Veeva Quality Content Reference Model is publicly available to any life sciences company looking to modernize their content management system. It provides a starting point for quality and document teams to align stakeholders across various business functions and create a strong foundation for harmonization across GxPs.

This whitepaper provides an overview of the reference model and explains the benefits of leveraging standardized best practices.

How Does Standardization Help?

Establishing document hierarchy and taxonomy is the first and most crucial step of a well-designed content management system. Yet, most organizations find it challenging to navigate and complete. They spend months gathering requirements from cross-functional stakeholders. However, they end up with an inconsistent taxonomy and structure that increases compliance risk—for example, inaccessibility to key documents during audits and inspections.

The reference model provides a standard document hierarchy, taxonomy, and metadata for organizing and processing quality documentation across GxP domains. This allows end users to search, navigate, and locate documents quickly and easily, enhancing their overall experience.

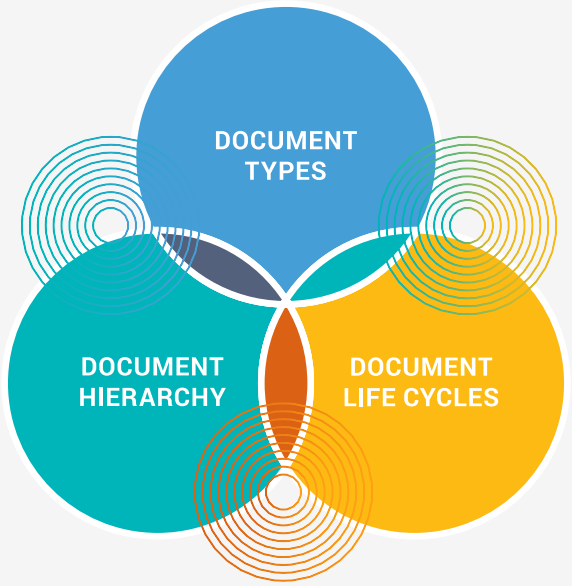
The model includes Veeva's learnings from collaborating and deploying content management application for hundreds of life sciences organizations from emerging biotechs to the top 20 pharmaceutical companies.

Benefits Beyond Speed of Search and Document Navigation

In addition to enhancing user experience, the reference model serves as a starting point for companies to gain stakeholder alignment on the overall document structure and taxonomy before implementing a content management system. The Veeva Quality Content Reference Model enables organizations to:

- Accelerate system implementation by avoiding roadblocks that often occur due to misalignment across business functions (including the consideration for variability across GxP disciplines, business units, and regional requirements)
- Reduce deployment and maintenance costs by streamlining configuration and validation through proven strategies and repeatable deliverables
- Improve quality and compliance by keeping the processing and organization of documents simple and consistent
- Increase system adoption through training and user-friendly capabilities, enabling users to access the right information at the right time
- Increase collaboration by streamlining information exchange across external partners and the extended supply chain
- Simplify content migration and consolidation during quality transformation efforts and mergers and acquisitions
- Drive continuous improvement through best practices gathered with each engagement

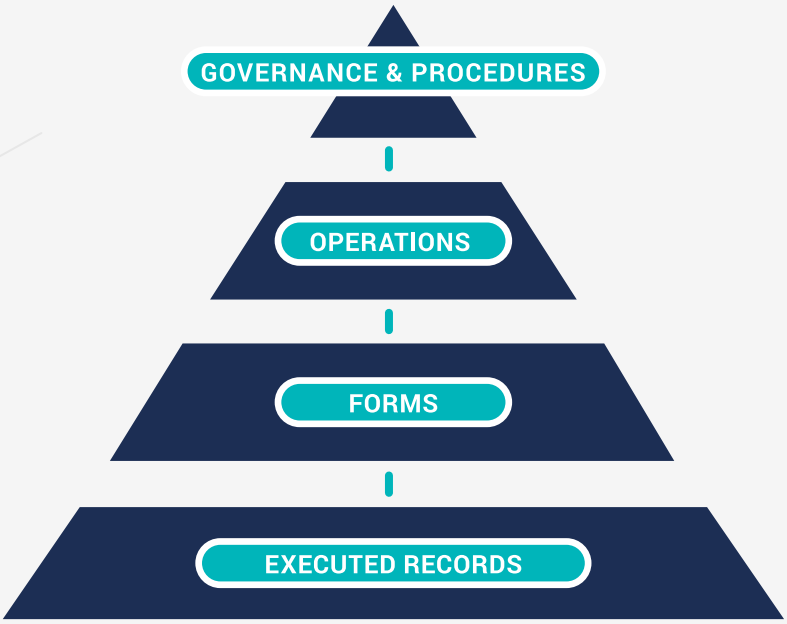
Three D's of the Reference Model



Document Hierarchy

The reference model includes a document hierarchy that spans across the organization and provides a framework for aligning documents to the appropriate life cycle and organizing them by relevant types and subtypes.

