How CSL Behring Unified Regulatory Processes in Life Sciences Across 3 Continents

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Agenda

• Introduction – Who We Are
• How We Got Here and Where We Are Now
• Our Future Roadmap and Rollout Plan
• The Journey to Implement R&D and the First QM Site
• Out of Box vs Customization
• Requests and Considerations
• Life Sciences Solution 4.2 – What’s New (Yelena Shafir)
• Questions
CSL Behring

A global leader in the plasma protein biotherapeutics industry, dedicated to treating rare and serious diseases and passionate about improving the quality of life for patients throughout the world. We provide life-saving treatments for a range of rare and serious conditions.
CSL Behring at-a-Glance

• A Global leader in $24 billion plasma therapeutics market
• Owns and operates CSL Plasma, one of world’s largest plasma collection networks
• Subsidiary of CSL Limited, a biopharmaceutical company with headquarters in Melbourne, Australia
• Approximately 12,000+ employees worldwide
• Operational headquarters in King of Prussia, Pennsylvania, USA
• Four manufacturing facilities
• Six research facilities
Leveraging Global Capabilities
The Initial Footprint

We need a system

Is this an upgrade?

How do we fit in?

Don’t forget R&D

We have dependencies

Can we go next?

What is changing?

What are we gaining?

What are we losing?

Lengnau

Kankakee

Global Functions/ BT

Bern

BMW

CSL Plasma

Marburg

Melbourne

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Document Management; Strategic Direction at CSL Behring

- Provide access to secure versions of controlled documents
- Migrate toward common global systems
- Integrate Collaboration and Document Management solutions
- Focus on a limited set of Enterprise Class platforms
- Improve “findability” of documents within our core platforms
- Exploit existing global solutions with standard functionality and workflows for immediate needs
- Make tools easier to use and access
A program has been established at CSL to migrate toward a common global document management platform utilizing EMC’s Documentum D2 technology.

Goal: To leverage Out of the Box functionality and standards whenever possible.

The first two projects within the program are:

- Project 1: Quality Document Management
- Project 2: Research & Development Document Management

The resulting system has been named [text obscured by image].
Project Roadmap Building Blocks

Phase 1
- R&D DMS
- Quality DMS (Q DMS Standard Layer)
- KAN Quality Docs

Phase II
- R&D DMS
- Global SOP Mgmt
  - BMW Quality Docs
  - MBR Quality Docs
  - BRN Quality Docs
  - BCT Quality Docs
  - BT Quality Docs
  - Lengnau Docs

Phase III
- R&D DMS
- Phase II
- Phase III

Prioritize & break into small projects

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Phase 1 Go-Live: September 13, 2016

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Unified Solution Approach for Quality and R&D Document Management

Unified Solution Approach

- Manage R&D and Quality Documents within the same Platform
- Use of one repository for R&D and Quality Documents
- Separate R&D and Quality Requirements by document types and access control

Advantages:

- High amount of shared GxP documents (e.g. product validation, SOP’s, Manufacturing Production Records)
- The majority of User Requirements are shared
- Common Quality Approach to all documents
- Consistent Use of shared Metadata
- Selected solution, EMC Standard Life Science Product covers both Quality and R&D
- Reduced likelihood of uncontrolled copies.
Unified Solution Approach for Quality and R&D Document Management

Impact of a unified approach

- Common Architecture \ Design needs to be agreed upon
- Governance for Document Management needs to be put in place
- Communication, Training, Validation, Support, Branding will need to be adopted
The Journey: Activities Leading up to Go-Live

- Workshops conducted with EMC, FME, BT and Business
- Requirements Gathering with both local site and global committee
- Proof of concept built and utilized to understand processes
- Aligned Document Types and Categories to standards
- Created As-Is and To-Be Process models
- Identified gaps with OOB processes
- Determined process changes or workarounds vs customization
- Assessed risks for each requirement
- BT performed System Testing (functional)
- Business performed User Acceptance Testing (processes)
- Migrated documents from Legacy system
Document Management Requirements

- Workflow
- Document Lifecycle Mgmt
- Version Control
- Audit Trail
- PDF Annotations
- Rendition Creation
- Template Integration
- Metadata Mgmt
- eSignature
- Controlled Printing
- Stamping / Barcoding
- Redlining
- Reports
- Search
Leveraging Out of the Box Functionality

- Category 1, 2 and 3 Document Approval processes/Workflow
- Roles
- Folder Structure
- Version Control/Audit Trail
- Document naming/numbering
- Core Attributes/Properties
- Creating Relationships
- System Notifications
- Periodic Review process
- Widgets and Searches
- eDRG reports
- Migration Center D2 Connectors
Need for Adaptations

- Temporary Document Change (with expiration date)
- Redline
- Final Draft status
- Binding Rule (has been implemented by EMC in base product)
- Effectivity Hold
- Watermarking
- Custom Attributes
- Control Print (with print stop, verify and reconcile)
- Query Form searches
- eDRG custom reports
- Integration to Learning Management System and Sharepoint
Requests and Considerations

Requested Changes:

• Withdrawn to Draft to Effective functionality requires configuration changes (expected in future release)
• Need ability to make documents effective per site
• Temporary Document Change
• PDF Redline

Future Considerations:

• Collaborative Editing: Track Changes will not appear after accept all changes has been selected. Will not create a Redline pdf.
• Compare functionality: Need specific permissions. Readers and Author/Approvers roles are unable to utilize this.
Temporary Document Change


TDC Effective
Redline

STANDARD OPERATING PROCEDURE

CSL BEHRING LLC.
QS Document Control
Kankakee, Illinois

Test Standard Operating Procedure 18/20

1.0 Purpose:

This is a test document.

