DOCS AND PROCESSES UNDER CONTROL

QUALITY PHARMA

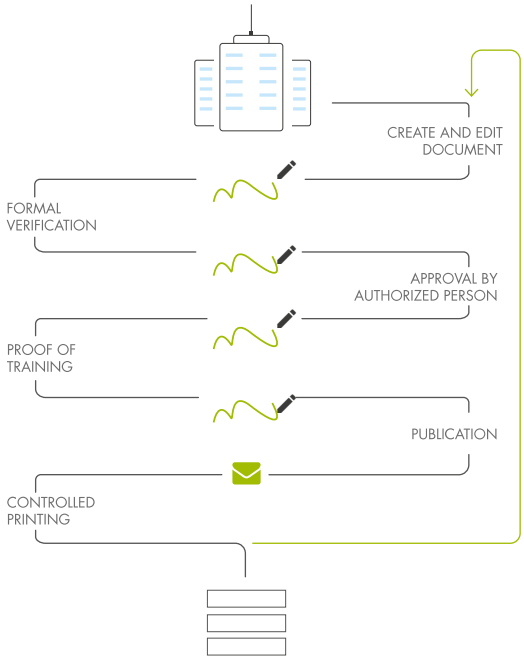
MUNICH - BERLIN - PHOENIX

BM-Flow

BM-Flow supplements its BM-windream system with functions for document control (for example SOPs, batch records, test plans, validation documents and many more) and the management of typical quality management processes (for example deviations, Out-Of-Specification, complaints and others). Thanks to the high degree of integration possible with BM-Flow, you always have an overview of all processes and their interrelationships.

- Reduce Errors
- Accelerate Processes
- Manage Documents
- Manage Processes
- Trainings Management
- Process Designer
- Web Client
- Archiving

MODULE MANAGED DOCUMENTS



Challenge

Companies in GxP- or 21 CFR Part 11-regulated areas have high requirements with regards to document control. Lots of time and energy have to be invested to keep track of documents. For example, what processing status is the document in? Which employee has the document for signature? Which employees still need to be trained before this document can be implemented? For which documents is the revision deadline approaching? Great effort is required for this information to be included in a paper-based system or a conventional electronic document management system.

Solution

arivis BM-Flow offers a manageable solution for every company size, which proves itself in operational use and at the same time fulfils the requirements of the local and international regulatory authorities. arivis BM-Flow supports the complete approval process of a document from the first draft to publication. Users can create and edit drafts with Microsoft Office products. The documents are then automatically converted into PDF format, which authors, reviewers and approvers sign using electronic signatures. The use of the PDF standard guarantees the long-term availability of the generated files.

FUNCTIONS

Document creation and editing

- Use of company-owned document templates, changeable only by authorized users
- Integration of Microsoft Office products (Word, Excel, Powerpoint, Visio etc.) for editing
- Maximum freedom, familiar software environment and easy transfer of existing document content
- Automatic allocation of version numbers
- Notification of users by e-mail when tasks are assigned or deadlines are exceeded
- Possibility of importing controlled documents (e.g. for development documents)
- Add dependencies of one document to multiple documents at one go
- Administration of templates for role assignments
- Interruption (stop/pause) and new recording of processing steps with other participants

Document verification and approval

- Automatic creation of PDF documents based on drafts via integrated PDF converter
- Electronic signature of PDF documents
- Advanced or qualified signature according signature law, possible according to 21 CFR Part 11
- Management of inspection plans, inspection reports according GLP through qualified signature
- Integration of external users in the signature process possible, e.g. for contract manufacturing partners or CROs

Document protection and monitoring

- Read rights only for authorized users (no access for unauthorized persons)
- Write protection for all valid and archived documents
- Each document has a change history (“audit trail”).
- Configuration of review periods per document type
- Timely notification before expiry of inspection deadlines
- Editing a new draft while the current version is still valid

Print control and print functions

- Integrated protection of PDF documents against unauthorized printing
- Use of integrated print functions for authorized users
- Comprehensive print history for each document: Who printed what and when
- Various configuration options for the print functions: Numbering, reason, recipient, signature
- Form printing: Imprint with limited validity period
- Day copy/training copy: Print with watermark
- Multiple printing (print a single linked document several times in a single operation in a controlled manner)
- Collective printing (select several documents and print them in one operation)
- Collection of old printed copies by tracking the recipients

Appendices and references

- Creation of attachments to main documents, e.g. operating instructions or scans
- Documents can reference each other. The document owner is informed when a document that refers to "their" document is revised.

