



SharePoint for Pharma - Going Paperless: Executing Validation of GxP Systems Electronically using SharePoint

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SharePoint for Pharma Series

- Webinar series that aims to highlight the different aspects of the use and validation of SharePoint in GxP environments.
- 5 different sessions covering the different aspects of deployment, use and validation of SharePoint.
- Should provide attendees with a good grounding for their SharePoint projects.
- Slides can be distributed upon request.

Thank you for your interest!



Recap of Previous Webinars

- **SharePoint and 21 CFR Part 11** – the approaches being taken by companies to validate their SharePoint environments, and emerged with a set of guidelines for a risk-based validation strategy for SharePoint.
- **Effective Configuration Management** – the various elements of the system that must be managed under configuration control as well techniques and tools that can be used to facilitate this requirement.
- **Extracting Actionable Intelligence from SharePoint** – how GxP operational components can be organized and connected to act as a Business Intelligence (BI) and Business Process Management (BPM) solution that integrates people, platforms and processes and delivers actionable intelligence back to the organization.
- **Computer System Lifecycle Management** – how SharePoint can be configured to help maintain control and manage changes throughout the life of a validated system.

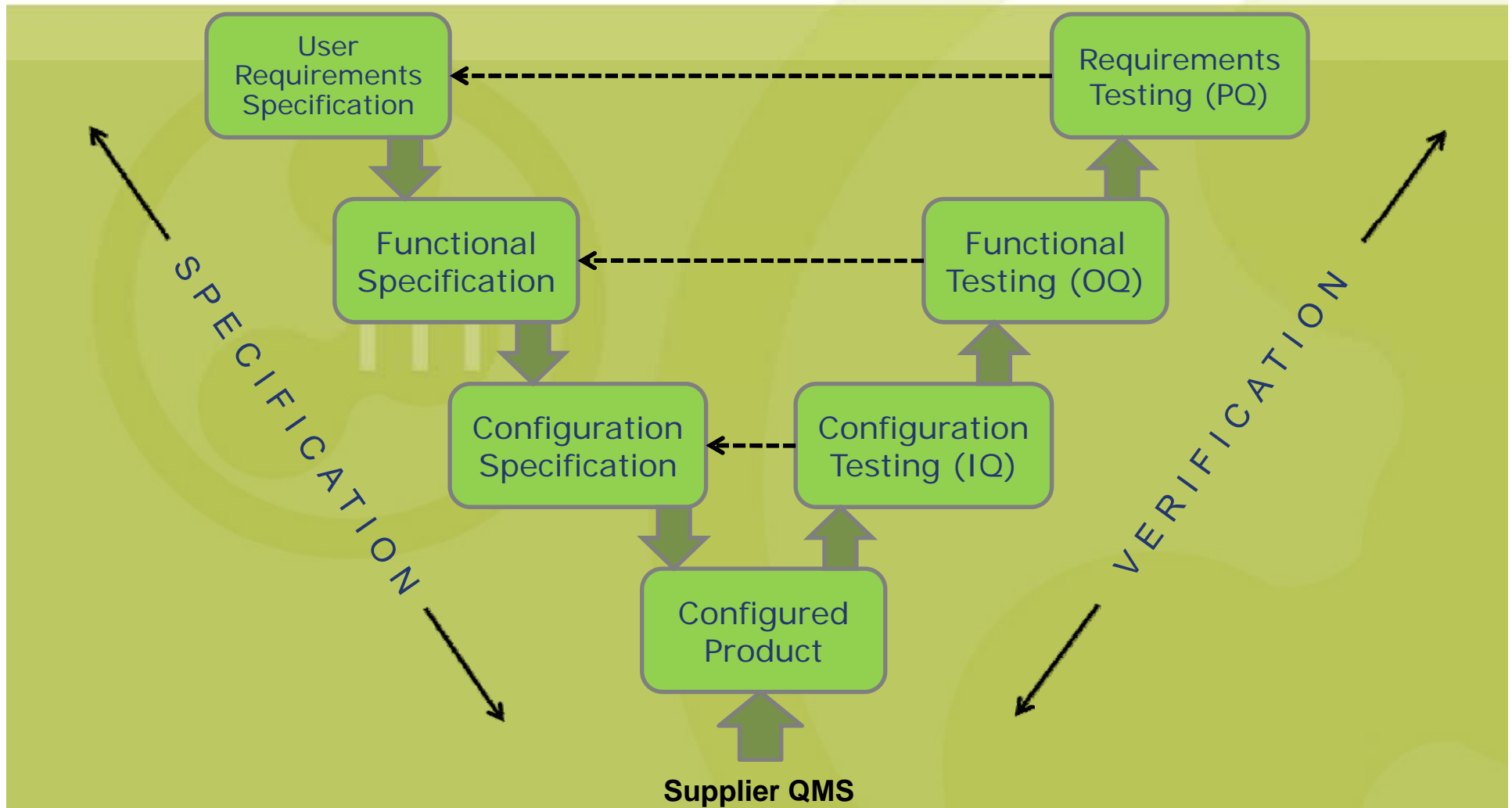
- Review of the current state of validation and current challenges
- Use of SharePoint can be used to automate validation projects through the use of:
 - Electronic document templates and forms
 - Electronic signatures
 - Automated workflows
- Use of integrated workspaces in SharePoint to manage validation documentation and maintain the system's validated state
- Leveraging dashboards to acquire intelligence about validation projects



What is Computer System Validation?

