Introductions

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How Did We Choose Veeva?

Evaluated 10 CMS companies
3 brought in-house for live demos

Why was Veeva chosen:
1. User friendly
2. Linked with other Sysmex systems
3. Multiple options to tailor to our needs

is dead—Long live Veeva Vault!

Veeva VAULT

How Efficient Document Control is Essential to Positive Audit Outcomes

Audits and document changes can be disruptive. Sysmex shares how using Vault QualityDocs for Document Control accelerates audits, change control processes, and reduces audit preparation times.

Presentation Objectives

Routine use to ensure compliance

Use of tokens

Change Control

Impact Assessments

Approval process – based on Lifecycle

Version History

During an Audit

Regulatory File

Document Approvers

Change information

Periodic Review History

> How we use ➤ How this complies

Complies with 21 CFR part 820 and ISO 13485:2016

Routine Use
to Assure Compliance

Use of Tokens

Header

Footer

	Doc. No.:	Revision	Effective Date:	Author(s):
	${vault:document_number__v}	${vault:major_version_number__v}.${vault:minor_version_number__v}	${vault:effective_date__v}	
Document Title:	${vault:name__v}			

Revision: ${vault:major_version_number__v}.${vault:minor_version_number__v}

Effective Date: ${vault:effective_date__v}

Doc. #: ${vault:document_number__v}

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REVISION HISTORY				
Revision #	Effective Date (DD-MMM-YY)	Author(s) (First Last)	Change Description and Rationale (What is being changed and why)	Training Required COP/SOP only; Justify if "No"
${vault:major_version_number__v}.${vault:minor_version_number__v}	${vault:effective_date__v}			☐ Yes ☐ No:

Change Management: DCC (Doc Change Control)

NEW WAY
OLD WAY

Complies with 21 CFR part 820
and ISO 13485:2016

Document Change Control: DCC-000595 ⭐ OPEN

▸ **Workflow Timeline**

▾ **Change Details**

Document Change Control	DCC-000595	**Lifecycle State** Open
Description and Reason for Change	This is where we put an explanation of WHAT was changed and WHY its changed	
Justification for Change	This is where we put WHY it's ok to make the change / Regulatory Impact? Adverse Effects on other documents/processes?	
Change Assessment		
Regulatory Impact?	Yes	
Urgency	High	
		Linked Documents PowerPoint slide
Proposed Implementation Date	18 Sep 2018	

Change Management: DCC (Doc Change Control)

▼ Workflow Timeline

ACTION		DETAILS	
▼ MDCC: Release Approval ⚙▾		▶ SME Change Execution & Release Approval ⚙▾	
Rachael Garcia		👤	
Started: **04 Sep 2018 2:59 PM EDT**		Due: **18 Sep 2018**	
		▶ SME Change Execution & Release Approval ⚙▾	
		👤	
		Due: **18 Sep 2018**	
		▶ SME Change Execution & Release Approval ⚙▾	
		👤	
		Due: **18 Sep 2018**	
		⊘ SME Change Execution & Release Approval	Approve changes & release (Departmental Management Approval)
		👤	
		Completed: **06 Sep 2018 3:28 PM EDT**	
		⊘ SME Change Execution & Release Approval	Approve changes & release (Departmental Management Approval)
		👤	
		Completed: **05 Sep 2018 5:33 PM EDT**	
		⊘ SME Change Execution & Release Approval	Approve changes & release (Departmental Management Approval)
		👤	
		Completed: **05 Sep 2018 10:06 AM EDT**	

Impact Assessments: Dropdowns

Impact Assessment

Complete this task to indicate the outcome of the Impact Assessment. All areas of impact should be captured before proceeding.