2.0 Scope:

3.0 Responsibility:

4.0 Definitions:

5.0 References:

6.0 Safety Requirements:

7.0 Procedure:

8.0 Calculations/Data Handling/Record Keeping Requirements:

9.0 Process Flow Diagram (optional)
CSL Next Steps

• Architectural changes to improve performance of global environment

• Complete the CSL rollout within upcoming years

• Consolidation of existing legacy CSL solutions

• Improve Integration
Life Sciences Solution 4.2 - What’s New
LS Solution v4.2 New Release Big Benefits

Harmonized Medical Device Solution
- Complete EDMS solution for Medical Device Documents
- Fully harmonized solution supporting Clinical, Regulatory, and DHF/DMR documents

Expanded Best Practices
- Expanded R&D inventory beyond DIA Reference Model to better support global Quality, Clinical Trial, and Regulatory Document Types
- eTMF support for both the 2.0 and 3.0 DIA eTMF Reference Models

Controlled Print Module
- Dedicated module to meet and exceed GxP regulatory requirements when managing controlled paper copies

Maturation of the eTMF Solution
- Expanded capabilities for better insight at the Trial, Country and Site Levels
- Enhanced QC features and new dashboard metrics to ensure optimal ongoing quality of the trial
LS R&D Enhancements – Summary

1. Updated configurations to streamline UI Workspaces availability

2. Updated system to allow to specify binding rules for Virtual Document components:
   1. When Virtual Document is approved the structure is frozen and specific versions of components are displayed
   2. When Virtual Document is in progress Current versions of components are displayed

3. Updated system with multiple inventory enhancements to extend EDM DIA Reference Model:
   1. Clinical domain
   2. Regulatory domain
   3. Quality domain
   4. Safety domain

4. New Medical Devices inventory to manage submittable documents

5. New Medical Devices data model with Registration Forms shared across R&D and Q&M
Virtual Document Binding Rule

• Business Problem:
  – Virtual Document (Vdoc) is a collection of components and at the same time Virtual Document is a record in its own right. Clients use Virtual Documents to organize packages of documents in a defined structures and require to treat a collection of components as a single entity.

• LS R&D Solution Provides:
  – Enhanced functionality to determine versions of components displayed (bound) in the Virtual Document structure:
    ▪ Approved VDoc displays versions of components as it exists at the time of the VDoc Approval
    ▪ VDoc in progress state (Draft) displays Current version of components
R&D Solution Inventory Updates

• Business Problem:
  – DIA EDM Reference Model does not cover full inventory for various regional regulatory requirements

• LS R&D Solution Provides:
  – Extended inventory in the following domains:
    ▪ Clinical
    ▪ Regulatory
    ▪ Quality
    ▪ Safety-PVG
R&D Solution Inventory Updates – Regulatory

- Updated underlying framework to allow business administrator to update Regulatory inventory and assign applicable workflows per artifact
- New Creation Profile
• Filter list of available artifacts based on regional requirements
Medical Device EDMS Challenges

- Electronic document management standards for Medical Device to date have not fully materialized
- Fully electronic submissions, with XML data standards not yet required
- Due to lack of industry standards, few if any vendors provide out of the box inventories for medical device documentation

Medical Device EDMS Drivers and Benefits

- EMC’s LS Solution Provides:
  - Standardized Document Inventory harmonizing across Regulatory and Manufacturing
    - Lesson learned from Pharma
  - Implementation Efficiency
    - Leverage existing business rule configurations for workflow, lifecycle and security Workflow
  - Process improvement and global harmonization
EMC’s Medical Device Solution

- Solution spans across both R&D and Q&M
- Within the R&D Solution…
  - Nonclinical, Clinical and Regulatory Documents
- Within the Q&M Solution…
  - Design History File (DHF)
  - Device Master Record (DMR)
- Customers can implement:
  - Both solutions together in a single repository for a single Medical Device Solution
  - R&D and Q&M independently to align with business functional areas (similar to traditional pharmas)
  - Only one or the other depending on the organization’s EDMS needs
DHF and DMR Document Inventory

**Design History File**
- DHF Vdoc Parent (no content)
- Sections (no content)
- Index
- Protocols
- Reports
- Requirements
- Reviews
- Plans
- Checklists
- Specifications
- Risk Documentation
- Matrix

**Device Master Record**
- DMR Vdoc Parent (no content)
- Sections (no content)
- Index
- Bill of Materials
- Labeling
- Specifications
- Production Documents
- Customer Documents
- Service Documents
- Software Release
- Drawings
Medical Device R&D Inventory

Nonclinical
- IMDRF Chapter 3 – Supporting Evidence
  - Software and Firmware
    - Architecture Design Chart
    - Software Design Specification
  - Benchmark Performance Testing
    - Description of Test Protocol
  - Nonclinical and Animal Testing

Clinical
- IMDRF Chapter 4
  - Clinical Evaluation Report
  - Literature Review
  - Investigator Brochure

Regulatory
- IMDRF Chapter 1 – Regional Administrative
  - Cover Letter
  - List of Standards
  - Essential Checklist
- IMDRF Chapter 2 - Submission Context
  - Device Description
  - History of Development
- IMDRF Chapter 5 – Labeling and Promotional Material
  - Product Brochure
  - Package Insert
LS Solution Medical Device OOB Content Organization
Thank You and Questions
JOIN THE CONVERSATION!
#MMTM16

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Garden Level
Foyer
DOWNLOAD

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