- Validation is the act of establishing objective (documented) evidence that:
 - User, business and regulatory system requirements are met.
 - A system operates as intended in a consistent and reliable manner.
 - System performance (speed and accessibility) is acceptable.
 - Information is secure and properly managed by the system and data integrity is properly maintained.
 - Procedures and processes are in place for the use and management of the system.

Validation: The Traditional Way





Test Scripts: The Traditional Way

- Following the paper-based approach, test results are recorded manually (wet ink) directly on a copy of the approved test script.

Step ID	Instructions	Expected Result	Actual Result	Pass/Fail	Performed By (Initials & Date)
6.	<p><u>Verify a PDF document can be electronically signed by providing a user ID, password and reason for signature.</u></p> <p>a) Right click on the first signature field. b) Select Sign from the drop down menu. c) Select "I am the author of this document" from the drop down menu in the Select Reason field. d) Click OK e) Enter the user ID for User #1 in the Username field. f) Enter the password for User #1 in the Password field. g) Click OK h) Generate a screen capture.</p>	<p>The PDF document is successfully signed by User #1.</p> <p>The complete name, date, time (including time zone offset) and reason for signature appear on the document.</p>	<p>Reviewer's note: The time zone offset is not shown due to CoSign configuration settings. <i>Doc 24apr2010.</i> As expected</p> <p>Time zone offset is not displayed. See Attachment #28 <i>Doc 15 24apr2010</i> Attachment(s) #: <u>14</u> <i>TC 19 Apr 2010</i></p>	<p>Pass FAIL See NCR# 03. <i>Doc 24 apr 2010</i></p>	<p><i>TC 19 Apr 2010</i></p>



Example: CTMS Validation Effort

Document	# of Pages
Validation Plan	22
Risk Analysis	9
User Requirements Specification	17
Vendor Audit	1
System Specification	15
Functional Design Specification	428
Software Configuration Specification	38
Installation Verification	42
Functional Verification	1216
User Acceptance Testing	200
Traceability Matrix	47
Validation Summary Report	35
Total	2070



Hours
>500



Current Challenges

- Industry experts estimate that the financial burden related to validation activities can reach 30-50% of the total cost of a project.
- The time and resource commitment to accomplish a typical system validation can be a major challenge to an organization.
- Depending on scope and system complexity, validation commonly requires at least 6-8 weeks of effort (often longer) with a minimum of 3-4 resources.
- A paper-intensive validation process is inefficient and expensive.



Trials & Tribulations

- Processes that require a manual signature for review and approvals tend to be slow.
- Distribution of documents for approval or execution when resources are working off-site is difficult and generally leads to additional copies of the document.
- Manipulation of a document may lead to accidental loss or misplacement of the physical document.
- Physical storage of documents in a secure location throughout the required retention period is a challenge in records management.
- Requirements traceability can be incomplete and hard to track in a non-automated environment.

- Hybrid paper-electronic approach to executing validation testing (paper-lite)
- Separate documents for test script instructions and results
- The Test Script Instructions are:
 - Static
 - Printed and approved
- The Test Results Worksheets are:
 - Dynamic
 - Filled in manually, in electronic format
 - Printed and signed upon completion



Test Script



Validation: The Future

- To reduce the documentation burden associated with paper-based validation:

Go Paperless!

- The current industry trend is to use validation toolkits and online electronic validation systems.
- Paperless systems allow you to track and manage requirements and validation protocols online and effectively produce validation document deliverables using an automated approach.



Using SharePoint for Paperless Validation

- SharePoint Sites, Libraries & Lists for storage of system documents and data
- Integration with 3rd party software solutions for:
 - Automated workflow capabilities
 - Document conversion into PDF format
 - Digital signature capabilities
- Integration with web-based InfoPath forms for capturing user process inputs
- Dashboards for tracking of KPIs and process metrics



Benefits

- Document versioning (major, minor) and document version history are built-in.
- Access to sites can be controlled so that only authorized users are allowed to access the information shared therein.
- SharePoint has superb MS Office client integration.
 - The Document Information Panel (DIP) enables users to enter document metadata (properties) at anytime from within the MS Office system client application.
 - Metadata entered in the DIP (such as Status, Document Reviewers) can be used to drive automated processes for routing documents.



The DIP

The screenshot shows a Microsoft Word document titled "CSV-SYS2-VPL-0001 (Read-Only) - Microsoft Word". The ribbon includes Home, Insert, Page Layout, References, Mailings, Review, View, Developer, and Livelihood. The document contains a form for "Validation Plan Properties - Server" with the following fields:

- Title: Montrium Validation Plan Te...
- Document Status: Draft
- Process Owner: [User]
- QA Representative: [User]
- Author: Stefanie Wu
- Revision: [Empty]
- Department: Administration
- Abbreviation: VPL
- Document Type Name: Validation Plan
- IMP:
- Linked Form: [Empty]
- Linked Template: [Empty]
- RegContentType: [Empty]
- Regulatory review requi...:
- Section: CSV Files
- Linked CSV Pack ID: [Empty]
- ICH Section Number: NA