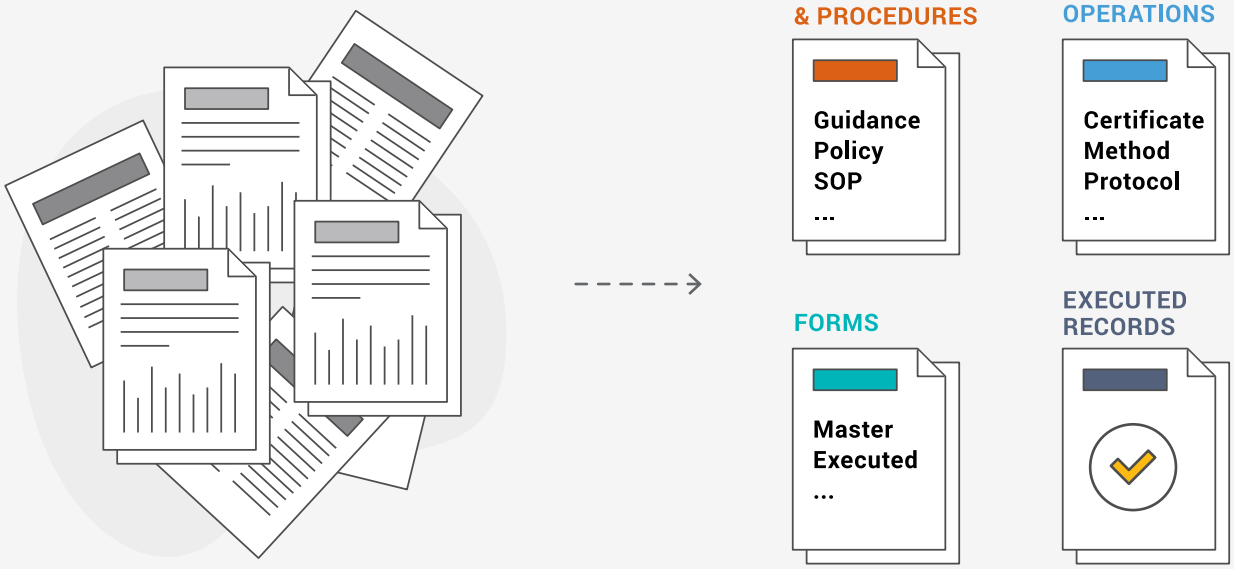
Document Governance



Business Units

CLINICAL | MFG | REGULATORY | LAB | QUALITY | VALIDATION | SUPPLY CHAIN | OTHER

Document Types



Here are the four main document types included in the reference model:

1. **Governance and Procedures**
2. **Operations**
3. **Forms**
4. **Executed Records**

This standardized grouping of document types and subtypes streamlines document mapping, eliminates redundant documents, and drives easy adoption. Any life sciences company can streamline quality system documents with this fundamental structure.

1. Governance and Procedures

All documentation related to processes and procedures for delivering a quality product is placed under Governance and Procedures. They help organizations ensure regulatory compliance and provide evidence of conformity and knowledge sharing. Example documents in this category include a quality manual, quality policy, documented procedures, and work instructions.

Most documents in this category require training and a periodic review to ensure compliance. They usually start in the Draft state and end in the Effective state, until they become Obsolete. The document subtypes under the Governance and Procedures category are:

SUBTYPE	DEFINITION
Job Aid	A tool or other resource that provides guidance and support as part of a job.
Standard	Provides the industry and regulatory requirements (the "what").
Guidance	Guides users on their day-to-day responsibilities.
Policy	Describes a company's intentions, direction towards meeting requirements, and facilitate the development of objectives.
Quality Manual	Describes a company's position or approach toward quality.
Standard Operating Procedure (SOP):	Includes process instructions to ensure the requirements are met (the "how").
Work Instruction	Provides information to assist a user in performing a specific task or activity.
Master Template	Serves as a starting point for creating a new document. It includes a preset format and content to ensure consistency.

2. Operations

In the context of the reference model, Operations is a generic term used to define all documents that support the performance of practical work across all functional areas of an organization (including but not limited to R&D, Manufacturing, Commercialization, IT, etc.).

These documents ensure compliance with GxP guidelines such as Good Manufacturing Practices (GMP) and Good Documentation Practices throughout the product manufacturing process.

Many pharma companies outsource drug manufacturing to contract manufacturing organizations (CMOs). The reference model includes all documents required to manufacture products taking into account both in-house and outsourced manufacturing models.

The majority of Operations documents may not require ongoing training or periodic review. Therefore, these documents follow the "Draft to Approved" document life cycle, starting in the Draft state and ending in the Approved state.

