



MONTRIUM

SharePoint for Pharma - Configuration Management Effective Techniques for Regulated SharePoint Environments

Presented by
Paul Fenton
VP Pharmaceutical Processes
and Technology

May 7th 2010



SharePoint for Pharma Series

- Webinar series that aims to highlight the different aspects of validation and the use of SharePoint in GxP environments
- 5 different sessions covering the different aspects of deployment, use and validation of MOSS
- Should provide attendees with a good grounding for their SharePoint projects
- Slides can be distributed upon request. Details on how to request slides will be distributed to attendees following each webinar.
- Thank you for your interest!

- Recap of A Risk-based Approach to Validating SharePoint for Regulated Environments
- SharePoint within the GxP context
- Regulatory Requirements
- Industry Standards
- Corporate Standards
- What is Configuration Management?
- Implementation of formal system specific configuration control procedures
- Configuration deployment and version control techniques
- Integration with the validation and change control process
- Importance of leveraging a risk based approach to QC
- Using SharePoint to manage configuration control

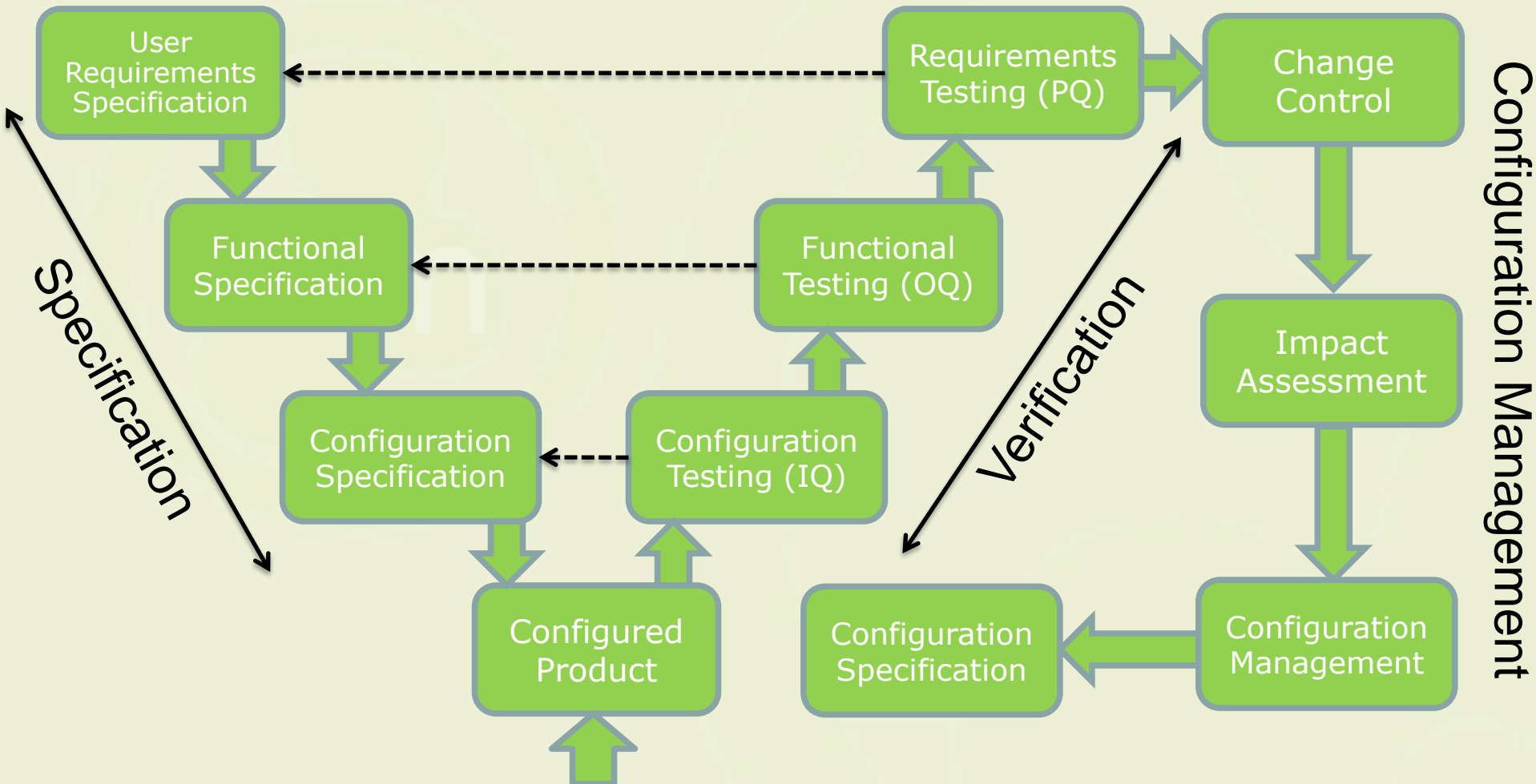


Recap of last webinar

- Create a '**Big Picture**' of your MOSS deployment so as to ensure that you are able to adequately accommodate all of your **controlled** and **non-controlled** needs
- Use a **risk based approach** to focus and reduce validation efforts – be strict otherwise everything becomes high risk...
- Remember that **MOSS** is an **off-the-shelf product** and that you should **limit validation scope** to high risk business and regulatory requirements as much as possible
- Establish a **MOSS validation team** to oversee and manage the validation process and **changes** to the controlled MOSS environment
- Implement **SOPs** and WIs which clearly define how the environment is configured and **administered** and which level of documentation / re-validation is required by type of **change**
- Use a **step by step deployment** methodology to keep things manageable



GAMP5 – CSV Framework for a Configured Product





Use of SharePoint within a GxP context

- Microsoft SharePoint is a **web portal technology** that is highly customizable and very user friendly
- Within a GxP context, Microsoft SharePoint can be used to:
 - **Manage documents** and GxP records
 - Design **electronic forms** for the collection of data for everyday operational GxP activities
 - Manage **lists and trackers** of information centrally, replacing Excel spreadsheets and Access databases
 - Manage distribution of information and **collaboration** between geographically dispersed teams
 - Implement **interactive workflows** in line with **SOPs** to better manage processes
 - Provide real-time GxP **metrics** and **KPIs** through dashboards to facilitate decision making



Challenges of SharePoint within the GxP Context

- SharePoint technology is being used more and more in **many functional areas** within the life science industry
- Within the context of a **regulated environment**, it is imperative to maintain **proper configuration control** over the validated SharePoint environment
- This can represent a **significant challenge** given the granularity and the large scope of SharePoint, particularly when using this platform as a document and records management solution
- Organizations need to **plan** their SharePoint Architectures and configuration to **ensure scalability** and **compliance**

- 21 CFR part 11 (Scope and Application 2003)
 - 11.10(c) Protection of records to enable their **accurate and ready retrieval** throughout the records retention period
 - 11.10(k) Use of appropriate **controls** over systems **documentation** including :
 - (1) Adequate controls over the distribution of, access to, and **use of documentation** for system operation and **maintenance**
 - (2) Revision and **change control procedures** to maintain an audit trail that documents time-sequenced development and modification of systems documentation



Regulatory Requirements

- FDA: CSUCI – May 2007

§ F5 Change Control - The **integrity** of the data and the integrity of the protocols should be **maintained when making changes** to the computerized system, such as software upgrades, including security and performance patches, equipment, or component replacement, or new instrumentation. The **effects of any changes** to the system should be **evaluated** and some should be **validated depending on risk**.

Changes that exceed previously established operational limits or design specifications should be validated. Finally, all changes to the system should be documented.

