QUALIS DMS®

PRODUCT NOTE

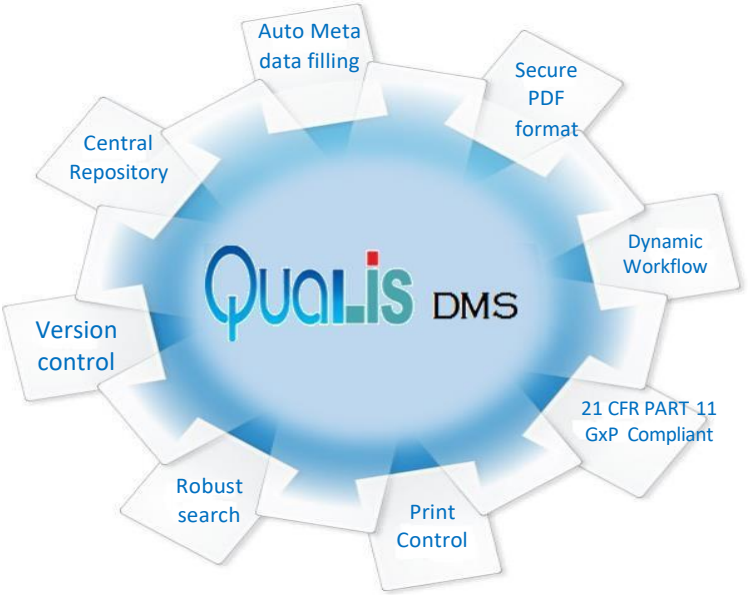
QUALIS DMS (DOCUMENT MANAGEMENT & CONTROL SYSTEM)

Take full control of your documents right from creation, collaborative content management, approval, request, issuance and print controls. Stay in compliance with cGMP prescribed by US FDA, Eudralex and MHRA and at same time adhere to data integrity guidelines as well.

Qualis DMS is a web based solution to connect and streamline your entire organization's documents with full control and traceability. Qualis DMS will ensure quality department to always deliver the latest approved and released documents. An effective DMS can streamline the whole of document management control process. The solution enables documents to be stored in a structured & Systematic filing method and to be distributed efficiently across your organization. This enables smoother and faster work, providing staff of all departments with the latest version of documents at any point & time. The system supports electronic records protection and electronic signatures and helps regulated industries to be 21 CFR Part 11 and GAMP compliant

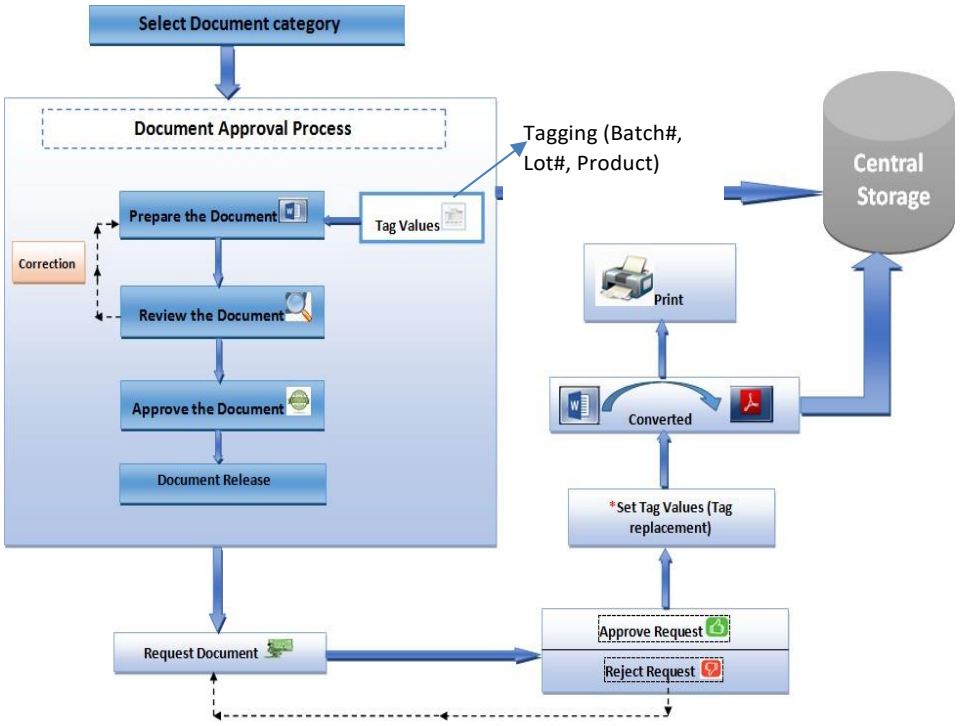
FUNCTIONAL FEATURES

- Securely store and keep track of electronic documents
- Configurable workflows based on category of document
- Collaborative Platform- for parallel content creation
- Configurable approval and release workflows
- System & Email alerts for workflow actions
- Easy User Interface
- Version and release control
- Request and Issue of documents
- Automatic filling of GMP info like batch#, lot #
- Print Control
- Secure and controlled distribution
- Search tool for document finding



QUALIS DMS WORKFLOW ENGINE

Qualis DMS has a built-in workflow engine which can be configured to meet complex workflows based on document categories.



