Overview	The Veeva Quality Content Reference Model provides the industry with best practices for managing content and metadata that are used to manage controlled content within quality systems. This document will help companies implement with speed and standardize document management across the enterprise, streamlining business processes across various business functions.

Veeva Quality Content Reference Model

Function	Title	Responsible Individual	Version
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This workbook includes the following tabs:	
1. Overview	Provides general information about the model
2. Document Hierarchy and Life Cycles	List of suggested document types and subtypes and their associated fields
3. Definitions	Definition of document hierarchy and fields on the QualityDocs Reference Model tab
4. Tree View	Document types and subtypes provided in a hierarchy view

Document Life Cycles	Description
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 Over time, documents in this life cycle will transition to Obsolete when they are no longer valid for use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 Over time, documents in this life cycle will transition to Retired when they are no longer valid for use.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.

R= Required
O= Optional
S= System generated
C= Conditional field based on another value selected

Document Hierarchy and Life Cycles

Information Panel

Lifecycle	DocType	Subtype	General Section: Name	Title	Previous Document Number	Document Number	Created by	Last Modified by	Version	Lifecycle	Status	Template Document Type	Reference Model Category	Reference Model Sub-Category	Product Information: Product	Active Substance	Excipient	Supplier	Applicability: Owning Facility	Owning Department	Impacted Facility	Impacted Department	Country	Scope	Training: Training Impact	Training Period (Days)	Change Information: Requires DCC?	Obsolete Change Control	Release Change Control	Status Dates: Approved Date	Proposed Effective Date	Effective Date	Final Date	Superseded Date	Proposed Obsolescence Date	Obsolescence Approved	Obsolete Date	Periodic Review: Periodic Review Frequency	Last Periodic Review Date	Next Periodic Review Date	Last Periodic Review Decision
Draft to Effective	Governance and Procedures	Job Aid	R	O	O	S	S	S	S	S	S								R	R	O	O	R	R	R	C	R	S	S	S	S	S		S	S	S	S	R	S	S	S
Draft to Effective	Governance and Procedures	Standard	R	O	O	S	S	S	S	S	S								R	R	O	O	R	R	R	C	R	S	S	S	S	S		S	S	S	S	R	S	S	S
Draft to Effective	Governance and Procedures	Guidance	R	O	O	S	S	S	S	S	S								R	R	O	O	R	R	R	C	R	S	S	S	S	S		S	S	S	S	R	S	S	S
Draft to Effective	Governance and Procedures	Policy	R	O	O	S	S	S	S	S	S								R	R	O	O	R	R	R	C	R	S	S	S	S	S		S	S	S	S	R	S	S	S
Draft to Effective	Governance and Procedures	Quality Manual	R	O	O	S	S	S	S	S	S								R	R	O	O	R	R	R	C	R	S	S	S	S	S		S	S	S	S	R	S	S	S
Draft to Effective	Governance and Procedures	Standard Operating Procedure (SOP)	R	O	O	S	S	S	S	S	S		R						R	R	O	O	R	R	R	C	R	S	S	S	S	S		S	S	S	S	R	S	S	S
Draft to Effective	Governance and Procedures	Work Instruction	R	O	O	S	S	S	S	S	S								R	R	O	O	R	R	R	C	R	S	S	S	S	S		S	S	S	S	R	S	S	S
Draft to Effective	Governance and Procedures	Master Template	R	O	O	S	S	S	S	S	S	R							R	R	O	O	R	R	R	C	R	S	S	S	S	S		S	S	S	S	R	S	S	S
Draft to Effective	Forms	Master Form	R	O	O	S	S	S	S	S	S	O							R	R	O	O	R	R	R	C	R	S	S	S	S	S		S	S	S	S	R	S	S	S
Draft to Approved	Forms	Fillable Form	R	O	O	S	S	S	S	S	S								R	R	O	O	R	R						S				S							
Initial to Final	Forms	Executed Form	R	O	O	S	S	S	S	S	S								R	R	O	O	R	R									S								
Draft to Approved	Operations	Certificate	R	O	O	S	S	S	S	S	S		R	C	O	O	O	O	R	R	O	O	R	R						S				S							
Draft to Effective	Operations	Master Batch Record	R	O	O	S	S	S	S	S	S				O	O	O	O	R	R	O	O	R	R	R	C	R	S	S	S	S	S		S	S	S	S	R	S	S	S
Draft to Approved	Operations	Method	R	O	O	S	S	S	S	S	S		R	C	O	O	O	O	R	R	O	O	R	R						S				S							
Draft to Approved	Operations	Safety Data Sheet	R	O	O	S	S	S	S	S	S				O	O	O	O	R	R	O	O	R	R						S				S							
Draft to Approved	Operations	Logbook	R	O	O	S	S	S	S	S	S				O	O	O	O	R	R	O	O	R	R						S				S							
Draft to Effective	Operations	Specification	R	O	O	S	S	S	S	S	S		R	C	O	O	O	O	R	R	O	O	R	R	R	C	R	S	S	S	S	S		S	S	S	S	R	S	S	S
Draft to Approved	Operations	Requirement	R	O	O	S	S	S	S	S	S		R	C	O	O	O	O	R	R	O	O	R	R						S				S							
Draft to Approved	Operations	Protocol	R	O	O	S	S	S	S	S	S		R	C	O	O	O	O	R	R	O	O	R	R						S				S							
Draft to Approved	Operations	Plan	R	O	O	S	S	S	S	S	S		R	C	O	O	O	O	R	R	O	O	R	R						S				S							
Draft to Approved	Operations	Report	R	O	O	S	S	S	S	S	S		R	C	O	O	O	O	R	R	O	O	R	R						S				S							
Draft to Approved	Operations	Assessment	R	O	O	S	S	S	S	S	S		R	C	O	O	O	O	R	R	O	O	R	R						S				S							
Draft to Approved	Operations	Agreement	R	O	O	S	S	S	S	S	S		R	C	O	O	O	O	R	R	O	O	R	R						S				S							
Draft to Approved	Operations	Training Material	R	O	O	S	S	S	S	S	S		R	C	O	O	O	O	R	R	O	O	R	R						S				S							
Initial to Final	Executed Record	na	R	O	O	S	S	S	S	S	S		R	C					R	R	O	O	R	R								S									