- PIC/S PI 001-3 – September 2007 (Annex 11)
 - § 7.2. - Clearly identifies **ISO** standards and **GAMP5** as acceptable practices for configuration management
 - § 18.1 The formal **change control procedure** should outline the necessary information and records for the following areas:
 - [...]
 - **Interface of change control** procedure with **configuration management** system
 - § 24.10 – Inspector's **Checklist** clearly indicates need for **configuration management**
- Other GMP / GLP related guidance also exists...

- That configuration of systems is **clearly documented**
- That configuration **documentation** is **maintained and controlled**
- That configuration management **forms part of change control**
- That changes to systems (including configuration changes) be **evaluated for impact and risk**
- That **formal** change control and configuration management **procedures** be in place
- That the **integrity** of the **system** and **data** contained within is guaranteed

- ISPE GAMP5
 - GAMP 5 section 4.3.4.1 – Change Management
 - GAMP 5 Section 4.3.4.2 – Configuration Management

Critical areas for business wide standardization:

- Clear and formal corporate **Taxonomies**
- Alignment with adopted **industry standards**:
 - ICH guidance and reference models such as TMF / EDM, etc.
 - CDISC data standards where applicable
 - Quality methodologies (Six Sigma, ISO, TQM, etc.)
- Document **classification** and records management / retention
- Uniform **site structures, content types** and **metadata** across all departmental sites and libraries (should be aligned with Taxonomy)
- Formal **procedures** and policies to govern the **use** of the regulated SharePoint environment
- Standardized **Metrics** and KPIs across the organization
- Numbering and **Nomenclature** standards

- Configuration Management is:
 - The **establishment** and **maintenance** of a system's **features** and **performance** within the context of its requirements, design and operational information throughout its **lifetime**
 - A sub-process of Change Control
 - A formal process for defining and maintaining system configuration within the context of Change Control
 - Required by **regulation** for systems used to generate **electronic records** or manage GxP regulated activities required by **predicate rule**

What is Configuration Management?

- According to GAMP 5, configuration management consists of the following activities:

Configuration Identification

WHAT to keep under control

Configuration Control

HOW to **perform** the control

Configuration Status Accounting

HOW to **document** the control

Configuration Evaluation

HOW to **verify** that control

What and How?

Configuration Identification

WHAT to keep
under control

- The **components** of the system subject to configuration management should be clearly established
- The system should be **broken down** into ***configuration items***, which are clearly identified and documented during system specification and development (Configuration Specifications)
- A ***configuration item*** is a component of the system which does not change as a result of the **normal operation** of the system
- Configuration items should be **modified only** by application of a **change management process**

Configuration
Control
HOW to
perform the
control

Changes to configuration items should be coordinated and controlled. This includes the following activities:

- **Version Control** - A unique name and a version number should identify each configuration item
- **Change Control** - Change control should be applied to all configuration items
- **Configuration Item Storage** - Configuration items should be stored and controlled in such a way that they are protected from unwanted or unauthorized changes
- **Delivery Control** - The release and delivery of software and documentation should be controlled

Source: GAMP5

Configuration
Status
Accounting

HOW to
document the
control

- Appropriate **SOPs** should be in place to **govern** the configuration control **process**
- **Documentation** showing the **status** and **history** of configuration items should be maintained.
- The documentation **should include** the details of the **changes made** and demonstrate that the requested changes were **approved for** execution, **reviewed** and **approved after** execution

Source: GAMP5

Configuration
Evaluation

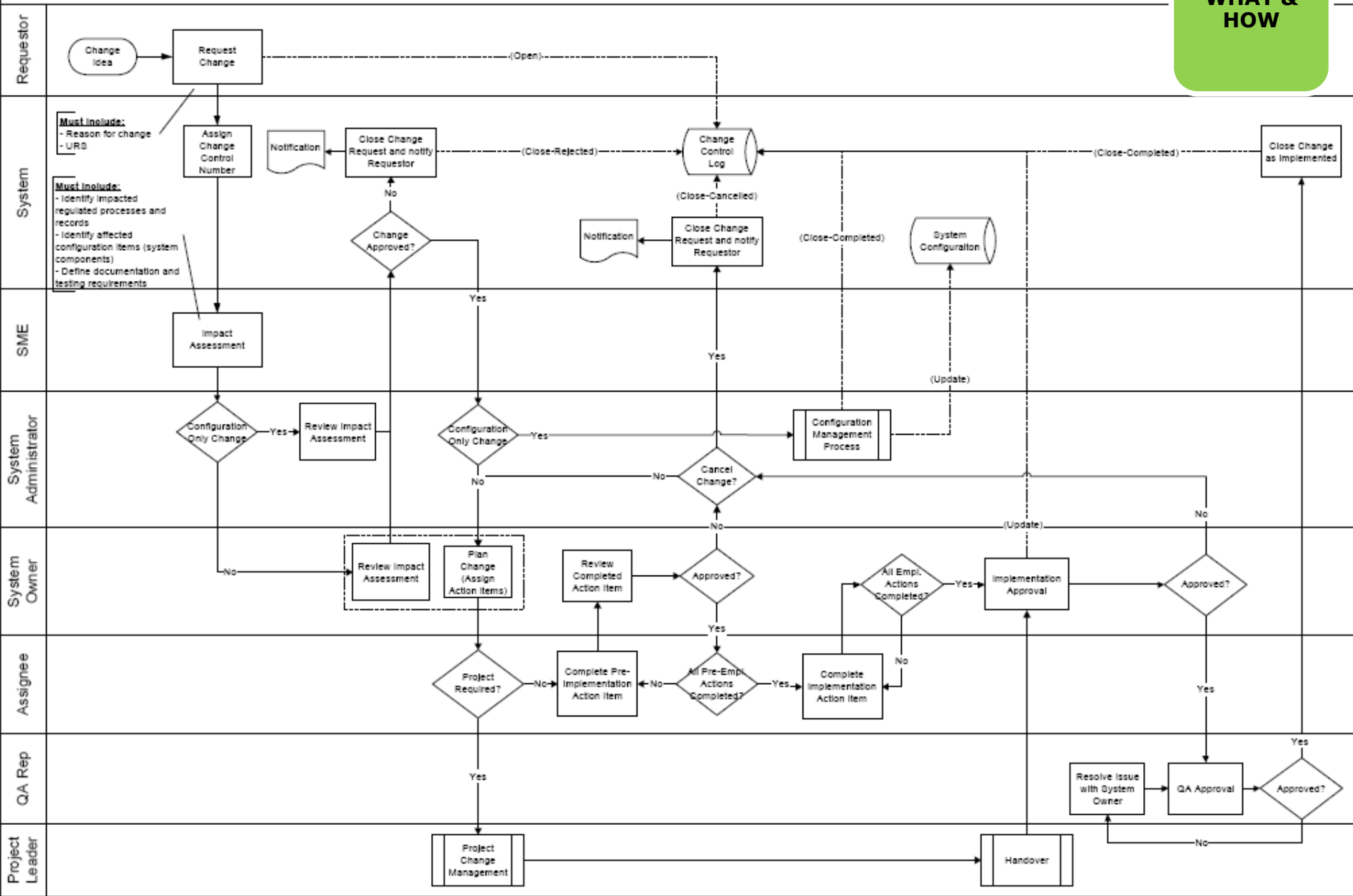
HOW to **verify**
that control

- The configuration control documentation should be subject to **document control**, review and approval process according to defined procedures
- The document control process should ensure that the configuration **status** accounting is **accurate** and **up to date**
- The document control process should **provide** an **audit** of the configuration management process

Source: GAMP5

- In order to use SharePoint for **regulated activities**, a clear process for deploying and controlling the environment is required
- This process should **aim to document** the design, configuration, QC and maintenance of **controlled** SharePoint workspaces including **3rd party applications**
- **Required SOPs:**
 - SharePoint Admin/Configuration SOP
 - Configuration Management SOP
 - Change Control SOP
 - Other IT SOPs such as Backup, Security, Non-Conformance Management