Verdict*

(•) Impact Assessment Approved
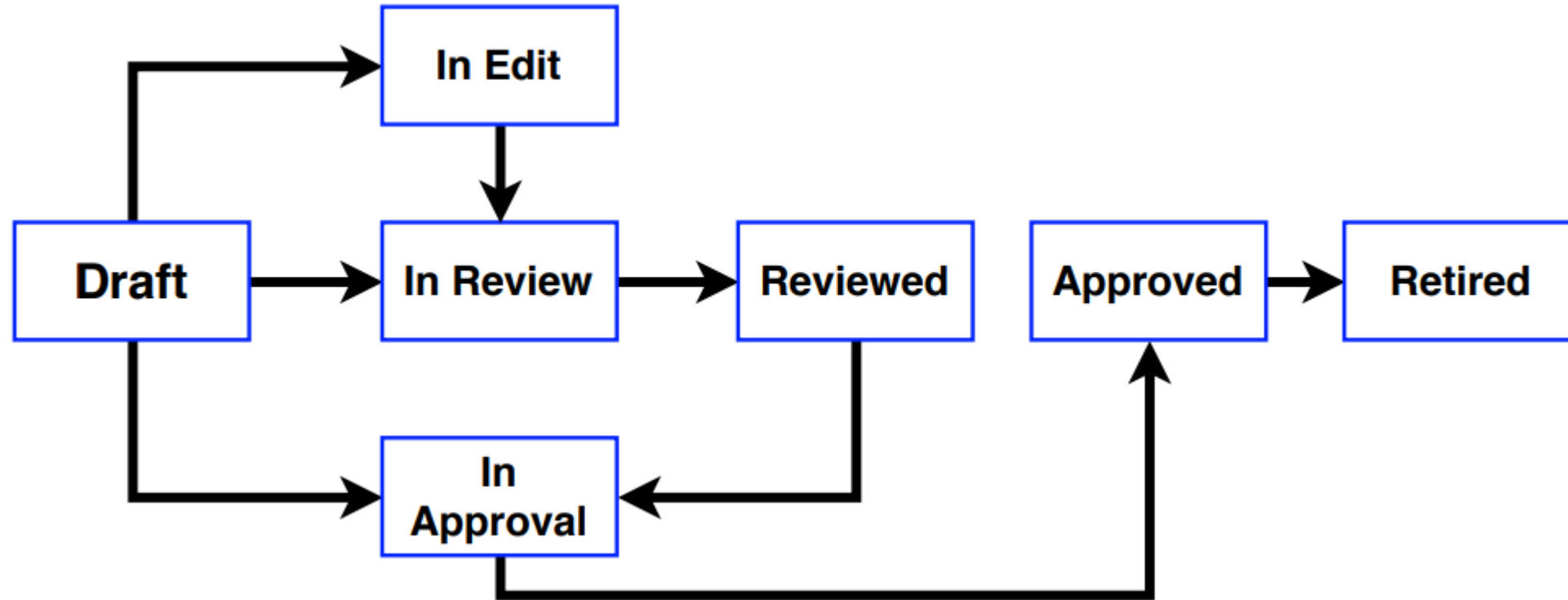( ) Impact Assessment Rejected