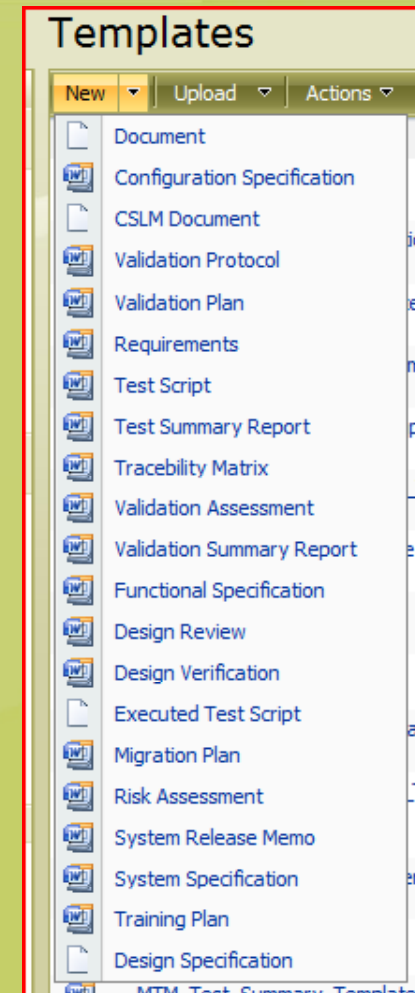
Location: <http://demo/it/CSLM/CSV%20Documents/Planning/CSV-SYS2-VPL-000> * Required field

Server Document: To modify this document, you must check it out. Check Out

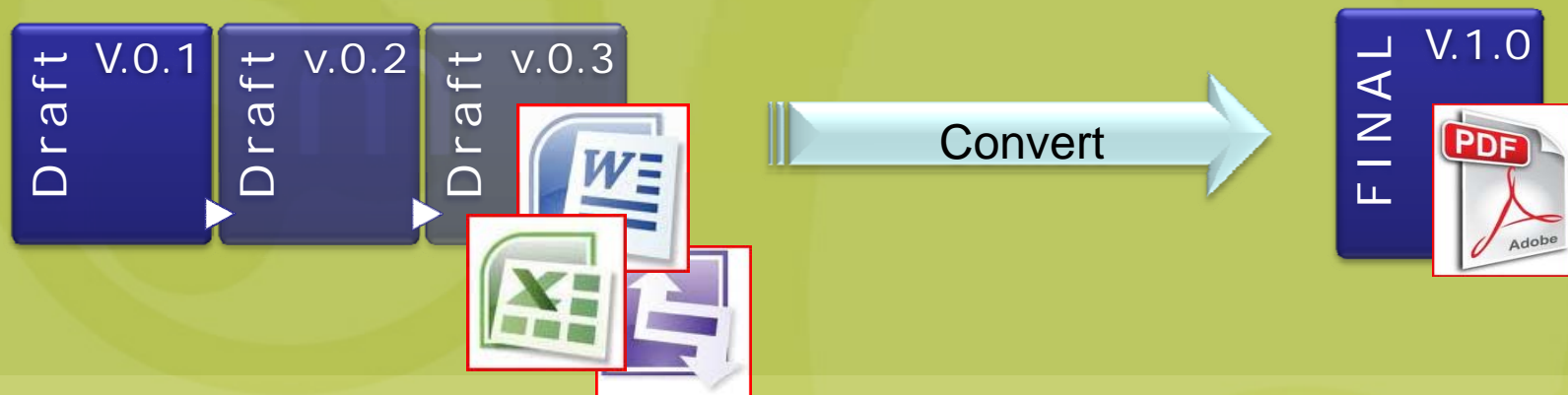
	Validation Plan	Document N°
	TITLE Montrium Validation Plan Template	Revision:

Author Signature:

- Sites can be used to collect, store, and organise data and information into system-specific document libraries.
- Using pre-set Content Types in combination with document libraries, we can have a set of document templates that users can choose from.
- Document templates facilitate the creation of standardized system validation documentation.

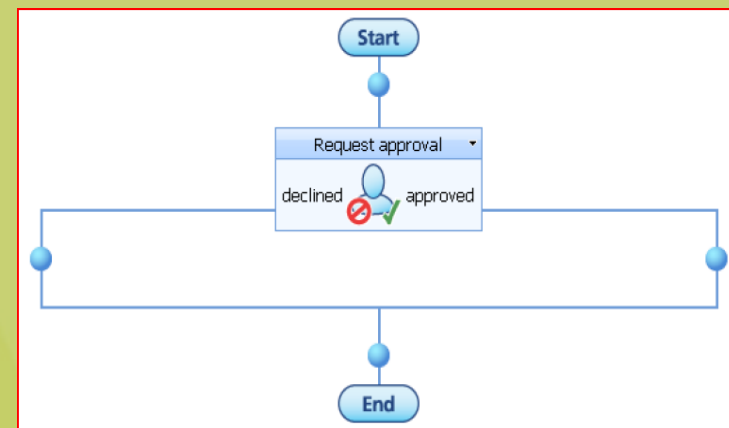


- SharePoint integrates with document conversion software for automatic conversion of electronic documents into PDF format.



- Benefit(s):
 - PDFs are the preferred format for archival of records.
 - PDFs can be electronically signed.

- A workflow is the automation of (a part of) a business process. Through workflows, documents, information, or tasks are passed from one participant to the next for action according to a set of procedural rules.
- SharePoint has built-in workflow design functionality that is ideal for simple workflows only.
- For the design of complex workflows, SharePoint integrates with Nintex Workflow.





Using Workflows for Document Approval

- The Document Lifecycle Process (DLP) Workflow drives the document approval process by:
 - Guiding individuals through the document lifecycle through the use of automated task assignment and email alerts to inform users when their input (actions) are required.
 - Routing documents to the relevant reviewers and approvers based on document status and characteristics defined in the file plan.





Benefits of Using Workflows

- Replaces more traditional collaboration tools (such as email).
- Manages document status and versioning as it moves through review and approval.
- Enhances traditional tracking and reporting tools (such as Excel).
- Feeds the dashboard for tracking of KPIs and process metrics.