Overview and search functions

- With the extensive search function, specific documents can be found to gain an overview or to answer common questions during the audit. E.g. the search for documents, which:
- are currently valid
- have a specific document type
- are in a specific processing step
- will expire before a certain date
- have been maintained, created, or reviewed by a specific user

Web client

- Search and display of documents and attachments
- Controlled pressure
- training tasks
- Execution of trainings incl. training success control
- Documentation of the destruction of controlled copies

BENEFITS

From the point of view of the QA department:

- Overview of all current QA procedures from deviations, customer complaints and changes
- Maximum flexibility because direct intervention in ongoing processes (selection of other parties involved in the process, new deadlines) is possible at any time.
- Overview of complex hierarchical dependencies, e.g. all measures of a deviation
- Quick access to accompanying documents (e.g. photos, documents) and referenced, controlled documents, e.g. in case of deviations from the process
- Integrated electronic signature (complies with 21 CFR Part 11, GxP, Signature Act) makes administration of signed paper documents superfluous
- Deadline monitoring for ongoing processes
- Extensive support in the creation of PQR/AQR through efficient reporting function
- Notification if deadline is exceeded
- Availability of all information for audits and inspections with just a few clicks
- Guided documents, guided processes (CAPA, OOS, Deviations, Change Control,etc.) and training courses in an application
- Adaptability to individual requirements

From the point of view of the User:

- Fast processing of all tasks through uniform task list
- Low training effort, as the training is limited to what is really important
- When using the "Module Managed Documents", only one training session is required for document control, QA processes and training sessions
- Overview of an entire process, not only of the tasks to be completed in each case

From the point of view of the Company:

- Cost-effective solution, also for small and medium-sized companies
- Transparency and acceleration of the QA processes and other business processes (vacation planning, invoice verification, incoming mail) through efficient paperless communication.
- Reduction of paper volume and associated printing, administration and storage costs
- Reduction of regulatory risks by avoiding errors in the maintenance of Excel lists or the like
- "Swiss Army Knife", only one application for many pharma-specific requirements as well as for general business requirements (e.g. connections to common ERP systems or e-mail systems are also possible)
- Fast amortization due to high acceptance and high productivity by the users

From the point of view of the IT department:

- Complete integration into the existing IT landscape, e.g. Active Directory, Microsoft SQL Server, existing archives based on EMC Centera, IBM DR, IBM Tivoli Storage Manager or NetApp
- Simple and manageable configuration options with good graphical support
- Manageable system with client-server architecture
- Use of existing database servers possible (MS SQL Server)
- Good scalability from 10 to 10,000 users
- Excellent technical support

MODULE TRAINING MANAGEMENT

Challenge

Training management requires a precise overview of both document control and personnel processes. If employees change their position in the company or new employees enter the company, the traditional way of paper-based training planning offers little security at great expense. The same applies to regularly recurring internal and external training courses and to the coordination between document managers and training managers when new documents are published.

Solution

The training module of arivis BM-Flow supports document managers, training managers, trainers and participants comprehensively with their respective tasks. This includes the automatic determination of demand for documents requiring training, the possibility of detailed training planning for those responsible for training, the specification of training rules for the respective training contents and reporting. In addition, a quiz module can be used to monitor training success.

Document training is supported as well as non-document training content. Attendance confirmations can be made both by electronic signature and on paper (also within a training course). When designing the application, we paid particular attention to compliance with data protection requirements.

All users can only view the relevant training information: Document managers can only view the training status of the documents for which they are responsible, training managers can only view the training status of the training groups for which they are responsible, and normal users can only view their own training status. *

* The creation of the reports required for inspections by authorized users is of course still possible for the members of the QA group.

Concept

The content of a training course can be selected from a list of BM-Flow module "Managed Documents" or from any other content. One or more training groups can be assigned to each training content. Training needs are generated for the users in these training groups for certain events, e.g. for the approval of a document, for reaching an adjustable deadline, or for the approval of a subsequent version. In addition, training requirements are also generated when new users join a training group. It is also possible to create training needs manually to enable spontaneous training.

At least one training manager is assigned to each training group. All training managers can view the training needs of their training area and plan their training accordingly. It is possible to bundle several course contents in one course. The individual training participants then receive the training contents in the form of self-training or classroom training (presence training). Both types of training are documented using electronic signatures. Alternatively, classroom students can also sign on paper on a printable training certificate. The trainer then signs electronically for the presence of these signatures.

It can be configured in the system that the owners of certain roles (e.g. the author and reviewer of a document) are implicitly regarded as trained. This type of training is displayed in the system accordingly, and no training requirements are generated for the corresponding users. In addition, there may be versions of a document that are not relevant for training. For these versions, successfully trained users of the previous version are also regarded as trained. At the end of the training, the trainer evaluates the success of each participant's training. Unsuccessful participants are not documented, but release the demand again until all trainees have been successfully trained. Of course, an audit trail is kept of all changes made to a training course. Furthermore, it is of course possible to generate almost any report on the training courses, training contents and individual training statuses.

Benefit

The document managers can task the authors or other persons at any time with the creation of a Question catalogue for the training success control. The creation and review of the question and answer catalogue is workflow-supported, i.e. it is ensured that the question catalogues are created and checked before the training begins. Questions can be designed as multiple-choice or value requests. The creation of questions is conveniently web-based.