- The SharePoint specific SOP that governs the configuration and maintenance of the SharePoint platform should include:
 - Roles and Responsibilities
 - Identification and classification the configuration items
 - Procedure for initial configuration of the system
 - Procedure for requesting, approving, executing and verifying changes
 - References to the tools / mechanism used in the configuration of the system, such as a “SharePoint Configuration Specifications” document, SharePoint Administration Guide



The configuration items for SharePoint can be divided into 4 levels:

Application level items

(InfoPath forms, Workflows)

User (site collection) level items

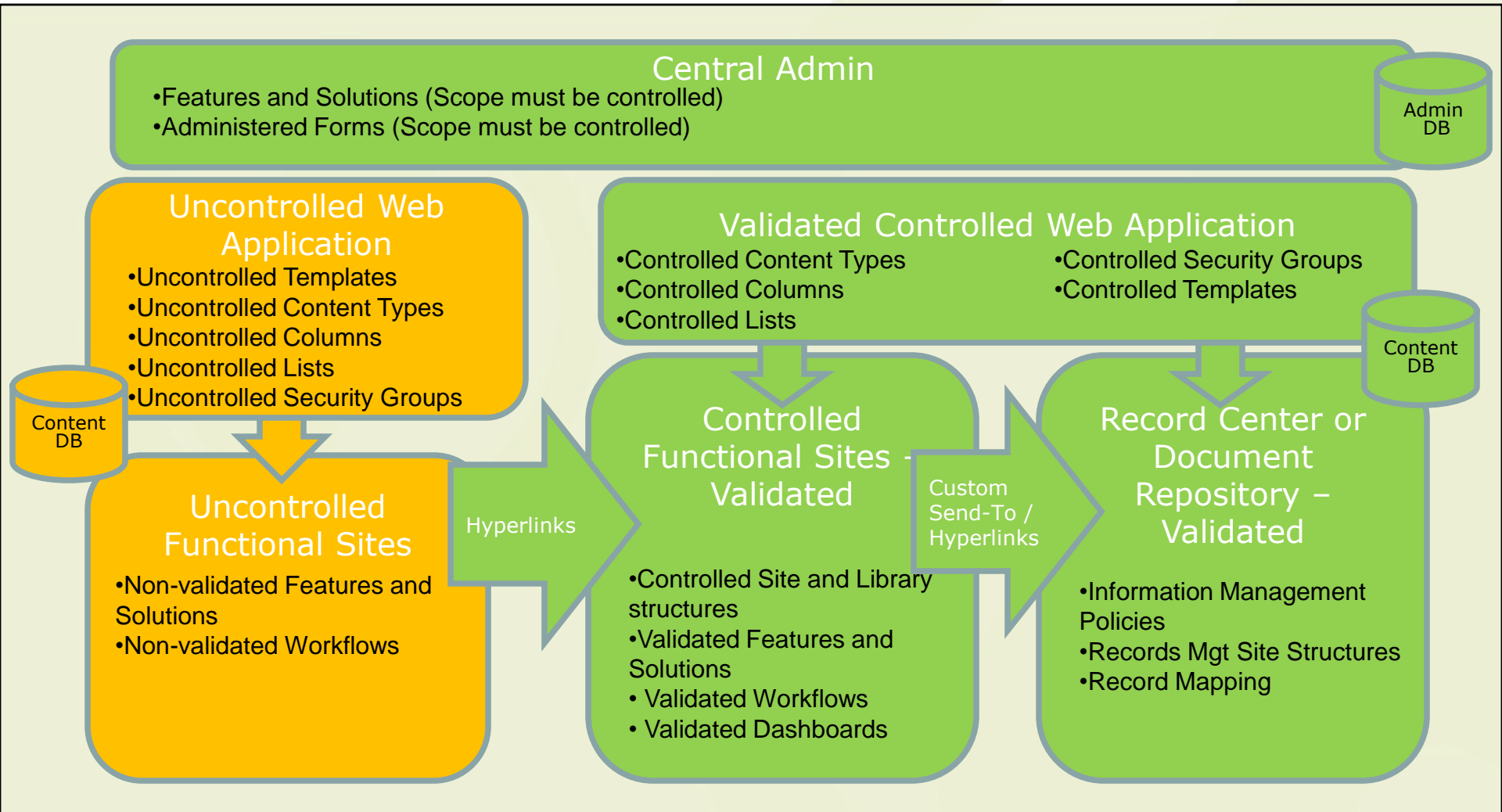
(Site, Libraries, Lists, Content types, Metadata, User management)

Administrative (farm) level items

(Farm level settings, Web application management, Shared Services administration)

System level items

(Servers, OS, Patches, AD)



User / Application level items (SharePoint Workspace Configuration)

SharePoint
Configuration
Specification

System
Description

Functional
Specification

Administrative (farm) level items (Application/Services Configuration)

User Access
Matrix

Application
Configuration
Specification

System level items (Hardware, OS Configuration)

IT System Inventory

System Configuration
Specification

- **Verify...**

- ... if **other dependant systems** will be affected
- ... what **configuration items** of the system being changed will be affected (i.e. libraries, forms, columns etc.)
- ... what **functionalities** of the system will be affected (workflows, web-services, user interface, etc.)
- ... if **data** integrity will be affected
- ... if any **documentation** will be affected

- There are no known solutions which allow fully automated configuration and verification of SharePoint...but...
- There are two primary approaches that could be considered for configuration verification:
 - 100% Manual verification
 - Time consuming
 - Still prone to human error
 - Data extract and compare
 - Define a standard format in Excel between the SCS and the configured environment
 - Perform an automated compare to detect discrepancies
 - Perform a secondary manual review of a sample based on risk i.e. High risk areas
- Important: Ensure that verification is documented, reviewed and approved

- Typically configuration changes to the **application level** may require retesting using existing or new **test scripts**
- The same **risk assessment** techniques and risk criteria should be used as during the **initial validation**
- Should **significant** configuration and/or application changes be required a new version of the **FS** may be required
- **Change control** should govern the QC exercise
- **Impact** assessment should also be done for the **user** and **administration** layer



Example of Configuration Control in SharePoint

- This example will take us through the following process in line with our SharePoint Configuration Management SOP based on the GAMP 5 methodology using simple tools in SharePoint itself
 - **Change Request** by end-user
 - System administrator **update configuration specification** identifying which configuration items are to be updated
 - Configuration specification is **approved for execution**
 - Implementer executes the **configuration specification**
 - A **QC / Verification** is performed to ensure that the system was configured as per specification
 - Creation of CS record and **electronic approval**
 - Change Request is closed
- Throughout this process, we'll also see the integration with the validation and change control process

Change Control Requests

- View All Site Content
- Computerized Systems**
 - Validated IT System Inventory
 - System Component List
 - Hardware Inventory
 - Software Inventory
 - System Documentation
- System Validation Documents**
 - CSV Documents
 - CSV Packs
 - Standard User Requirements Bank
 - Standard Test Scripts Bank
 - Other deliverables
 - Templates
 - SharePoint Configuration Specifications
- Executed Scripts**
 - Executed Test Scripts
 - NCRs
- Change Control**