A screenshot of a dashboard titled "Key Performance Indicators" with a dropdown menu set to "Show Only Problems". The dashboard displays a table with two columns: "Indicator" and "Status".

Indicator	Status
Systems Under Validation	▲
Systems Under Change Control	●
Systems Validated	◆
CSV Documents Awaiting Approval	●



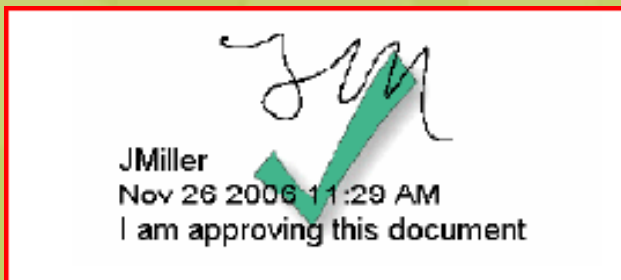
Electronic Signatures

- SharePoint integrates with 3rd party solutions for digital signatures.
- This is a fundamental facet of paperless validation.
- Benefit(s):
 - Validation documents and records can be digitally signed directly within the document, from a SharePoint library, or within a SharePoint workflow tasks.



Electronic Signatures vs. Approvals

- An electronic signature is required on electronic record only when a handwritten signature is required, per predicate rules, on the equivalent paper record.



- Otherwise, it is sufficient for data to respect ALCOA. This can be done through a simple approval operation that logs the identity of the involved individual in an audit trail.

ALCOA: Accurate – Legible – Contemporaneous – Original - Atributable



Using InfoPath Forms

- SharePoint integrates with InfoPath technology using InfoPath Form Services.
- InfoPath is a MS Windows–based application that is used to create dynamic forms based on XML and its associated technologies.
 - All data stored in InfoPath forms are stored in an XML format.
 - XML is an open standard that allows other systems to access information, making it easier for other applications to use, store, transmit, and display data.

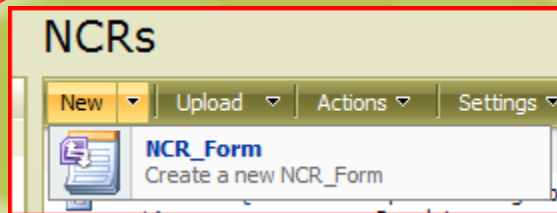


InfoPath Form Libraries

- Create browser-enabled interactive form templates for reporting:
 - Executed Test Scripts (Test Results)
 - Non-Conformances
 - Change Requests
 - ... and more!
- Completed InfoPath forms are submitted to designated Form Libraries in SharePoint.
 - User inputs captured in InfoPath fields can be exported as Columns in the form library and can be directly read in SharePoint or be used as part of web services results in workflow development.

Non-Conformance Report Library

- The NCR Library contains InfoPath forms for reporting non-conformances encountered during validation.
- The associated NCR workflow manages the process of reporting, reviewing, and closing out NCRs.



NCRs

New Upload Actions Settings View: Webinar

Type	Name	NCR Status	Criticality	Non Conformance ID	Validation Protocol Number	Description Of Non Conformance	NCR Approver	NCR Implementer	NCR Investigator	NCR Reviewer
	NCR-IPI-VQP-008-14	Open - Investigation Complete	Non-Blocking	NCR-IPI-VQP-008-14	IPI-VQP-008	blah	Michael Zwetkow	Stefanie Wu	Stefanie Wu	Michael Zwetkow
	NCR-IPI-VQP-007-8	Open - Investigation Complete	Blocking	NCR-IPI-VQP-007-8	IPI-VQP-007	Test step failed to meet expected result	Michael Zwetkow	Tevin Pathareddy	Michael Zwetkow	Paul Fenton
	NCR-IPI-VQP-007-17	Open - Investigation Complete	Non-Blocking	NCR-IPI-VQP-007-17	IPI-VQP-007	ds	Stefanie Wu	Stefanie Wu	Stefanie Wu	Stefanie Wu
	NCR-IPI-VQP-007-16	Open - Not Investigated		NCR-IPI-VQP-007-16	IPI-VQP-007	adf	Stefanie Wu	Stefanie Wu	Stefanie Wu	Stefanie Wu



Example: NCR Form, Report Information

Non-Conformance Report - Report Details	
Author:	Michael Zwetkow
Non-Conformance ID:	NCR-IPI-VQP-007-8
System:	EDMS
NCR Status:	Open - Investigation Complete
Report Information Investigation Corrective Action Print View	
Information	
Non Conformance ID:	NCR-IPI-VQP-007-8
Report Date:	21-Jul-2009
CSV ID:	CSV-EDMS-01
System Name:	EDMS
System Description:	Livelihood for Regulated Documents
Validation Document ID:	IPI-VQP-007
Non-Conformance Type:	Protocol generation error
Description	
Test Script No.:	EDMS-OQ-15.01
Test Script Title:	Password Management
Execution Run:	1
Test Step(s):	1-4
Description Of Non Conformance:	Test step failed to meet expected result
NCR Investigator:	Michael Zwetkow
NCR Reviewer:	Paul Fenton
NCR Corrective Action Implementer:	Tevin Pathareddy
NCR Approver:	Michael Zwetkow
Attachments	
Attachment	Attachment Description
Click here to attach a file	
<input checked="" type="checkbox"/> Insert item	



Example: NCR Form, Investigation

Submit NCR Save Save As... Close View Investigation Print View

Non-Conformance Report - Report Details	
Author:	Michael Zwetkow
Non-Conformance ID:	NCR-IPi-VQP-007-8
System:	EDMS
NCR Status:	Open - Investigation Complete
Report Information	Investigation Corrective Action Print View