The document subtypes under the Operations category are:

SUBTYPE	DEFINITION
Certificate	Attests to a status or achievement level for a system or a process.
Master Batch Record	Provides the "recipe" for manufacturing a product.
Method	Contains the detailed step-by-step instructions for performing a test.
Safety Data Sheet	Provides both workers and emergency personnel with the proper procedures for handling or working with a particular substance.
Logbook	Provides recorded activities and reference to relative information that are critical to operations.
Specification	Identifies and establishes conformance requirements or criteria for a material, product, or system to be considered acceptable for its intended use.
Requirement	Supports execution of a standard or procedure and assists users in complying with instructions. Requirements are established to provide assurance for its intended use.
Protocol	Specifies critical steps for conducting activities and their acceptance criteria. A protocol is approved before an activity begins.
Plan	Describes the detailed scheme or method for attaining an objective.
Report	Includes information or a summary of a process, activity, or investigation for a specific audience or purpose.
Assessment	Identifies and evaluates potential risks, evaluates suitability and whether the assessment meets requirements and expectations, and documents the outcome of the assessment activity.
Agreement	A negotiated arrangement between parties that outlines requirements and expectations.
Training Material	Documents or content used for learning and development.

3. Forms

The reference model includes three different types of forms: Master Form, eForm, and Executed Form. Here are their definitions:

SUBTYPE	DEFINITION
Master Form	A starting point for a new document. It includes predefined fields for consistent collection of data or information.
Fillable Form	Uses a Master Form as a starting point. Downloaded, populated, and then routed within the Vault application for review and approval.
Executed Form	Executed outside the system then housed back in the system as a document of reference. Created from a Master Form.

Each form type follows a specific life cycle. A Master Form may not require training but needs a periodic review. Hence, it starts in a Draft state and ends in Effective. Fillable Forms are downloaded, filled out, and processed for review and approval; therefore, they start in the Draft state and end in the Approved state. Executed Forms are processed outside of the system and then entered into the system as a document of record providing details about a point in time.

The Fillable Form adoption has increased due to remote work during COVID-19. Because remote work limits users' ability to access shared resources like printers and scanners, more companies are converting paper forms to electronic forms to drive business continuity. The conversion to electronic forms has enabled companies to increase efficiency without sacrificing control and compliance.

4. Executed Records

Executed Records include documents that are executed and completed externally and then stored in the system as a record. They provide historical proof of a task completed with quality and compliance. Executed records are not editable and should not be recreated or versioned. They follow a simple Initial to Final life cycle; the documents are brought into the system in the Initial state and end in the steady Final state.

Document Life Cycles

Each document in a quality content management system has a life cycle governed by industry regulations like 21CFR part 210 and 211. All documents outlined in the reference model follow one of the following life cycles:

- **Draft to Effective** — Documents that follow the Draft to Effective life cycle start in the Draft state and end in the Effective state (steady state). These documents usually require training and have periodic reviews associated with them. Over time, documents in this life cycle will transition to Obsolete when they are no longer valid for use.
- **Draft to Approved** — Documents that follow the Draft to Approve life cycle start in the Draft state and end in the Approved state (steady state). Over time, documents in this life cycle will transition to Retired when they are no longer valid for use.
- **Initial to Final** — Documents that follow the Initial to Final life cycle start in the Initial state and end in the Final state (steady state). This life cycle is mostly used for Documents of record (i.e., executed batch record), where no versioning is required.

Each life cycle includes workflows that determine how the documents are processed as they move from the starting state to the steady state. Standardized workflows accelerate review and approval processes and streamline SOPs and other GxP document sharing among all stakeholders.

Next Steps in Standardizing Content Management for Your Enterprise

Standardizing and simplifying quality content management across the enterprise is fundamental to a robust quality system. A standardized document structure and nomenclature based on industry best practices accelerates system implementation, improves system usability, and simplifies overall content management.

Based on industry best practices, the Veeva Quality Content Reference Model provides a simple framework that can save you months of efforts in defining document hierarchy and taxonomy, accelerating the implementation process.

Get a copy of the reference model and use it as a starting point to align stakeholders across different business functions.

This will help you build a strong foundation for a compliant, easy-to-use quality content management system across the enterprise.

Learn More About Vault QualityDocs

Vault QualityDocs is a modern, cloud application for GxP content control and management that improves quality and compliance. It provides automated workflows, and a pre-validated system that is compliant with industry regulations. Predefined taxonomy, metadata, and pick lists for quality and manufacturing documents facilitate operational harmonization and allow organizations to quickly adopt best practices.

Vault QualityDocs is part of Veeva Vault Quality Suite which brings together quality processes, content management, and training on a single cloud platform. The unified suite enables companies to build a strong quality system foundation for greater collaboration, transparency, and oversight across the global supply chain including contract manufacturers and partners.