Newgen Quality & Manufacturing Solution for Pharmaceuticals

Overview

The Good Manufacturing Practices (GMP) come with extensive documentation needs to meet certain standards to ensure optimum product quality and safety. If an instruction or record is poorly documented, then the quality of manufactured product can be negatively impacted.

The GMP regulations include mandatory sections on documentation. Documentation provides both:

- Information on when, where, who, why and how to complete tasks, and
- Evidence proving that the tasks have been completed as per the guidelines

Consequently, the documentation practices within a company can directly impact the level of success in manufacturing quality products that are safe to use. This can be easily verified during internal and external audits.

The Solution

Pharmaceutical and Life Sciences organizations depend on secure, version-controlled document management to meet the strict regulatory requirements during manufacturing of drugs. Effective document and information management are vital for them to achieve and demonstrate high quality.

Many pharmaceutical and life sciences companies have turned to enterprise content management (ECM), a combination of technologies and business processes used to create, manage and leverage business insights from an organization's structured and unstructured information pool. The principal component of ECM is the electronic document management system (EDMS) that provides content creation, storage, metadata indexing, versioning, publishing, and security as well as retrieval capabilities.

Challenges

- Consistently maintaining high quality of drug output
- Maintenance of FDA manufacturing 21 CFR part 11 compliances
- Storing exhaustive production records and ensuring their fast retreival
- Producing mandatory documentation for regulatory GMP Audits
- Deploying Compliant processes for change control and CAPA

Transforming Document Management with Newgen

Newgen's powerful Document Management Solution(DMS) enables efficient management of all controlled quality and manufac-turing related information.

Newgen Solution Feature Set

Content Creation

- Dictionaries and Taxonomies
- Document Templates
- Auto-Naming/Linking

Content Transformation

- PDF Rendering
- Overlay
- Watermark
- Controlled Printing
- PDF Annotation

Content Lifecycle Management

- Workflow
- Task Notification
- Change Control
- Version Management

Content Compliance

- Electronic Signature
- Audit Trail
- Search
- Reporting Dashboards
- Support for 21 CFR Part 11

Newgen's Quality and Manufacturing Solution for Pharmaceuticals ensures organization-wide consistency and compliance. It enables organizations to create, manage, and securely store documents with built in password policies to protect against unauthorized access. It provides full support for electronic records and electronic signatures as per FDA 21 CFR Part 11 requirements. Robust document management workflows ensure that right content is created, reviewed, approved, consumed, distributed and retired in an efficient manner. Flexible workflow enables easily replication of existing organizational structures and practices, while the intuitive user interface ensures ease-of-use for all end users. Some key solution highlights are given below:-

- Fully manages all quality and manufacturing specific documents that fall under Good Manufacturing Practices (GMP), such as material and packaging specifications documents and master formula/ batch manufacturing record documents
- Provides controlled print functionality and the ability to regulate issuance of controlled copies
- Provides periodic review capability that fully automates recurring review cycles
- Effectively manages both electronic and paper documents through out of the box document and record management capabilities

Key Features

21 CFR Part 11 Compliance — The solution comes with electronic signature capability, document-level audit trail reporting and enhanced security capabilities

Document and Version Management — Users can create requests for new documents as well as revise documents as part of change control. The solution tracks and manages their version (check-in and check-out) and ensures that only the latest and effective version is available to users.

Document Templates — The solution automatically provides the correct template to the author, based selected property values.

Document Lifecycle Management — Predefined lifecycles automatically guide documents from creation through review, approval, effective, supersede and retirement.

Advanced Workflow — Highly flexible workflow engine can be configured to support multiple business processes. Workflows can be initiated manually or automatically based on metadata conditions or business rules. Reviewers and approvers are automatically notified of required workflow tasks to take actions based on business rules including escalation rules. Newgen's Solution captures, manages and tracks all approvals, comments, rejection activities and various other actions as part of audit trail.

Dynamic Security — Access control is automatically applied based on a document's lifecycle state, document-specific parameters and user roles.

Master Data Management — Easily manages master data and the hierarchy of relationships between data values.

To Be Read and Understood — SOP or procedural documents can be delivered easily to employees via browser based access. Audit reports on all 'To Be Read and Understood' user actions, such as view content, sign-offs and overdue tasks, can be viewed in the system.

Watermarking and Overlays — Watermarks and overlays can be applied on a document's header, footer, or across each page to see the current status or effective date of the document. During controlled printing, the document type, user details, and access information are overlaid onto printed versions of controlled documents.

Document Change Control — Users can easily request, review and approve, or reject changes to controlled documents.

Relationships — Multiple documents/records can be linked as references to main document under creation or revision. These related documents help author in creating/revising main documents as well as linking the related content among documents.

Periodic Review — Quality managers can easily ensure that reviews are started and completed in a timely manner. The periodic review automatically triggers review reminders for documents based on pre-defined rules. Reports can be generated on the status of each review task.

Reports and Dashboards — Real-time and role-based reports can be generated to keep stakeholders updated on current activities like documents set to expire, documents with upcoming periodic reviews, and more. Users and administrators can quickly create their own reports and share them with other team members, providing a comprehensive view of all content-related activities.

Controlled Copies — Get complete control over issuing document copies. Control who can create document copies and take them outside of the solution. Overlay master/ controlled/ uncontrolled/ draft copy on relevant documents along with user information and justification details onto printed versions of controlled documents to avoid any wrong usage.

Search, browse and retrieve documents — Productivity suffers when users struggle to find documents, verify latest versions, and put context around content created by other people. Newgen's Solution provides advanced methods for browsing documents. The powerful search feature allows users to quickly find and retrieve documents that they need through full text and attribute/metadata searches.

Records Management — Solution provides capabilities for managing archival, retention and disposition policies for both paper-based and electronic documents. The system provides administrative reports for easy and efficient management of records as well as management of the entire system.

Benefits

- Out of Box compliance with FDA 21 CFR part 11 regulations
- Quick access to document audit reports for GMP compliance audits
- Controlled access to all pharmaceutical quality & manufacturing documents from single repository
- Easy distribution of SOPs for employee training and enable TBR audits
- Shortened document review-approval timelines
- Increased productivity through re-use of existing document templates

About Newgen

Newgen is the leading provider of a unified digital transformation platform with native process automation, content services, and communication management capabilities. Globally, successful enterprises rely on Newgen's industry-recognized low code application platform to develop and deploy complex, content-driven, and customer-engaging business applications on the cloud. From onboarding to service requests, lending to underwriting, and for many more use cases across industries. Newgen unlocks simple with speed and agility.

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