In the question catalogue, sections can be created to which any number of questions can be assigned. The number of questions the which the respective user has to answer and how many questions have to be answered correctly, can be set in order to note the training success control as passed. During each training session, the questions presented to the user are randomly selected from the question catalogue. If a training success check has been successfully completed, the result is automatically presented to the trainer who can then confirm this with his electronic signature. After confirmation of the training result by the trainer, the user is noted as trained in the system.

From the point of view of the QA department:

- Up-to-date overview of the training status at all times
- Overview even in complex situations, e.g. entry of an employee into the company, new organizational structure and more
- Integrated electronic signature (complies with 21 CFR Part 11, GxP, Signature law)
- Makes the administration of paper documentation superfluous
- Availability of meaningful reports for inspection purposes with a few mouse clicks
- Consideration of all regulatory requirements
- Successful audits by German, American and Swiss regulatory authorities

From the point of view of the User:

- Fast access to necessary information
- Shortening of the search time
- Easy to use system

From the point of view of the Company:

- Cost-effective solution also for small and medium-sized companies
- Greater transparency and acceleration of processes
- Reduction of regulatory risk
- High user acceptance

From the point of view of the IT department:

- Easy integration into existing IT environment
- Excellent support
- Standard product with low adaptation and follow-up effort

From the point of view of the User:

- Fast processing of all tasks through uniform task list
- Low training effort, as the training is limited to what is really important
- When using the "Module Managed Documents", only one training session is required for document control, QA processes and training sessions
- Overview of an entire process, not only of the tasks to be completed in each case

From the point of view of the Company:

- Cost-effective solution, also for small and medium-sized companies
- Transparency and acceleration of the QA processes and other business processes (vacation planning, invoice verification, incoming mail) through efficient paperless communication.
- Reduction of paper volume and associated printing, administration and storage costs
- Reduction of regulatory risks by avoiding errors in the maintenance of Excel lists or the like

- "Swiss Army Knife", only one application for many pharma-specific requirements as well as for general business requirements (e.g. connections to common ERP systems or e-mail systems are also possible)
- Fast amortization due to high acceptance and high productivity by the users

From the point of view of the IT department:

- Complete integration into the existing IT landscape, e.g. Active Directory, Microsoft SQL Server, existing archives based on EMC Centera, IBM DR, IBM Tivoli Storage Manager or NetApp
- Simple and manageable configuration options with good graphical support
- Manageable system with client-server architecture
- Use of existing database servers possible (MS SQL Server)
- Good scalability from 10 to 10,000 users
- Excellent technical support

MODULE MANAGED PROCESSES

Challenge

QA departments invest a lot of time in tracking processes such as CAPA or OOS. Nowadays, this is usually done on a document basis, e.g. Excel tables. These procedures are complex and error-prone. The arivis BM-Flow module "Managed Processes" reduces the effort for the administration of these QA measures considerably. At the same time, the overview of the state of affairs for involved users increases on all levels.

Solution

arivis BM-Flow allows you to design your own processes with the help of a process designer. This enables the definition of own process steps ("states") and from there steps and roles.

In addition, it is possible to define which users must give their consent so that the next state can take place or which sub-processes ("child processes") are started automatically during a state. When a user is assigned a task, he becomes the task manager and the task becomes visible to him. The task manager enters his results in the electronic form. Depending on the configuration, the main task cannot be completed until all sub tasks have been completed.

In a CAPA process, for example, measures can be determined and assigned to task owners. The entire process is documented electronically. For this purpose, an audit trail is provided in which all user entries are visible and all statuses of the process are comprehensibly documented. A special feature is the integration of the electronic signature: this not only allows information of a specific state, but also all information in planned sub-processes. Thus, for example, the member of a QA group can sign a deviation report including all planned activities.

FUNCTIONS

Process Designer

- Graphical creation of own processes
- Assignment of roles from users and groups of the Windows environment
- Automatic start of sub-operations when certain states are reached
- Directly usable templates for deviations, change management, customer complaints according to best practice!
- Directly usable or add and modify your own fields and processes

Form Designer

- Own creation of forms
- Definition of own selection lists with possible connection to existing databases
- Definition of mandatory fields

Process Control

- Definition of users and groups who are allowed to start and view processes
- Complete overview over all running and completed processes for authorized users
- Browse through the past states of an active operation
- Clear presentation of all necessary information at a glance

Search and Reporting

- Search and evaluation by transaction type, index fields, status, user
- Export of search results and reports for PQR and AQR archiving (csv format, PDF)

Archiving

- Possibility of archiving completed processes in a PDF document

Benefit

From the point of view of the QA department:

- Overview of all ongoing QA procedures from deviations, customer complaints to changes
- Highest flexibility, because of direct intervention in running processes (selection of other processes, new deadlines) is possible at any time.
- Overview also of complex hierarchical dependencies, e.g. all measures of a deviation
- Fast access to accompanying documents (e.g. photos, documents) and referenced, guided documents, e.g. in case of deviations from the process
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