New Upload Actions Settings												
Type	Name	System ID	Checked Out To	CR Status	System Owner	System Admin	Project Leader	QA Rep	SME	Change Perm Temp	Change Type	Change Urgency
CR Status : PreferredName (1)												
	CC-002	SYS1		PreferredName	Paul Fenton	Michael Zwetkow		Michael Zwetkow	Michael Zwetkow	Permanent	Functional	Emergency
CR Status : Pre-Implementation Approval (3)												
	CC-003	SYS2		Pre-Implementation Approval	Michael Zwetkow	Francois Baudoin	Michael Zwetkow	Michael Zwetkow	Michael Zwetkow	Permanent	System Admin and Maintenance	Emergency
	CC-008	SYS2		Pre-Implementation Approval	Michael Zwetkow	Francois Baudoin	Michael Zwetkow	Michael Zwetkow	Michael Zwetkow	Permanent	Configuration Only	Low
	CC-020	SYS2		Pre-Implementation Approval	Michael Zwetkow	Francois Baudoin	Paul Fenton	Michael Zwetkow	Michael Zwetkow	Permanent	Functional	Emergency
CR Status : Under Review (5)												
	CC-004	SYS1		Under Review	Paul Fenton	Michael Zwetkow	Paul Fenton	Paul Fenton	Paul Fenton	Permanent	Configuration Only	High
	CC-005	SYS1		Under Review	Paul Fenton	Michael Zwetkow						
	CC-006	SYS1		Under Review	Paul Fenton	Michael Zwetkow	Michael Zwetkow	Michael Zwetkow	Michael Zwetkow	Permanent	Functional	Low
	CC-007	SYS2		Under Review	Michael Zwetkow	Francois Baudoin	Michael Zwetkow	Michael Zwetkow	Michael Zwetkow	Permanent	Configuration Only	Low
	CC-009	SYS3		Under Review	Paul Fenton	Michael Zwetkow	Paul Fenton	Paul Fenton	Paul Fenton	Permanent	System Admin and Maintenance	High



Change Control Form

Submit Save Save As... Close View CR Information Print View

Powered by: InfoPath Forms Services

	IT Change Control Form	
	CC #: CC-056	Status: Under Review

CR Information Analysis Disposition Acceptance




Information			
Change Requestor:	Paul Fenton	Request Date:	06/05/2010
System ID:	SYS1	System State:	Validated
System Description:	Electronic Document Management System		
Component ID	Component Description	Component State	
SYS1C002	Test Server	Qualified	
<input checked="" type="checkbox"/> Insert item			
Comments:	Need to add a column to Clinical Operations		

Description			
Change Type:	Configuration Only	<input checked="" type="radio"/> Permanent <input type="radio"/> Temporary	If temporary, enter date:
Change Urgency:	High	Target Completion Date:	22/04/2010
Proposed Change:	Clinical Operations would like to add column 'Investigator Name' for all Investigator content types		
Justification:	Standard column addition for SharePoint Clinical Operations Work Center		

Change Roles			
System Owner	Paul Fenton		
System Administrator	Michael Zwetkow		
SME (Technical Expert)	Tevin Pathareddy		
Project Leader (if applicable)	John Smith		

Workflow Actions

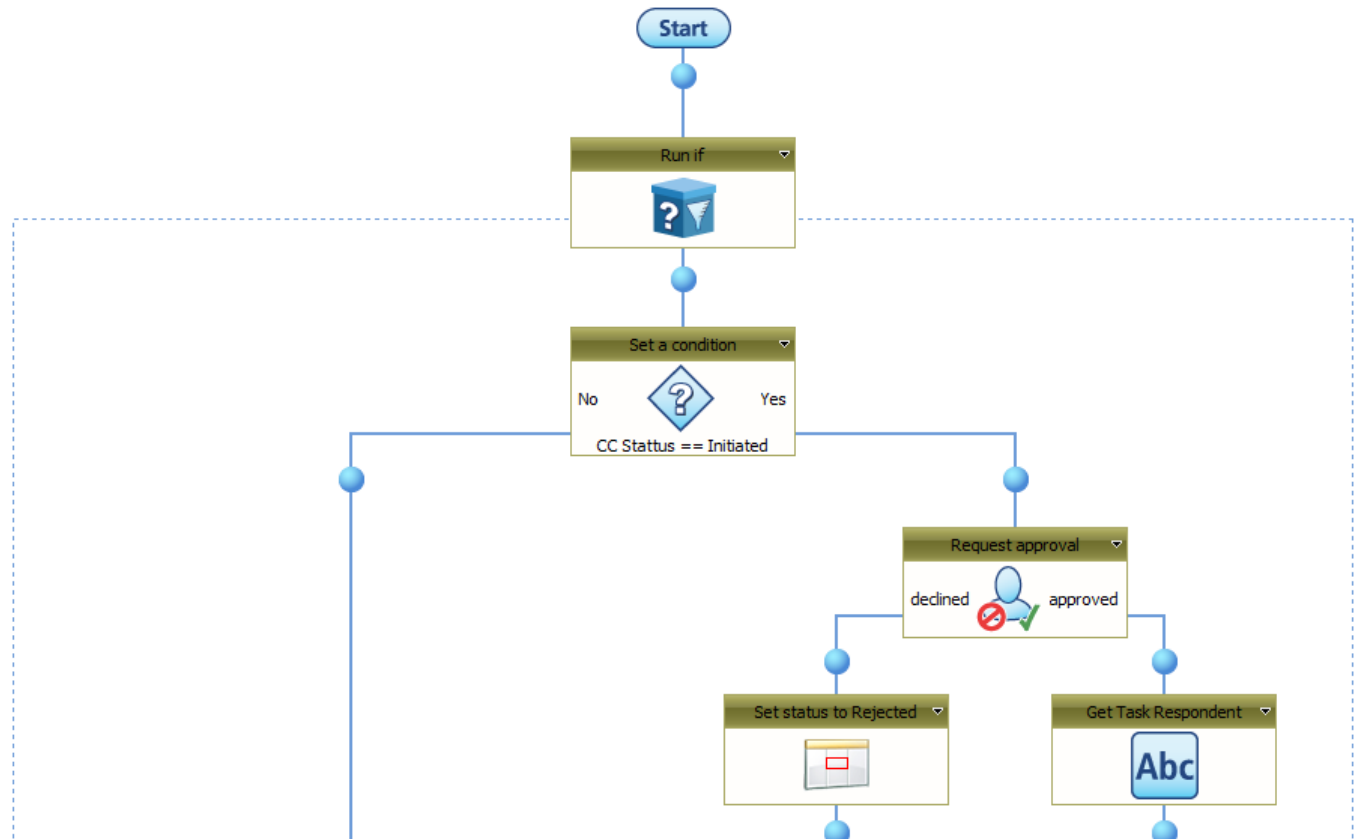
Commonly used

-  Set a condition
-  Request approval
-  Send a notification

- Exchange 2007
- Integration
- Libraries and lists
- Logic and flow
- Operations
- Provisioning
- Publishing
- SharePoint profiles
- Sites and workspaces
- User interaction
- My Snippets

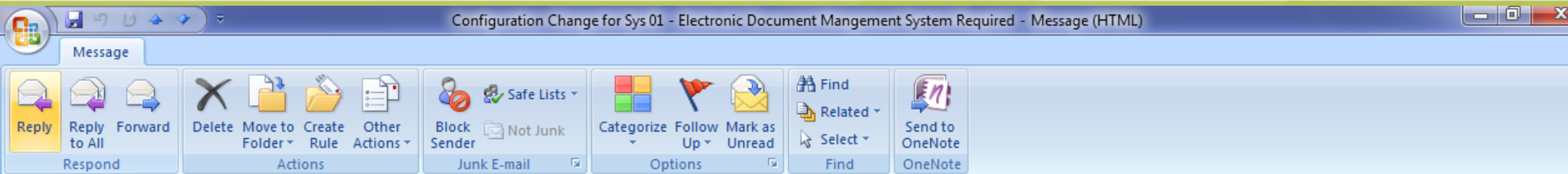
Create and modify Nintex workflows.