Investigation

Cause and Proposed Corrective Action:	The incorrect version was installed
Criticality:	Blocking
Criticality Justification:	This is a critical
Testing Required:	<input checked="" type="radio"/> Yes <input type="radio"/> No

Test Scripts to be Executed

New?	Test Script No.	Test Description	Test Steps
<input checked="" type="checkbox"/>	TS-1234	Security Test	1-4

Insert test script

Approval

Investigated by:	Michael Zwetkow	Date:	21-Jul-2009	Confirm
Reviewed and Approved by:		Date:		Approve Disapprove

Attachments

Attachment	Attachment Description
<input type="button" value="Click here to attach a file"/>	

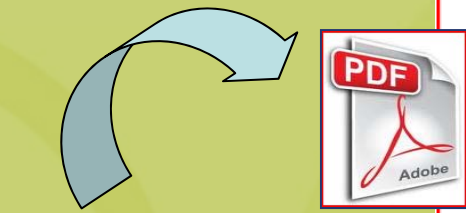
Insert item

Example: NCR Form, Corrective Action

Submit NCR | Save | Save As... | Close | View Corrective Actio | Print View

Non-Conformance Report - Report Details			
Author:	Michael Zwetkow		
Non-Conformance ID:	NCR-IPI-VQP-007-8		
System:	EDMS		
NCR Status:	Open - Investigation Complete		
Report Information		Investigation	Corrective Action
Print View			
Corrective Action			
Corrective Action Implemented:			
Test Script No.	Test Steps	Execution Run	Test Result
TS-1234	1-4	<input type="text"/>	<input type="checkbox"/> type ...
Approval			
Implemented by:		Date:	<input type="text"/>
Reviewed and Approved by:		Date:	
			Confirm
			Closed - Resolved
			Closed - Not Resolved
			Disapprove
Attachments			
Attachment	Attachment Description		
<input type="button" value="Click here to attach a file"/>			
<input checked="" type="checkbox"/> Insert item			

Example: NCR Form, Print View



Non-Conformance Report

1.0 Report Information

Author: Michael Zwetkow
 System: EDMS
 Non-Conformance ID: NCR-IPI-VQP-007-8 Report Date: 21-Jul-2009
 Validation Document ID: IPI-VQP-007 Execution Run: 1
 NCR Type: Protocol generation error

2.0 Description

Test Script No.: EDMS-OQ-15.01 Test Step(s): 1-4
 Test Script Title: Password Management
 Description Of Non-Conformance:
 Test step failed to meet expected result

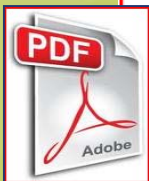
3.0 Investigation

Cause And Proposed Corrective Action:
 The incorrect version was installed

Criticality: Blocking Criticality justification: This is a critical
 Testing required: true Justification for no Testing: N/A
 Investigated By: Michael Zwetkow Date: 21-Jul-2009
 Corrective Action approved by: Date:

4.0 Corrective Action

Corrective Action Implemented:



Non-Conformance Report page 1 of 1

1.0 Report Information

Author: Michael Zwetkow
 System: EDMS
 Non-Conformance ID: NCR-IPI-VQP-007-8 Report Date: 21-July-2009
 Validation Document ID: IPI-VQP-007 Execution Run:
 NCR Type: Protocol generation error

2.0 Description

Test Script No.: EDMS-OQ-15.01 Test Step(s): 1-4
 Test Script Title: Password Management
 Description of Non-Conformance:
 Test step failed to meet expected result

3.0 Investigation

Cause and Proposed Corrective Action:

Criticality: Criticality Justification:
 Testing Required: Justification for no Testing:
 Investigated By: Date:
 Corrective Action Approved By: Date:

4.0 Corrective Action

Corrective Action Implemented:

Test Scripts Executed:

Test Script ID	Test Run	Test Steps	Test Script Description	Test Result
				type ...

Implemented By: Date:
 Closed By: Date:
 NCR Status:
 Approval Signature: X Approval Signature Date:

5.0 Attachments

Example: Test Script

montrium TEST RESULTS WORKSHEET
Title: Model Test Script

Test Identification	
Test ID	S01-VTS-001-00
Title	Test Script for Logical Access to a System
Purpose	To verify that user authentication is required before being granted access to the system
Test Run Number	Choose an item
System ID and Version	Click here to enter text.
Test Environment	Click here to enter text.

PRQ-# Value / Result	
PRQ-1	Username: Click here to enter text. Password (optional): Click here to enter text.

Step #	Actual Result	Related NCR	Control Point	Pass / Fail
1.	Click here to enter text.	Click here to enter text.	CP-1	Choose an item.
2.	Click here to enter text.	Click here to enter text.	CP-2	Choose an item.