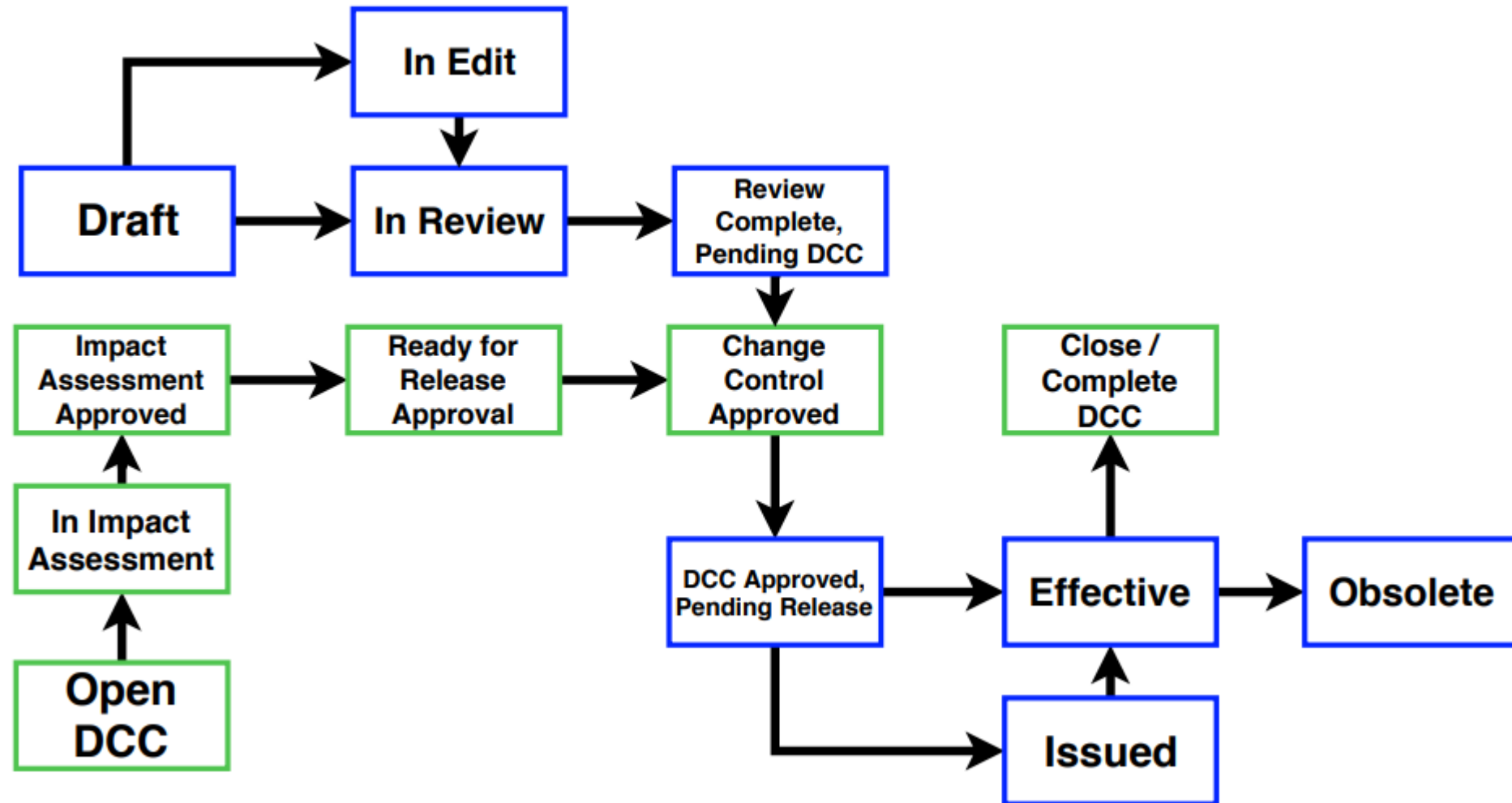Provide your credentials to certify completion of the Impact Assessment.
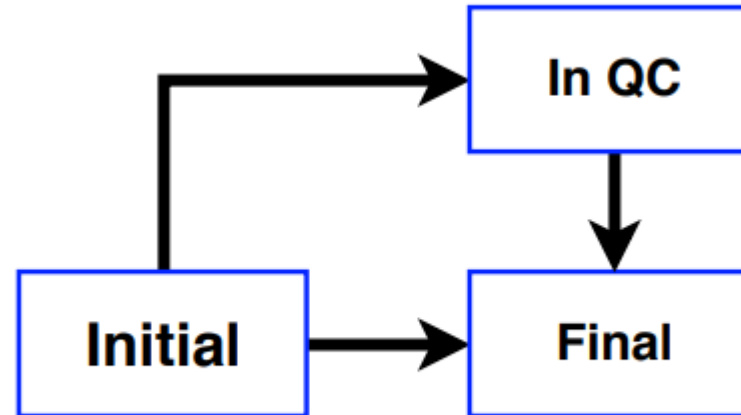
Capacity*

| |

Software Validation Impact
Process Validation Impact
Regulatory Impact
Training Impact
Quality Impact

- o Software validation:
  - * Effect on current validation
  - * Risk assessment
- o Process validation:
  - * Effect on current processes
  - * Risk assessment
- o Regulatory Impact:
  - * Regulatory requirements
  - * FDA, ISO Standards, Health Canada etc.
- o Training Impact:
  - * Any effect on training
- o Quality Impact:
  - * Any quality related impact