Actions ▾ Settings ▾





Change Control Workflow



From: Paul Fenton
To: Paul Fenton
Cc:
Subject: Configuration Change for Sys 01 - Electronic Document Mangement System Required

Sent: Thu 06/05/2010 8:39 P



Change Control

Workflow Notification

Change Control number **CC-056** was submitted by Paul Fenton on 4th April 2010. The change control details are as follows:

System:	Electronic Document Management System (Sys-01)
System Component:	Test Server
Urgency:	High
Change Type:	Configuration Only
Target Completion Date:	4 th June 2010
Change Description	Clinical Operations would like to add 'Investigator Name' column to all content types 'Investigator Documents'

You can access the configuration file [here](#)

Once you have defined the required changes in the configuration file, please close this task [here](#).

The next step in this workflow will be Configuration Change Approval for Execution

Demo Platform Welcome Paul Fenton

CSLM All Sites

[Demo Platform](#)
[Biometrics](#)
[Clinical Ops](#)
[IT](#)
[Pre-Clinical](#)
[QA](#)
[Regulatory](#)
[Pharmaceutical Development](#)
[Pharmacovigilance](#)
[Search](#)
[Records Center](#)
[Business Architecture](#)
[Documentation Management](#)
[Program Management](#)

Demo Platform > IT > CSLM > SharePoint Configuration Specifications

SharePoint Configuration Specifications

SCS for all departments

New | Upload | Actions | Settings

Type	Name	Author	Modified	Status	Version Number	Check In Comment
	MTM-SCS-Biometrics <small>NEW</small>	Stephanie Tanguay	5/5/2010 16:54	Verified	2.0	
	MTM-SCS-Clinical <small>NEW</small>	Tevin Pathareddy	5/5/2010 16:54	Verified	4.0	
	MTM-SCS-CSLM <small>NEW</small>	Michael Zwetkow	5/5/2010 16:53	Verified	3.0	
	MTM-SCS-DataManagement <small>NEW</small>	Paul fenton	5/5/2010 16:54	Authoring	1.0	
	MTM-SCS-Global <small>NEW</small>	Tevin Pathareddy	5/5/2010 17:26	Authoring	3.1	
	MTM-SCS-PreClinical <small>NEW</small>	Tevin Pathareddy	5/5/2010 16:53	Execution	1.3	
	MTM-SCS-Regulatory Affairs <small>NEW</small>	Michael Zwetkow	5/5/2010 16:54	Approval	2.2	

View All Site Content

Computerized Systems

- Validated IT System Inventory
- System Component List
- Hardware Inventory
- Software Inventory
- System Documentation

System Validation Documents

- CSV Documents
- CSV Packs
- Standard User Requirements Bank
- Standard Test Scripts Bank
- Other deliverables
- Templates
- SharePoint Configuration Specifications

Executed Scripts

- Executed Test Scripts
- NCRs

Change Control

- Change Control Requests
- CC Impact Actions



SharePoint Configuration Specification

- Excel based configuration specification
- Allows the definition of all configuration parameters at the global and functional level
- Serves as the basis for configuration definition and verification
- Version controlled within SharePoint
- Approved prior to execution
- PDF rendition of executed configuration specification
- Can be maintained in paper or electronic form (eSigs) as a record

Role	Name	Initial	Signature	Date	DCW Version	Comments
SCS Author	Tevin Pathareddy	TP			2.0	Adding a new library
Approver (for execution)	Stephanie Tanguay	ST		22-Aug-08	2.1	Approved for execution
Implementer	Louis-Philippe Lavoie	LPL		24-Aug-08	2.2	Implemented in Test
Verifier	Stephanie Tanguay	ST		26-Aug-08	2.3	verified
Approver (for execution)	Stephanie Tanguay	ST		6-Oct-08	3.1	verified version 2.4 was published to Major version 3.0 as "Implemented". 3.1 approved for execution on Sharepoint side.
Implementer	Louis-Philippe Lavoie	LPL		7-Oct-08	3.1	
SCS Author	Tevin Pathareddy	TP		15-Jan-09	3.2	Updated the following Sharepoint Sheets for implementation: Site-Library Spec - SP; Document Specs SP; Site Columns SP Searches SP; Security - SP
Approver (for execution)	Stephanie Tanguay	ST		16-Jan-09	3.3	Approved: Site-Library Spec - SP; Document Specs SP; Site Columns SP; Searches SP; Security - SP
Implementer	Tevin Pathareddy	TP		20-Jan-09	3.3	Implemented: Site-Library Spec - SP; Document Specs SP; Site Columns SP; Searches SP; Security - SP
Verifier	Louis-Philippe Lavoie	LPL		1-Feb-09	3.3	Verified: Site-Library Spec - SP; Document Specs SP; Site Columns SP; Searches SP; Security - SP
SCS Author	Tevin Pathareddy	TP		12-Feb-09	3.5	Update the following sheets: Initial Configuration Steps Document Spec - SP Site Columns - SP Searches - SP Security - SP Archiving Profile
Approver (for execution)	Stephanie Tanguay	ST		24-Feb-09	3.6	on SP test
Implementer	Louis-Philippe Lavoie	LPL		24-Feb-09	3.6	
Verifier	Tevin Pathareddy	TP		2-Mar-09	3.6	
Approver (for execution)	Stephanie Tanguay	ST		5-Mar-09	3.7	for implementation on sharepoint production
Implementer	Louis-Philippe Lavoie	LPL		9-Mar-09	3.7	
Verifier	Tevin Pathareddy	TP		9-Mar-09	3.7	
SCS Author	Tevin Pathareddy	TP		12-May-09	3.8	Archiving Profile: Changed the Status value to "Final Approved" for triggering the document to be sent to Livelink
Approver (for execution)	Stephanie Tanguay	ST		18-May-09	3.9	
Implementer	Louis-Philippe Lavoie	LPL		29-Jun-09	3.9	
Verifier	Tevin Pathareddy	TP		1-Jul-09	3.9	Added IPB content type at the study level



SCS Configuration Steps

Initial Configuration Steps		User Guide St	Implemented in Test	By	Date	Implemented in Prod	By
SharePoint Environment							
1	Create the Clinical Site within the Livelihood WorkCenter SharePoint Site as per the <i>"Site-Library Specs-Sp"</i> Sheet		Yes	TP	20-Jan-09	Yes	LPL
2	Create SharePoint libraries and define the settings as per <i>"Site-Library Specs-SP"</i> sheet		Yes	TP	20-Jan-09	Yes	LPL
3	Create SharePoint content types at departmental site level as per <i>"Document Specs-SP"</i> Sheet column C and associate any template as define by Column E		Yes	TP	20-Jan-09	Yes	LPL
4	Create site columns as defined by the <i>"Column - SP"</i> sheet column A		Yes	TP	20-Jan-09	Yes	LPL
5	Associate the Content Types to their respective Libraires as defined by the <i>"Document Specs-SP"</i> Sheet		Yes	TP	20-Jan-09	Yes	LPL
6	Create SharePoint folder for the respective libraries as per <i>"Document Specs -SP"</i> Sheet column B and for each folder, modify the "Change New Button Order" to associate the correct content type to the folder		Yes	TP	20-Jan-09	Yes	LPL
7	If <i>"Document Specs - SP"</i> Sheet column F specifies that a workflow exists, then create/use the associated workflows for the content type as defined in SRS document. Column H references the workflow ID		N/A			Yes	LPL
8	Implement the searches for each Content Type as defined by <i>"Searches-SP"</i> Sheet		Yes	TP	20-Jan-09	Yes	LPL
9	Implement the security for each Content Type as defined by <i>"Security-SP"</i> Sheet		Yes	TP	20-Jan-09	Yes	LPL
General Information							
DCW Version:	Version 3.17						
URS Version	1.0						
DS Version	1.3						
Server Name:	MOSS Prod / MOSS Dev						
Environment:	Production						