Control Point #		Screen Shot	
CP-1		Click here to insert a picture	
CP-2		Click here to insert a picture	



Test Identification			
Test ID	S01-VTS-001-00	Test Run Number	
System ID and Version			
Test Environment			

PRQ-# Value / Result	
PRQ-1	Username: Password (optional):

Step #	Actual Result	Related NCR	Control Point	Pass / Fail
1.			CP-1	<input type="radio"/> Pass <input type="radio"/> Fail
2.			CP-2	<input type="radio"/> Pass <input type="radio"/> Fail

Control Point #		Screen Shot	
CP-1		Click here to insert a picture	
CP-2		Click here to insert a picture	

Test Summary	
AC-#	Were Acceptance Criteria Met? (Yes / Conditional Yes / No)
AC-1	<input type="radio"/> Yes <input type="radio"/> Conditional Yes <input type="radio"/> No
AC-2	<input type="radio"/> Yes <input type="radio"/> Conditional Yes <input type="radio"/> No
Overall Result (Pass / Conditional Pass / Fail)	<input type="radio"/> Pass <input type="radio"/> Conditional Pass <input type="radio"/> Fail
Retest Required? (Yes / No)	<input type="radio"/> Yes <input type="radio"/> No
Test Performed By:	
Test Results Reviewed By :	

Executed Test Scripts

New Upload Actions Settings								View: Webinar 1
Name	CSVID	Execution Run	System ID	Test Run	Test Result	System Type	System Version	
[-] CSVID : CSV001 (12)								
[-] Test Result : Completed Successfully (4)								
IPI-VTS-xxx Set 01 - TS OQ01-11	CSV001	45	SYS3	5	Completed Successfully	Server	1.0	
IPI-VTS-xxx Set 01 - TS OQ01-12	CSV001	87	SYS4	5	Completed Successfully	eCTD	1.0	
IPI-VTS-xxx Set 01 - TS OQ01-2	CSV001	4	SYS1	4	Completed Successfully	EDMS	2.0	
IPI-VTS-xxx Set 01 - TS OQ01-5	CSV001	5	SYS1	5	Completed Successfully	EDMS	2.0	
[-] Test Result : Completed with Deviations (2)								
IPI-VTS-xxx Set 01 - TS OQ01-1	CSV001	9	SYS1	6	Completed with Deviations	EDMS	2.0	
IPI-VTS-xxx Set 01 - TS OQ01-15	CSV001	2	SYS3	5	Completed with Deviations	Server	1.0	
[-] Test Result : In Execution (3)								
IPI-VTS-xxx Set 01 - TS OQ01-13	CSV001	4	SYS5	3	In Execution	Web Service	1.0.	
IPI-VTS-xxx Set 01 - TS OQ01-14	CSV001	3	SYS2	4	In Execution	CTMS	1.5	
IPI-VTS-xxx Set 01 - TS OQ01-3	CSV001	2	SYS1	3	In Execution	EDMS	2.0	
[-] Test Result : Not Executed (3)								
IPI-VTS-xxx Set 01 - TS OQ01-10	CSV001	4	SYS2	5	Not Executed	CTMS	1.5	
IPI-VTS-xxx Set 01 - TS OQ01-4	CSV001	8	SYS1	8	Not Executed	EDMS	2.0	
IPI-VTS-xxx Set 01 - TS OQ01-6	CSV001	2	SYS1	9	Not Executed	EDMS	2.0	



Requirements Traceability

	EDMS Traceability Matrix	
	System Name:	EDMS
	Requirements Version:	2.0
	Requirements Version Date:	26/01/2009
	<div style="display: flex; justify-content: space-between;"> System Details Validation Assessment URS Risk Assessment </div> <div style="display: flex; justify-content: space-between; margin-top: 5px;"> Validation Plan Test Scripts Traceability Matrix NCR Summary </div>	

Test Phase ID:	TP1	Test Phase Description:	Initial Validation
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Test Protocol ID: IPI-IQ-001

1 The system must adhere to the minimum hardware and software requirements recommended by the vendor.

UR ID	Requirement	Priority	Risk				Test Required	Testing Scripts		
			Risk Scenario	Risk Relevance	Risk Priority	Risk Rationale		Test Script ID	Test Executed	Test Run ID
1-1	The Livelihood server shall include the following minimum hardware components:- 3.20 GHz processors (2x)- 4 GB RAM- 1 Gbit NIC	Mandatory	Risk Scenario	Risk Relevance	Risk Priority	Risk Rationale	true	Test Script ID	Test Executed	Test Run ID
			Components not installed	GxP	Low	Will be tested during HQ		EDMS-OQ-15.05	Not Executed	TP-001
			Components not installed	Business	Low	Will be tested during HQ		EDMS-OQ-15.02	Not Executed	TP-001
1-2	The Livelihood server shall operate with Microsoft Windows Server 2003 Server, SP1.	Mandatory	Risk Scenario	Risk Relevance	Risk Priority	Risk Rationale	true	Test Script ID	Test Executed	Test Run ID
			Components not installed	GxP	Low	Will be tested during HQ		EDMS-OQ-15.03	Not Executed	TP-001
			Components not installed	Business	Low	Will be tested during HQ				
1-3	The database server shall include the following minimum hardware components:- 2.80 GHz processors (x2)- 4 GB RAM- 1 Gbit NIC	Mandatory	Risk Scenario	Risk Relevance	Risk Priority	Risk Rationale	true	Test Script ID	Test Executed	Test Run ID
			Components not installed	GxP	Low	Will be tested during HQ		EDMS-OQ-15.07	Not Executed	
			Components not installed	Business	Low	Will be tested during HQ				



Benefits of Working with InfoPath

- InfoPath forms provide an enriched user experience by providing the following capabilities:
 - Data validation, conditional formatting, merging of data from multiple forms into one document.
- Each stage of the process (e.g. reporting, analysis, close-out) can be managed by an automated workflow.
- Using dashboards, it is possible to obtain a real-time view of:
 - Non-conformance status for a particular system.
 - Change control activity status.
 - Trends in root-causes within or across systems.
- Generate PDF renditions of the forms as records for long-term retention.



Validated IT System Inventory

- The Validated IT System Inventory is the control center, pooling together all documents that contribute to the validated state of a computerized system.