Complete Version History

Version History ⊗

📄 COP-0010 **Document Control and Procedure Writing**

Product:

Document Type: Governance and Procedure › Corporate Operating Procedure (COP)

Version	Checked in by	Status	
23.0	Checked in by: Rachael Garcia on 29 Jan 2018 9:21 AM EST	Effective	⊗
22.1	Checked in by: Rachael Garcia on 22 Jan 2018 10:12 AM EST	Draft	⊗
22.0	Checked in by: Rachael Garcia on 30 Nov 2017 10:34 AM EST	Superseded	⊗
21.0	Checked in by: Klaudia Lourde on 29 Aug 2017 5:23 PM EDT	Superseded	⊗
20.1	Checked in by: Rachael Garcia on 31 Jul 2017 1:11 PM EDT	Draft	⊗
20.0	Checked in by: Rachael Garcia on 30 May 2017 2:28 PM EDT	Superseded	⊗
19.0	Checked in by: Rachael Garcia on 30 May 2017 12:45 PM EDT	Superseded	⊗
18.0	Created by: Max Friel on 19 May 2017 10:07 AM EDT	Superseded	⊗

During an Audit

Audit Checklist
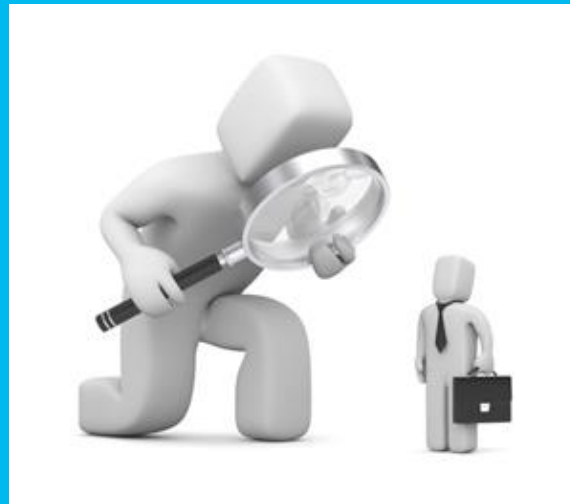
- # Creating a Regulatory File Allows you to:

  - ## Have the necessary documents at your fingertips when that call comes in
  - ## Get them printed prior to audit
  - ## Share the view so all auditees have easy accessibility
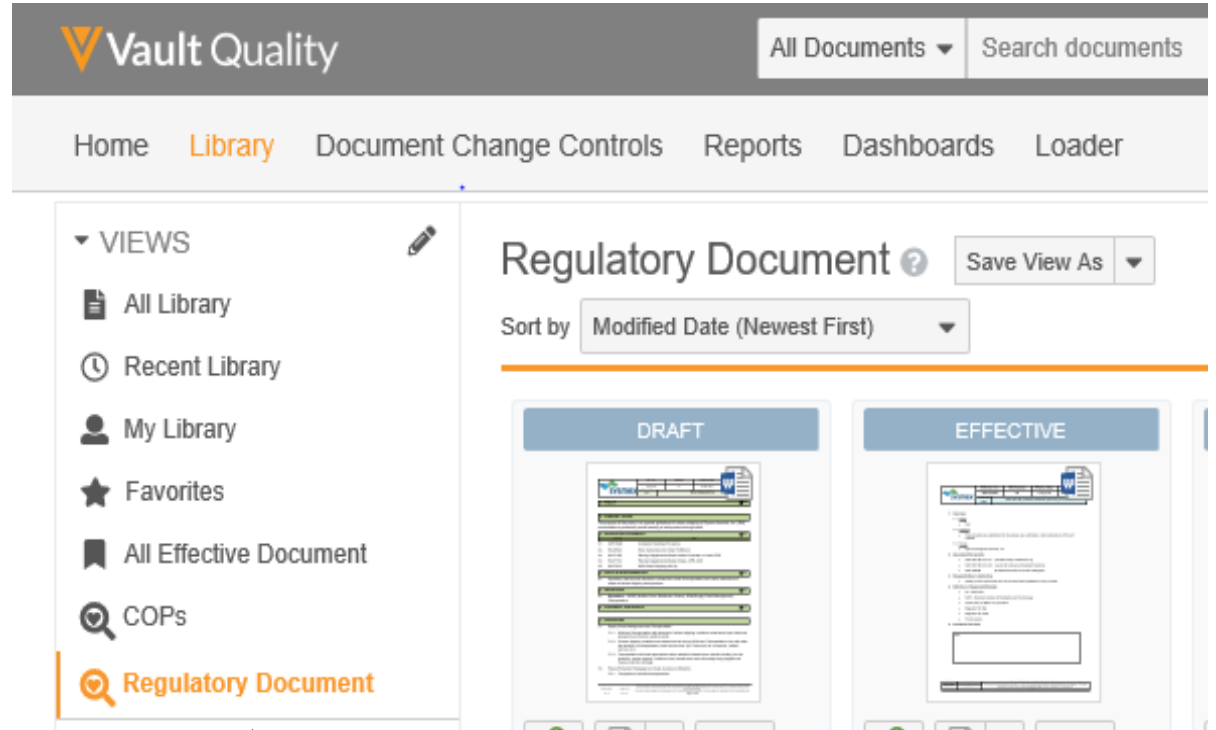
Document Approvers