DocType	Subtype	Defitionion
Governance and Procedures		**A generic term used to describe documents that advise**
Governance and Procedures	Job Aid	A tool or other resource that provides guidance and support as part of a job.
Governance and Procedures	Standard	Provides the industry and regulatory requirements (the "what").
Governance and Procedures	Guidance	Guides users on their day-to-day responsibilities.
Governance and Procedures	Policy	Describes a company's intentions, direction towards meeting requirements, and facilitates the development of objectives.
Governance and Procedures	Quality Manual	Describes a company's position or approach toward quality.
Governance and Procedures	Standard Operating Procedure (SOP)	Includes process instructions to ensure the requirements are met (the "how").
Governance and Procedures	Work Instruction	Provides information to assist a user in performing a specific task or activity.
Governance and Procedures	Master Template	Serves as a starting point for creating a new document. It includes a preset format and content to ensure consistency.
Forms		**A generic term used to describe a document with spaces in which to write or select, for a series of documents with similar contents**
Forms	Master Form	A starting point for a new document. It includes predefined fields for consistent collection of data or information.
Forms	Fillable Form	Uses a Master Form as a starting point. Downloaded, populated, and then routed within the Vault application for review and approval.
Forms	Executed Form	Executed outside the system then housed back in the system as a document of reference. Created from a Master Form.
Operations		**A generic term used to define all documents that supports the performance of practical work across all functional areas of an organization (including but not limited to R&D, Manufacturing, Lab, Supply Chain, Commercialization, and IT)**
Operations	Certificate	Attests to a status or achievement level for a system or a process.
Operations	Master Batch Record	Provides the "recipe" for manufacturing a product.
Operations	Method	Contains the detailed step-by-step instructions for performing a test.
Operations	Safety Data Sheet	Provides both workers and emergency personnel with the proper procedures for handling or working with a particular substance.
Operations	Logbook	Provides recorded activities and reference to relative information that are critical to operations.
Operations	Specification	Identifies and establishes conformance requirements or criteria for a material, product, or system to be considered acceptable for its intended use.
Operations	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.
Operations	Protocol	Specifies critical steps for conducting activities and their acceptance criteria. A protocol is approved before an activity begins.
Operations	Plan	Describes the detailed scheme or method for attaining an objective.
Operations	Report	Includes information or a summary of a process, activity, or investigation for a specific audience or purpose.
Operations	Assessment	Identifies and evaluates potential risks, evaluates suitability and whether the assessment meets requirements and expectations, and documents the outcome of the assessment activity.
Operations	Agreement	A negotiated arrangement between parties that outlines requirements and expectations.
Operations	Training Material	Documents or content used for learning and development.
Executed Record		**A document of record that includes completed information relating to the type of document executed (ie: Executed Batch Record, Executed Test Script)**