montrium

SCS – Site Admin

Site		Site Administration												
Level to create	Web Application	Title					Search Visibility							
			Enable an alternate Calendar	Define Your Work Week	First day of week	First week of year	Allow this web to appear in search results?	Indexing ASPX Page Content	Implemented in Test Env't	By	Date	Verified in Test Env't	By	Date
Top-Level Site		Document Management	None	Mon, Tue, Wed, Thu, Fri	Sunday, start at 8:00 AM	Jan 1, end time 5:00 PM	yes	Do not index ASPX pages if this site contains fine-grained permissions	Yes	GK	10-Apr-09	Yes	Gk	15-Apr-09
Subsite	NA	Finance	None	Mon, Tue, Wed, Thu, Fri	Sunday, start at 8:00 AM	Jan 1, end time 5:00 PM	yes	Do not index ASPX pages if this site contains fine-grained permissions	Yes	GK	11-Apr-09	Yes	Gk	16-Apr-09
Subsite	NA	Pharmaceutical Development	None	Mon, Tue, Wed, Thu, Fri	Sunday, start at 8:00 AM	Jan 1, end time 5:00 PM	yes	Do not index ASPX pages if this site contains fine-grained permissions	Yes	GK	12-Apr-09	Yes	Gk	17-Apr-09
Subsite	NA	Quality Assurance	None	Mon, Tue, Wed, Thu, Fri	Sunday, start at 8:00 AM	Jan 1, end time 5:00 PM	yes	Do not index ASPX pages if this site contains fine-grained permissions	Yes	GK	13-Apr-09	Yes	Gk	18-Apr-09
Subsite	NA	Clinical Operations	None	Mon, Tue, Wed, Thu, Fri	Sunday, start at 8:00 AM	Jan 1, end time 5:00 PM	yes	Do not index ASPX pages if this site contains fine-grained permissions	Yes	GK	14-Apr-09	Yes	Gk	19-Apr-09



SCS - Lists Management

LISTS														
List Settings on Creation														
Title, Description and Navigation			List Versioning Settings				List Advanced Settings							
Level to create	Name	Description	Navigation - Display this document library on the quick launch	Content Approval- Specify whether new items or changes to existing items should remain in a draft state until they have been approved	Item Version History- Specify whether a version is created each time you edit an item in this list	Draft Item Security	Content Types- Allow management of content types	Read Access	Edit Access	Add attachments column to default view	Attachments	Folder" command on the New menu	Search	New - Add users
Top Site	<u>Permission reference</u> (this line has been added to define only once the Users rights) Below lines just reference this line													Document Management Members Document Management Owners Document Management Visitors Home Visitors Business Data Custom List Members Records Center Web Service Submitters Viewers
Top site	API Producer		Yes	No	Yes	Any user who can read items	No	All Items	All Items		Enabled	No	Yes	Same as permission reference
Top site	API Supplier		Yes	No	Yes	Any user who can read items	No	All Items	All Items		Enabled	No	Yes	Same as permission reference
Top site	Area		Yes	No	Yes	Any user who can read items	No	All Items	All Items		Enabled	No	Yes	Same as permission reference
Top site	Business Unit		Yes	No	Yes	Any user who can read items	No	All Items	All Items		Enabled	No	Yes	Same as permission reference
Top site	Department		Yes	No	Yes	Any user who can read items	No	All Items	All Items		Enabled	No	Yes	Same as permission reference
Top site	Distributor		Yes	No	Yes	Any user who can read items	No	All Items	All Items		Enabled	No	Yes	Same as permission reference
Top site	Document Distribution Location		Yes	No	Yes	Any user who can read items	No	All Items	All Items		Enabled	No	Yes	Same as permission reference
Top site	Dosage		Yes	No	Yes	Any user who can read items	No	All Items	All Items		Enabled	No	Yes	Same as permission reference
Top site	Dosage Form		Yes	No	Yes	Any user who can read items	No	All Items	All Items		Enabled	No	Yes	Same as permission reference
Top site	Drug Product Name		Yes	No	Yes	Any user who can read items	No	All Items	All Items		Enabled	No	Yes	Same as permission reference
Top site	Drug Substance Name		Yes	No	Yes	Any user who can read items	No	All Items	All Items		Enabled	No	Yes	Same as permission reference



SCS – Content Types

Doc Library	Folder Level 1	Folder Level 2	Content Type - SharePoint	Template	DocTypeID	Workflow ID	Record	Implemented in Test	By
Clinical Template								Yes	GK
	General Clinical Files							Deviation	TP
		Investigator Brochure	Investigator Brochure	Yes	IB	DLP	Yes	Deviation	TP
	Study-Level Docs							Yes	GK
		Correspondence						Yes	GK
			General Correspondence	Yes	GEN	DLP	Yes	Yes	GK
			Meetings	No	MIN	DLP	No	Yes	GK
			Note to File	No	NOT	DLP	Yes	Yes	GK
		CRO		No				Yes	GK
			CRO Training Records	No	TRN	DLP	Yes	Yes	GK
			CRO Transfer of Obligations	No	XOB	DLP	Yes	Yes	GK
			CON - CRO Contact List	No	CON	DLP	Yes	Yes	GK
			CRO Personnel CV's	No	PCV	DLP	Yes	Yes	GK
			CRO Correspondence	No	COR	DLP	Yes	Yes	GK
			CRO Contract	No	CTR	DLP	Yes	Yes	GK
		CSR		No				Yes	GK
			Clinical Study Reports	No	CSR	DLP	Yes	Yes	GK
	General			No				Yes	GK
			Investigator List	No	INV	DLP	No	Yes	GK
			Study Procedure Manual	No	SPM	DLP	Yes	Yes	GK
			Study Randomization Process	No	SRP	DLP	No	Yes	GK
		Inform Consent Documents		No				Deviation	TP



SCS – Site Columns

Site Column - SharePoint	Level to Create column	Level to Configure	Type	Comments/Source	Values	Implemented in Te	By	Date
Program	Top-Level	Product 101 Library	Filtered Lookup	MTM_program_info / Program (Filter: None, Parent: None)	PI	Yes	GK	23-Feb-10
		Product 102 Library	Filtered Lookup	MTM_program_info / Program (Filter: None, Parent: None)	GI	Yes	GK	23-Feb-10
		Product 103 Library	Filtered Lookup	MTM_program_info / Program (Filter: None, Parent: None)	GI	Yes	GK	23-Feb-10
Molecule	Top-Level	Product 101 Library	Filtered Lookup	MTM_program_info / Molecule (Filter: Program, Parent: Program)	PD-101	Yes	GK	23-Feb-10
		Product 102 Library	Filtered Lookup	MTM_program_info / Molecule (Filter: Program, Parent: Program)	PD-102	Yes	GK	23-Feb-10
		Product 103 Library	Filtered Lookup	MTM_program_info / Molecule (Filter: Program, Parent: Program)	PD-103	Yes	GK	23-Feb-10
CRO or Partner Doc No	Top-Level	Top-Level	Single Line of text	Need to update all content type mappings with new mapping to Livelink		Yes	GK	4-Mar-10
Regulatory Number	Top-Level	Top-Level	Lookup			N/A		
Indication	Top-Level	Top-Level	Filtered Lookups	MTM_program_info / Indication (Filter: Molecule, Parent: Molecule)		N/A		
Clinical Study No	Top-Level	Top-Level	Filtered Lookup	MTM_clinical_directory / study number (Filter: None, Parent: None)		Yes	TP	4-Mar-10
Country	Top-Level	Top-Level	Single Line of text			N/A		
Expiration Date	Top-Level	Top-Level	Date			N/A		
Source Organization	Top-Level	Top-Level	Filtered Lookups	MTM_functional_organization / organization (Filter: None, Parent: None)		N/A		
Doc Status	Top-Level	Top-Level	Lookup			N/A		
Version Number	Top-Level	Top-Level	Single Line of text			N/A		
Content Type	Built-In	N/A				N/A		
Document Type Prefix	Site	Clinical Operations	Calculated Field	TRIM(LEFT([Content Type],4))		Yes	LPL	24-Feb-09
Author	Top-Level	Top-Level	Single Line of text					
Title	Built-In	N/A				N/A		
Created	Built-In	N/A				N/A		
Signature Date	Top-Level	Top-Level	Date			N/A		
				MTM_Original_Media / Title				