Select a CSV Pack to see related components and documents

CSV Navigator

System Description		CSV List	System Functional Area	System Components	CSV Documents	Executed Test Scripts	NCRs	Change Control Requests	Tabs		
<input type="radio"/>		SYS001	SharePoint For Pharma	Montrium	1.0	Validated	<input type="radio"/> System Administrator Paul Fenton	<input type="radio"/> System Owner Michael Zwetkow	SharePoint Collaborative Workspaces for GxP Environments	Production	Linked CSV Pack ID CSV001
<input type="radio"/>		SYS002	CTMS	Montrium	1.0	Under Validation	Michael Zwetkow	Michael Zwetkow	System used to manage clinical trials	Development	CSV002
<input type="radio"/>		SYS003	ERP	Montrium	2.5	Not Implemented	Frederic Landry	Mihai Popa	Enterprise Ressource Planning System	Testing	
<input type="radio"/>		SYS004	CDMS	Montrium	2.1	Validated	Paul Fenton	Francois Baudoin	Clinical Data Management System	Production	
<input type="radio"/>		SYS005	eCTD	Montrium	2.5	Validated	Mihai Popa	Frederic Landry	Electronic Common Transfer Document System (eCTD) used to transfer documents to regulatory agencies	Production	
<input type="radio"/>		SYS006	EDC	Montrium	1.0	Validated	Paul Fenton	Francois Baudoin	System used for the electronic data capture of CRF information	Production	
<input type="radio"/>		SYS007	IVRS	Montrium	2.0	Under Validation	Tevin Pathareddy	Mihai Popa	Interactive Voice Response System	Testing	
<input type="radio"/>		SYS008	Pharmacovigilance (PV)	Montrium	3.1	Not Implemented	Michael Zwetkow	Francois Baudoin	Management of adverse reactions and protection of patient safety	Development	



Hardware Inventory

- The inventory of hardware components can be linked in a hierarchical manner to form the complete system architecture for each validated system.

Hardware Inventory

List of all controlled hardware

HW ID	Server Name	Used for	OS	Machine Type	CPU	IP Address	RAM	HD	Vendor Name	Hardware State	Validated State	Linked CSV Pack ID
HW6	Fred	ARX CoSign Server	Server 2008 R2 - 64 bit	Physical	Quad Core	192.168.0.223	8 G	1.5 TB	DELL		Not Implemented	
HW5	Jack	Server used for MOSS	Server 2003 R2 - 64 bit	Physical	Xeon 5335	465.127.9.112	4Gb	250Gb	Dell		Validated	CSV001
HW1	Noah	Server for Adlib Express	Server 2008 R2 - 64 bit	Physical	Quad-Core	192.168.0.223	8Gb	220Gb	HP		Not Implemented	CSV002
HW2	Stef	Server for SQL	Server 2008 - 32 bit	Physical	Xeon 5130	123.153.2.123	8Gb	160Gb	Sony		Validated	CSV002
HW4	NAYA	Test Server for MOSS	VMWare ESXi	Virtual	Core 2 Duo	115.571.5.211	2Gb	500Gb	Dell		Validated	CSV002
HW3	Olive	Test server used for SQL	Server 2008 - 64 bit	Virtual	Core 2 Duo	987.214.4.247	4Gb	300Gb	Apple		Validated	CSV002

CSV List

CSV Pack ID	CSV Pack Description	CSV Pack Status	Linked Systems	Linked Functions	Linked Hardware
CSV001	Initial Validation Pack for baseline SharePoint validation plus three main components	Complete	SYS001	FUNC001; FUNC002	HW1; HW2
CSV002	MOSS 2007 Sever Qualification	Complete	SYS002		HW5; HW4
CSV003	CTMS Validation	Planned		FUNC006; FUNC007	HW6
CSV004	UDI Web service validation	Planned			







System Description

System Description Document				
montrium		System ID: SYS001	Validated State: Validated	
IT System ID	SYS001	System Name	SharePoint For Pharma	
System Description	SharePoint Collabroative Worksapces for GxP Environements			
System Owner		System Version	1.0	
System Vendor	Montirum			
System Hardware & COTS				
HW ID	HW Name	Machine Type	Environment	Validated State
HW1	Noah	Physical	Production	Validated
Description	Production			
COTS ID	COTS Name	COTS Version	Validated State	
COTS001	Microsoft Windows Server 2008	R2	Validated	
COTS007	Microsoft Office SharePoint	2007	Validated	
COTS006	Nintex Workflow Server	2007	Validated	
<input checked="" type="checkbox"/> Insert COTS Item				
HW ID	HW Name	Machine Type	Environment	Validated State
HW5	Jack	Physical	Test	Validated
Description	Finance			
COTS ID	COTS Name	COTS Version	Validated State	
COTS001	Microsoft Windows Server 2008	R2	Validated	
COTS007	Microsoft Office SharePoint	2007	Validated	
COTS006	Nintex Workflow Server	2007	Validated	
<input checked="" type="checkbox"/> Insert COTS Item				
HW ID	HW Name	Machine Type	Environment	Validated State
HW2	Stef	Physical	Production	Validated
Description	Consulting			
COTS ID	COTS Name	COTS Version	Validated State	
COTS002	Microsoft SQL Server 2008	2008	Validated	