The workflow engine has 2 powerful flows. The first type of flow will help in new document creation and collaborative content management by multiple people as a "Parallel "collaborative activity. This means anyone within the workflow can make changes in the new document and submit their content. The document owner can use the "Sequential" workflow to reconcile and merge the content from multiple such collaborators into a single document for review and approval.

DOCUMENT FORM FILLING AUTOMATION, ISSUANCE AND PRINT CONTROL

Traditional DMS systems are very good at document creation and management workflows but they lack the capability of dynamic content management which helps the regulated industry to achieve better compliance. Current GMP data integrity guidelines from US FDA and MHRA insist on Contemporaneous recording of information and control over usage of paper based system.

MANUAL SYSTEM:

Typical manual system where the issuance officer issues a controlled document by manually filling the header details such as product, batch# lot# etc. This is manually filled in a controlled copy. This system lacks the integrity that is required in the modern world.

QUALIS DMS AUTOMATED SYSTEM:

In Qualis DMS, the header information such as product name, batch#, lot #, issuance date and time etc. are filled automatically (electronically) into the corresponding forms before issuance. By making the source of truth available electronically and automatically, the integrity of the document is maintained by ensuring that the data is contemporaneous.

PRINT CONTROLS IN QUALIS DMS:

The printing of any documents is a controlled activity in Qualis DMS restricting the number of copies allowed to be printed. In case additional copies are required to be printed, it has to go through a workflow process of re-request and approval for repeat printing which will be audit trailed by the system.

BENEFITS OF IMPLEMENTING QUALIS DMS AT A GAMP / GLP ENVIRONMENT

ILLUSTRATION 1 [GAMP ENVIRONMENT]:

A regulated industry production department needs to record the batch manufacturing details in a BMR template. The production team knows the details of the next batch (Product, Batch #, Lot # etc.) to be manufactured. BMR being a controlled document is available only to authorized personnel. If a Manual system is followed in sharing the above information, significant time is spent in entering these data multiple times and also chances of human error in data entry is high.

Once the issuance of BMR is automated, it significantly reduces the time and the associated data entry related human error.

Qualis DMS automated “Tag filling” feature helps in filling form templates with appropriate Controlled data like batch#, Lot#, product name, manufacturing date etc. Once appropriate data is fed into the tag fields, all document templates pertaining to a batch are automatically filled with appropriate information. The issuance officer issues the pre-filled document with electronic signature as a PDF document to authorized personnel who need the document for further recording of information. The authorized person who will be filling additional details can either fill the PDF Electronically or simply print it on paper and record the details manually.

ILLUSTRATION 2 [GLP ENVIRONMENT]:

Analytical worksheets (AWS) are a controlled piece of document which is supposed to be used by an authorized person performing a specific task or analytical procedure. The analytical worksheet will contain controlled information like Sample-ID, Batch#, Product name etc. An organization operating without a DMS needs a person to issue these templates (blank) with their signature. These templates are further used by the receiving person to record details (results of analytical procedures etc.). Considering the importance of maintaining the integrity of the contents of such AWS, if issued manually, then there are no controls to prevent misuse or audit trail any manipulation.

By deploying Qualis DMS, laboratories can issue electronically pre-filled AWS templates and ensure that only authorized person receives, fills and prints these forms.

The above examples clearly illustrates the benefits of implementing Qualis DMS and how it helps in achieving better control over compliance to cGMP, GAMP 5, FDA 21 CFR 110, 111 and 21 CFR 210, 21 CFR 211.

TECHNICAL SPECIFICATION

Feature	Details
Technology	Web based DMS that runs on any browser
Webserver	Tomcat 7 or above
Database Supported	MS-SQL Server 2016 or above
Document Types	MS-Office documents, pdf
DMS Architecture	Multi-Site, Multi-Department, Roles and Rights
File Storage	FTP server
Compliance	21 CFR Part 11, Eudralex annex 11, GAMP 5
Workflow Engine	Configurable parallel and sequential workflows
Files Size limit	No limit on file size
Controls	File Version and Print controls

References

http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm090016.htm

Good Manufacturing Practice (GMP) data integrity MHRA Regulations

Data integrity definitions and guidance

MHRA GMP Data Integrity guidance for the industry 2015

FDA Focus on Data Integrity

Data Integrity Issues in Pharmaceutical Companies

FDA Warning letters on data integrity

https://www.parexel.com/files/2614/2184/8648/Schmitt_Regulatory_Handbook_final_Jan_2015.pdf

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