CSC – Site Library Specifications

Site Settings	Value				Implement ed in Te	By	Date	Implement ed in Pr	By
Title	Clinical Operations				Deviation	TP	20-Jan-09	Yes	LPL
Description	Clinical Site for regulated documents which will become records in Livelink				Yes	TP	20-Jan-09	Yes	LPL
URL Name	co				Deviation	TP	20-Jan-09	Yes	LPL
Site Template	Enterprise -> Document Center				Yes	TP	20-Jan-09	Yes	LPL
User Permissions	Use the same as parent site				Yes	TP	20-Jan-09	Yes	LPL
Use the top link bar from the parent site	Yes				Yes	TP	20-Jan-09	Yes	LPL
List this new site in the site directory	Yes				Yes	TP	20-Jan-09	Yes	LPL
Library Settings on Creation	Clinical Template	Created from Clinical Template	Created from Clinical Template	Created from Clinical Template					
Name	Clinical Template	Product-101	Product-102	Product-103	Yes	GK	23-Feb-10	Yes	TP
Description	Clinical Operations Template Library	Document Library for Molecule Product-101	Document Library for Molecule Product-102	Document Library for Molecule Product-103	Yes	GK	23-Feb-10	Yes	TP
Navigation - Display this document Library on the quick Launch	Yes	Yes	Yes	Yes	Yes	GK	23-Feb-10	Yes	TP
Document Version History - Create a version each time you edit a file in the library	Yes	Yes	Yes	Yes	Yes	GK	23-Feb-10	Yes	TP
Document Template	None	None	None	None	Yes	GK	23-Feb-10	Yes	TP
Document Library Advanced Settings	Value	Value	Value	Value					
Content Types - Allow management of content types	Yes	Yes	Yes	Yes	Yes	GK	23-Feb-10	Yes	TP
Browser-Enabled Documents	Open in the client application	Open in the client application	Open in the client application	Open in the client application	Yes	GK	23-Feb-10	Yes	TP
Custom Send to Destination	N/A	N/A	N/A	N/A	Yes	GK	23-Feb-10	Yes	TP
Folders - Display "New Folder" command on the New menu	No	No	No	No	Yes	GK	23-Feb-10	Yes	TP
Search	Yes	Yes	Yes	Yes	Yes	GK	23-Feb-10	Yes	TP
Document Library Versioning Settings	Value	Value	Value	Value					
Document Approval - Require content approval for submitted items	No	No	No	No	Yes	GK	23-Feb-10	Yes	TP
Document Version History - Create a version each time you edit a file in the library	Create Major	Create Major	Create Major	Create Major	Yes	GK	23-Feb-10	Yes	TP
Draft Item Security	N/A	N/A	N/A	N/A	Yes	GK	23-Feb-10	Yes	TP
Require Check Out	Yes	Yes	Yes	Yes	Yes	GK	23-Feb-10	Yes	TP



SCS – Global Permissions

Permission items	Permissions	Full Control	Design	Contribute	Read	Limited Access	View Only	Records Center Submission Completion	Privileges Level Administrator	Implemented in Test Env	B
List Permissions						System Defined				Yes	Gl
	Manage Lists - Create and delete lists, add or remove columns in a list, and add or remove public views of a list.	X	X						X	Yes	Gl
	Override Check Out - Discard or check in a document which is checked out to another user.	X	X							Yes	Gl
	Add Items - Add items to lists, add documents to document libraries, and add Web discussion comments.	X	X	X					X	Yes	Gl
	Edit Items - Edit items in lists, edit documents in document libraries, edit Web discussion comments in documents, and customize Web Part Pages in document libraries	X	X	X				X	X	Yes	Gl
	Delete Items - Delete items from a list, documents from a document library, and Web discussion comments in documents.	X							X	Yes	Gl
	View Items - View items in lists, documents in document libraries, and view Web discussion comments.	X	X	X	X		X	X	X	Yes	Gl
	Approve Items - Approve a minor version of a list item or document.	X	X						X	Yes	Gl
	Open Items - View the source of documents with server-side file	X	X	X	X				X	Yes	Gl
	View Versions - View past versions of a list item or document.	X	X	X	X		X		X	Yes	Gl
	Delete Versions - Delete past versions of a list item or document.	X								Yes	Gl
	Create Alerts - Create e-mail alerts	X	X	X	X		X		X	Yes	Gl
	View Application Pages - View forms, views, and application pages. Enumerate lists.	X	X	X	X	X	X		X	Yes	Gl
Site										Yes	Gl
	Manage Permissions - Create and change permission levels on the Web site and assign permissions to users and groups.	X							X	Yes	Gl
	View Usage Data - View reports on Web site usage	X								Yes	Gl
	Create Subsites - Create subsites such as team sites, Meeting Workspace sites, and Document Workspace sites.	X								Yes	Gl
	Manage Web Site - Grants the ability to perform all administration tasks for the Web site as well as manage content.	X								Yes	Gl
	Add and Customize Pages - Add, change, or delete HTML pages or Web Part Pages, and edit the Web site using a Windows SharePoint Services-compatible editor.	X	X							Yes	Gl
	Apply Themes and Borders - Apply a theme or borders to the entire	X	X							Yes	Gl
	Apply Style Sheets - Apply a style sheet (.CSS file) to the Web site.	X	X							Yes	Gl
	Create Groups - Create a group of users that can be used anywhere within the site collection.	X								Yes	Gl
	Browse Directories - Enumerate files and folders in a Web site using SharePoint Designer and Web DAV interfaces.	X	X	X					X	Yes	Gl
	View Pages - View pages in a Web site.	X	X	X	X		X		X	Yes	Gl
	Enumerate Permissions - Enumerate permissions on the Web site, list, folder, document, or list item.	X							X	Yes	Gl



SCS – Site Level Permissions

Site Name	Library name	List Name	Full Control	Manage Hierachy	Design	Contribute	Read
WorkCenter							ClinicalOps-Product101 ClinicalOps-Product102 ClinicalOps-Product103
Clinical Operations						ClinicalOps-Product101 ClinicalOps-Product102 ClinicalOps-Product103	QA Doc Man
	Clinical Template		IT				
	Porduct 101					ClinicalOps-Product101	QA Reg Ops Doc Man PM-PD-101
	Porduct 102					ClinicalOps-Product102	QA Reg Ops Doc Man PM-PD102
	Porduct 103					ClinicalOps-Product103	QA Reg Ops Doc Man IW9179 PM-PD103