Signatures (8)

Signature Page

▓▓▓▓▓▓	Quality Assurance Appro…
10 Aug 2018 2:20 PM EDT	Approve changes & rele…
▓▓▓▓▓▓	Departmental Managem…
10 Aug 2018 2:05 PM EDT	Approve changes & rele…
▓▓▓▓▓▓	Departmental Managem…
10 Aug 2018 11:06 AM E…	Approve changes & rele…
▓▓▓▓▓▓	Regulatory Approval
09 Aug 2018 10:55 AM E…	Approve changes & rele…
▓▓▓▓▓▓	Quality Approval
09 Aug 2018 9:03 AM EDT	Approve changes & rele…

Displaying 5 of 8

Number: COP-0011   Version: 25.0   Status: Issued

Corrective and Preventive Action Procedure (CAPA)

Document Approvals

Approved Date: 10 Aug 2018

Task: SME Approval Verdict: Approve changes & release	▓▓▓▓▓▓▓▓ Departmental Management Approval 10-Aug-2018 18:05:34 GMT+0000
Task: QA Approval Verdict: Approve changes & release	Kim Duffy, (duffyk@sysmex.com) Quality Assurance Approval 10-Aug-2018 18:20:07 GMT+0000

Change Information and Document Review

- What changes were made?
- Why did you make the changes?
- When was the last time the document was reviewed?

Change Details

Document Change Control	DCC-000960
Description and Reason for Change	Adding a new section (7.5) to state that form covers can be deleted if the form is being completed as a record. Updated section 7.3. to state that the system sends notifications for periodic reviews. Added new document reference for periodic review work instructions. Stating that document control will generate the periodic review workflow.
Justification for Change	It's important that we have the reference to the new document where document owners can go to in order to find the steps on completing the periodic review process. It's also important that the document states that document control will generate the review workflow instead of saying that system will.
Regulatory Impact?	No

Periodic Review

Next Periodic Review Date	21 Jul 2020
Last Periodic Review Date	21 Mar 2018
Last Periodic Review Decision	Revision Required

The Benefits of Veeva

Instant document retrieval time	* Internal / External audits * Daily usage	**IMPROVEMENT** Hunting → Instant
Faster Impact Assessments	* Due dates are set * Can route to multiple	**IMPROVEMENT** 1 month → 1 week
Open API – SSO (> usage / < resets)		**IMPROVEMENT** Saved 1 hour per day for resets Instant access from other systems Compatible with current systems

Purchase of Veeva Vault QMS to electronically assign and maintain:

- CAPA Reports
- Nonconforming Reports
- Internal Audit Files
- Supplier Quality Files

" As we continue our significant growth, Veeva Vault is a shift toward technology that **will grow** with us. It's a modern, more innovative tool, that's user friendly, efficient and facilitates doing business with ease."

- Peter Shearstone VP, RA/QA/CA/MA

Questions