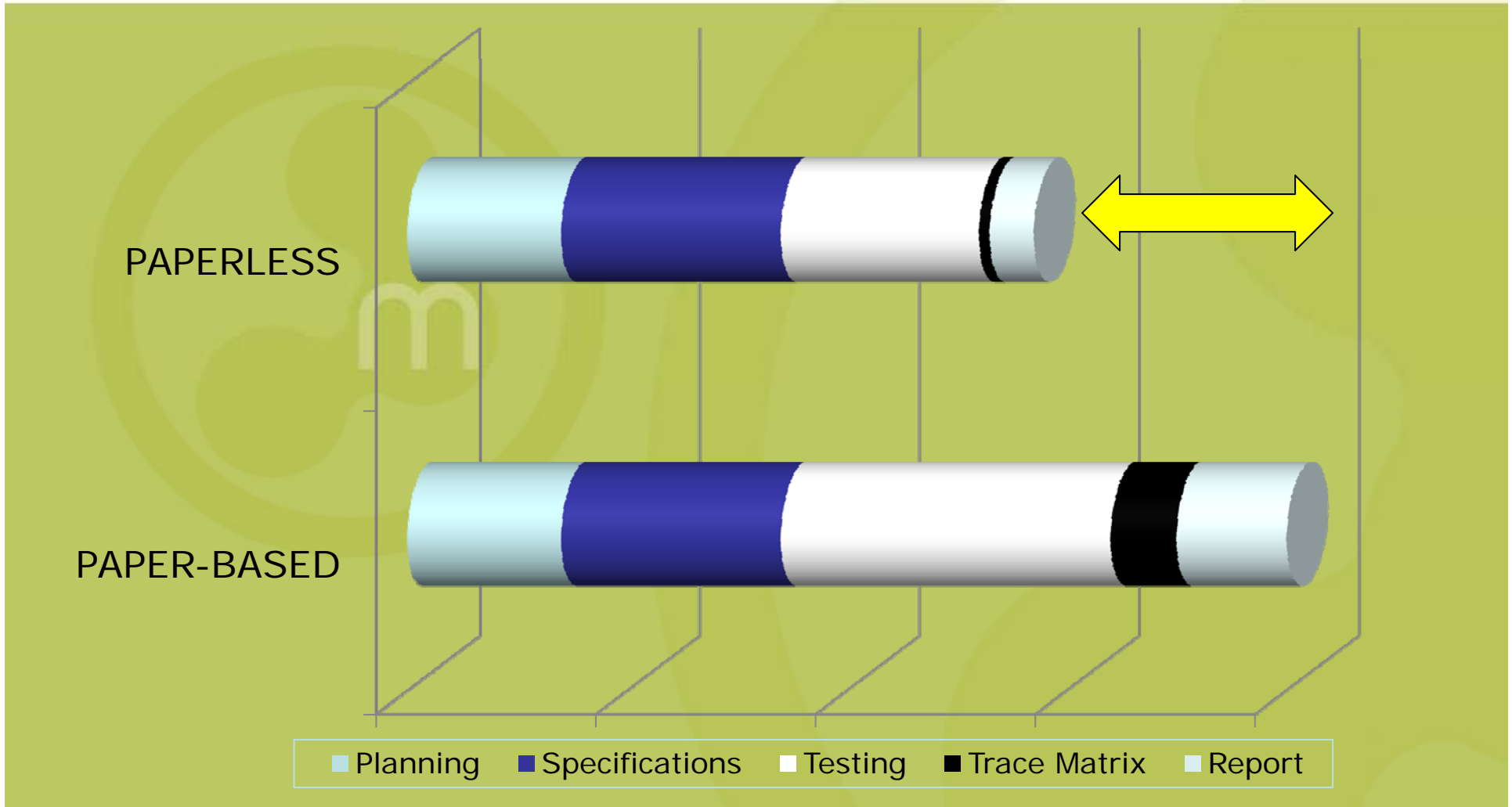
- The Validated IT System Reports allows us to view all documentation related to each system.

Select a CSV Pack to see related components and documents

CSV Navigator

System Description	CSV List	System Functional Area	System Components	CSV Documents	Executed Test Scripts	NCRs	Change Control Rec	
Type	Name	Revision	Content Type	Document Status	Created By	Checked Out To	System Description	System Version
System Description : Documentation Management Workspace (5)								
System Description : Electronic Document Management System (15)								
System Description : SharePoint SQL Server (4)								
	CSV-SYS3-REQ-0001		Requirements	Under Review	Stefanie Wu		SharePoint SQL Server	
	CSV-SYS3-TS-0002	2.0	Test Script	Under Review	Stefanie Wu		SharePoint SQL Server	
	CSV-SYS3--0001		Traceability Matrix	Draft	Michael Zwetkow		SharePoint SQL Server 1.0	
	CSV-SYS3-VSR-0001		Validation Summary Report	Under Review	Stefanie Wu		SharePoint SQL Server 1.0	

- Benefit(s):
 - Document traceability is transparent and can be easily rolled into the Validation Summary Report.





Drawbacks

- Any drawbacks are temporary in nature and are primarily going to be upfront in the establishment of a paperless system.
- The tools supporting the paperless validation process need to be validated.



Is Industry Ready to Forego Paper?

Yes, now more than ever!

- Advanced technologies now exist and complete the paperless validation toolkit.
 - ✓ Document management system
 - ✓ Document conversion software
 - ✓ Workflow management software
 - ✓ Digital signatures
 - ✓ Intelligent documents and forms
- Any improvement in operational efficiency and cost should be a compelling reason to drive a business to adopt a paperless validation process.



Wrap-up

- This webinar is the final webinar in a series of informative webinars on the validation and use of SharePoint within regulated pharmaceutical environments.
- Recordings of all webinar sessions will be made available on our website.
- *NEW!* A new series of webinars will be launched in Fall 2010 (Dates to be announced).
- For more information, please visit:
<http://www.montrium.com/en/home/webinars.php>



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