Field Section	Field	Definition
General	Name	The short title of a document (100 character limit).
General	Title	Full title as it appears on most documents (1500 character limit).
General	Previous Document Number	Document number migrated from a legacy system.
General	Document Number	A system generated number associated uniquely with a document for which change control is implemented.
General	Created by	Name of the person who created the original document (not to be confused with the author of the document).
General	Last Modified by	The name of the person who made the last change to the document or document fields.
General	Version	The current number in a sequence indicating the document's version.
General	Lifecycle	The life cycle type for a document that drives how each document is processed in the system.
General	Status	State of the document as defined by the life cycle (Draft, Approved, or Effective).
General	Template Document Type	Identifies the type of document the master template should be assigned to once it reaches the Effective state.
General	Reference Model Category	The reference model category is used to identify the type of document being created (for example Executed Record).
General	Reference Model Sub-Category	The reference model sub category is used to further identify the document type (for example Executed Record > test script)
Product Information	Product	A finished dosage form, for example, a tablet, capsule or solution that contains an active pharmaceutical ingredient (API), generally, but not necessarily, in association with inactive ingredients.
Product Information	Active Substance	Any substance or mixture of substances intended to be used in the manufacturing of a drug (medicinal) product and that, when used in the production of a drug, becomes an active ingredient of the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or function of the body.
Product Information	Excipient	Examples of excipients include fillers, extenders, diluents, wetting agents, solvents, emulsifiers, preservatives, flavors, absorption enhancers, sustained-release matrices, and coloring agents.
Product Information	Supplier	A company that supplies materials, products, or services.
Applicability	Owning Facility	Internal facility to which the document applies.
Applicability	Owning Department	Internal department to which the document applies.
Applicability	Impacted Facility	Internal facility that may be impacted by the details of the document.
Applicability	Impacted Department	Internal department that may be impacted by the details of the document.
Applicability	Country	The country to which the document applies.
Applicability	Scope	The picklist value selected in this field drives document security (i.e. Global, Clinical, Manufacturing).
Training	Training Impact	Indicates if training is required for the document.
Training	Training Period (Days)	Indicates the number of days this document will be out for training before transitioning to Effective.
Change Information	Requires DCC?	Determined if a Document Change Control is required for this document. If yes, the system will require the document to route through the DCC process.
Change Information	Obsolete Change Control	Indicates that this document is on a DCC to be made Obsolete.
Change Information	Release Change Control	Indicates that this document is on a DCC to be made Effective.
Status Dates	Approved Date	Date on which the document is Approved.
Status Dates	Proposed Effective Date	The date on which the document will automatically transition to Effective.
Status Dates	Effective Date	Date on which a controlled document is approved for use.
Status Dates	Superseded Date	The date at which the previous steady state document transition superseded.
Status Dates	Proposed Obsolescence Date	The date on which the document will automatically transition to Obsolete.
Status Dates	Obsolescence Approved	A radial field indicating the document is approved for Obsolescence and is waiting for the nightly job to transition to Obsolete.
Status Dates	Obsolete Date	The date on which the document is longer available for use.
Periodic Review	Periodic Review Frequency	The frequency determines the date (in years) of the next period review date (ie: 1 year, 2 years, NA) and is selectable on a document by document basis.
Periodic Review	Last Periodic Review Date	Date of the last periodic review of the document.
Periodic Review	Next Periodic Review Date	Date on which the document must be periodically reviewed.
Periodic Review	Last Periodic Review Decision	The recorded periodic review decision applied to the document field.

			New Document Fields	
Document Type	Document Subtype	Classification	Reference Model Category*	Reference Model Sub-Category*
Governance and Procedures				
	Job Aid			
	Standard			
	Guidance			
	Policy			
	Quality Manual			
	Standard Operating Procedure (SOP)		Reference Model Category	
				Validation
				Regulatory
				Safety
				Quality Systems
				Supply Chain Management
				Facility
				Equipment
				Nonclinical
	Work Instruction			
	Master Template			
Forms				
	Master Form			
	Fillable Form			
	Executed Form			
Operations				
	Certificate		Reference Model Category	
				Certificate of Analysis
				Certificate of Conformance
				Packaging Certificate
				Supplier Certificate
	Master Batch Record			
	Method		Reference Model Category	
				Equipment Method
				Raw Material Method
				Process Method
				Test Method
				Cleaning Method
	Safety Data Sheet			
	Logbook			
	Specification		Reference Model Category	
				Environment Specification
				Equipment Specification
				Design Specification
				Process Specification
	Requirement		Reference Model Category	
				User Requirements
				Functional requirements
	Protocol		Reference Model Category	
				Test Protocol
				Clinical Protocol
				Validation Protocol
	Plan		Reference Model Category	
				Test Plan
				Validation Master Plan
	Report		Reference Model Category	
				Validation Summary Report
				Qualification Summary Report
	Assessment		Reference Model Category	
				Impact Assessment
				Risk Assessment
	Agreement		Reference Model Category	
				Technical
				Service
				Quality
	Training Material		Reference Model Category	
				Course Material
				User Manual
Executed Records			Reference Model Category	
				Test Scripts
				Executed Batch Records

Note:

Instructions:

1. As part of the Reference Model Veeva has introduced two new fields to help further define the document type/subtype structure type/subtype in the hierarchy. These fields can be used on as many or few document type/subtype combinations as determined by the client requirements for the types of document supported in each of the document type/subtype combinations