Item Reference	Sheet Name	Item Name(s)	DCW Versio	Deviation Description	Deviation Classification	Reported by	Date Reported	Corrective Action	Corrected by	Date Correcte	Status
1	Configuration Steps	Steps 1-4	0.1	Creating the folders before creating the category forces to revisit all folders to assign the category to them. It is faster to create the category first and assign it to folders when they are created.		LPL	27-Jun-08	Steps 2 & 3 were performed before step 1. Step 4 was performed simultaneously as 1, during folder creation.	LPL	27-Jun-08	Closed
2	Document Specs - LL	Types CTSI, ECAI & RBAT	0.1	The dash between document prefix and type name is not placed consistently with other rows		LPL	27-Jun-08	Adjusted text to have no spaces before/after dash	LPL	27-Jun-08	Closed
3	Configuration Steps, Document Specs - LL, Category-	Multiple rows	0.1	Category name not consistent across all sheets		LPL	27-Jun-08	Changed category name to "Clinical Essential Documents"	LPL	27-Jun-08	Closed
4	Category-Attribute - LL	Regulatory Number	0.1	Following discussion, Regulatory Number was implemented as 3 separate fields of the same table in IPL_Program_Info. This was not updated in DCW, which still shows as one field with multiple values.		LPL	27-Jun-08	Regulatory Number split into 3 single-value attributes to reflect the DB table	LPL	27-Jun-08	Closed
5	Category-Attribute - LL	Data Type column	0.1	Data type names do not reflect Livelink's attribute types		LPL	27-Jun-08	Updated all attributes types to be consistent with Livelink nomenclature	LPL	27-Jun-08	Closed
6	Category-Attribute - LL	Multiple Values column	0.1	Some attributes with Multiple Values set to Yes do not indicate the number of possible multiple values		LPL	27-Jun-08	When no amount specified, number of possible values was set to 50 (Livelink's maximum), except for item Source Organisation where there is only 3 possible	LPL	27-Jun-08	Closed
7	Category-Attribute - LL	Column column	0.1	The corresponding Livelink setting is "Field in Table"		LPL	27-Jun-08	Renamed column in DCW to be consistent with the LL nomenclature	LPL	27-Jun-08	Closed
8	Category-Attribute - LL	Table and Column (Field in Table) columns	0.1	The table and field names for program info does not reflect the actual strings in the SQL database		LPL	27-Jun-08	Table name and columns edited to reflect the SQL DB	LPL	27-Jun-08	Closed
9	Category-Attribute - LL	Function	0.1	The table name does not reflect the actual string in the SQL database		LPL	27-Jun-08	Table name edited to reflect the SQL DB (microbia_functional_organisation)	LPL	27-Jun-08	Closed
10	Security - LL	Document Management - Operations, Clinical Development - Clinical Operations	0.1	Duplicate entries in the DCW, with different Add Item permissions		LPL	30/6/2008	Duplicate entries removed. Only Clinical Development - Clinical Operations was given Add Item permission	LPL	30/6/2008	Closed




Final Approval Request

Configuration Change for Sys 01 - Post Execution Approval Required - Message (HTML)

File Message

Ignore X Delete Reply Reply All Forward More Meeting Move to: ? To Manager Team E-mail Done Reply & Delete Create New Rules OneNote Mark Unread Categorize Follow Up Translate Find Related Select Zoom

From: Paul Fenton Sent: Fri 07/05/2010 7:33 AM
To: Paul Fenton
Cc:
Subject: Configuration Change for Sys 01 - Post Execution Approval Required

 **Change Control**

Quality Assurance Approval Workflow Notification

Change Control number **CC-056** was submitted by Paul Fenton on 4th April 2010. The change control details are as follows:

System:	Electronic Document Management System (Sys-01)
System Component:	Test Server
Urgency:	High
Change Type:	Configuration Only
Target Completion Date:	4 th June 2010
Change Description	Clinical Operations would like to add 'Investigator Name' column to all content types 'Investigator Documents'

You are required to approve the configuration changes made. To access the PDF record of changes click [here](#)

Once you have defined the required changes in the configuration file, please close your approval task [here](#).

Once approved all changes will be final and this change control will be closed.



PDF Record and Approval

Demo Platform > IT > CSLM > CSV Documents

CSV Documents

CSV Documents produced during the validation process.

New | Upload | Actions | Settings

Type	Name	System State	Content Type	System ID	Document Status	Author	Created By	Reviewed and Approved By	Modified	Checked Out To
------	------	--------------	--------------	-----------	-----------------	--------	------------	--------------------------	----------	----------------

System ID : SYS1 (10)

	CSV-SYS2-VPO-0001		Validation Protocol	SYS1		Mike Zwetkow	Michael Zwetkow		2/11/2010 8:21	Paul Fenton
	CSV-SYS1-TS-0001		Test Script	SYS1	Draft	Mike Zwetkow	Michael Zwetkow		2/11/2010 8:20	
	CSV-SYS1-VSR-0001		Validation Summary Report	SYS1		Mike Zwetkow	Michael Zwetkow		2/10/2010 21:28	
	CSV-SYS1-VPL-0001	Vaildated	Validation Plan	SYS1		Mike Zwetkow	Michael Zwetkow		2/11/2010 9:06	
	CSV-SYS1--0001		Tracebility Matrix	SYS1	Approved	Stefanie Wu	Stefanie Wu		2/23/2010 14:38	
	CSV-SYS1-VA-0001		Validation Assessment	SYS1	Awaiting Approval	Stefanie Wu	Stefanie Wu		2/11/2010 12:32	
	CSV-SYS1-SCS-0003		Configuration Specification	SYS1	Awaiting Approval		System Account		5/5/2010 15:32	
	CSV-SYS1-REQ-0001		Requirements	SYS1	Draft	Stefanie Wu	Stefanie Wu		2/11/2010 13:05	
	CSV-SYS1--0002		Configuration Specification	SYS1	Draft	Stefanie Wu	Stefanie Wu		2/12/2010 16:25	
	CSV-SYS1--0004 <small>NEW</small>		Configuration Specification	SYS1	Approved	Tevin Pathareddy	Tevin Pathareddy		5/5/2010 18:21	

System ID : SYS2 (7)

	CSV-SYS2-TSR-0002	Vaildated	Test Summary Report	SYS2	Under Review	Stefanie Wu	Stefanie Wu		2/11/2010 12:26	
	CSV-SYS2-TSR-0001	Vaildated	Test Summary Report	SYS2		Stefanie Wu	Stefanie Wu		2/11/2010 12:23	

- View All Site Content
- Computerized Systems**
 - Validated IT System Inventory
 - System Component List
 - Hardware Inventory
 - Software Inventory
 - System Documentation
- System Validation Documents**
 - CSV Documents
 - CSV Packs
 - Standard User Requirements Bank
 - Standard Test Scripts Bank
 - Other deliverables
 - Templates
 - SharePoint Configuration Specifications


Executed Scripts

- Executed Test Scripts
- NCRs


Change Control

- Change Control Requests
- CC Impact Actions

Demo Platform > QA

 QA

Demo Platform | Biometrics | Clinical Ops | IT | Pre-Clinical | **QA** | Regulatory | Pharmaceutical Development | Pharmacovigilance | Search | Records Center | Business Architecture



[Learn about requiring approval.](#)

Please select the signature you would like to create

Reason

Account credentials

User Name

Password

Comment



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Best Practices

- Define a clear change control and **configuration management process** which allows you to easily understand what is required
- **Use SharePoint** to govern the process and manage all documentation
- Apply **standards** across the enterprise for taxonomy and nomenclature
- Develop appropriate **QC techniques** which ensure accuracy whilst being streamlined
- Make sure that **users understand** that all system configuration is under change control
- Implement **controlled** and **non-controlled** environments to minimize overhead



What's next...

- Montrium will present the third webinar in its SharePoint for Pharma series on Extracting Actionable Intelligence from Clinical Trials in SharePoint on Friday May 21st 2010 at 11am EST
- This webinar will cover:
 - Setting the foundation of business process maps
 - Understanding how to identify metrics and KPIs within your organization
 - Importance of establishing cross functional standards
 - BPM and BI capabilities of SharePoint and how to exploit them
 - Integration of data sources
 - Examples of SharePoint BPM and BI implementation within clinical trials

We look forward to seeing you there!



Contact Details

Montrium Inc.
361 St-Joseph West,
Montreal (QC) H2V 2P1
Canada

Tel. 514-223-9153
info@montrium.com
www.montrium.com