

## All data in compliance

Raw data securely managed, easily found, reprocessed, and archived.

# BM

### BM-Windream ECM

BM-Windream is the 21 CFR Part 11 compliant data and document management system for the pharmaceutical industry. It is based on the market leading windream document management system from windream GmbH, Bochum. In addition to our industry-specific modules, we have access to a series of tried and tested windream add-on modules from our partner network, e.g. for e-mail archiving, linking to ERP systems, CRM systems, knowledge management or scanning solutions.



## The current situation

GxP-regulated companies of all sizes are facing the challenge of managing their raw data according to 21 CFR Part 11 regulations. There are many deficits when data is managed in classic file systems.

For example they do not offer sufficient protection from unauthorized modification or deletion of files. The Part 11 functionality of device software may be avoided in a number of cases.

Additionally many older laboratory systems lack basic 21 CFR Part 11 compliant functionality.

- » Centralized raw data management
- » Centralized accompanying reports and assessments
- » Audit trail
- » Electronic signature
- » Version control
- » Electronic archiving
- » Powerful search

**LIMS**

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DEVICE DATA 

STANDARD FILE FORMATS 

(e.g. WORD, EXCEL, PDF)

**BIOMEDION**






**BM-Windream**

LONGTERM ARCHIVE

**ELN**

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-  WINDOWS EXPLORER
-  BROWSER
-  MOBILE APPLICATIONS
-  POWERFUL SEARCH

LINUX / MACOS

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## Functionality

BM-windream protects data and recordings generated by devices, in Excel or any other format, against unauthorized modification. Changes are documented by an audit trail and can be reversed with the built in automatic

versioning. BM-windream works with any file based software, either integrated with devices (e.g. Agilent, Waters, Thermo Fisher, Varian and many more) or standard software like MS Word, Excel or Adobe Acrobat.



## Typical laboratory applications

The system displays itself as a network drive to the laboratory software, which can be used the usual way. Hence no modification of the laboratory software is necessary and training effort is little. Adding new laboratory software is simple as well.

BM-windream can automatically extract meta-data from device data and generate indexes of raw data files. Using the powerful integrated search tool the user can access and reprocess files easily and fast.

Since BM-windream is accessible as a network drive, there is usually no need for local retrieval of the files

which may be reprocessed directly from within the network storage. This is a great advantage over traditional archiving systems, which often generate problems while retrieving files, since the links between sequences, methods and raw data might go amiss.

BM-Windream can easily interlink managed data with LIMS or ELN systems via stable links. File access can be granted through a web interface or mobile application.

The application runs on MS Windows, however Linux or Apple computers can also access the data files.

### Features Functionality

- » Supports all file formats
- » Fully integrated into MS Windows Explorer
- » Alternative access via web browser possible
- » Automatic transfer of search criteria from raw data indexes
- » Automatic generation of audit trails for all files
- » Automatic version control of files when modified
- » Secure, server based file management and archiving
- » Easy report generation
- » Powerful search
- » Optional: conversion of files to manufacturer independent AniML-format with long term stability
- » Optional: electronic signature + approval workflow

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## Your Advantages Benefits

- » All data is stored in conformity with 21 CFR Part-11 over the entire life cycle
- » Greatly improves the ability to produce evidence for patent litigations
- » Fast access of all laboratory data from a workstation, significantly speeding up report generation



## Search

Use the powerful search tool, to look for users, devices, creation- or modification time stamps or many other freely configurable attributes. Complex Search terms can be configured and saved for later reuse. It is also possible to adapt columns in the search results grid to your indi-

vidual needs. Search results can be exported to CSV-files for easy report generation. Furthermore the export of all meta-data (including the complete audit trail and version history) of an individual file into HTML can be achieved with a few mouse clicks.



## Workflow Designer

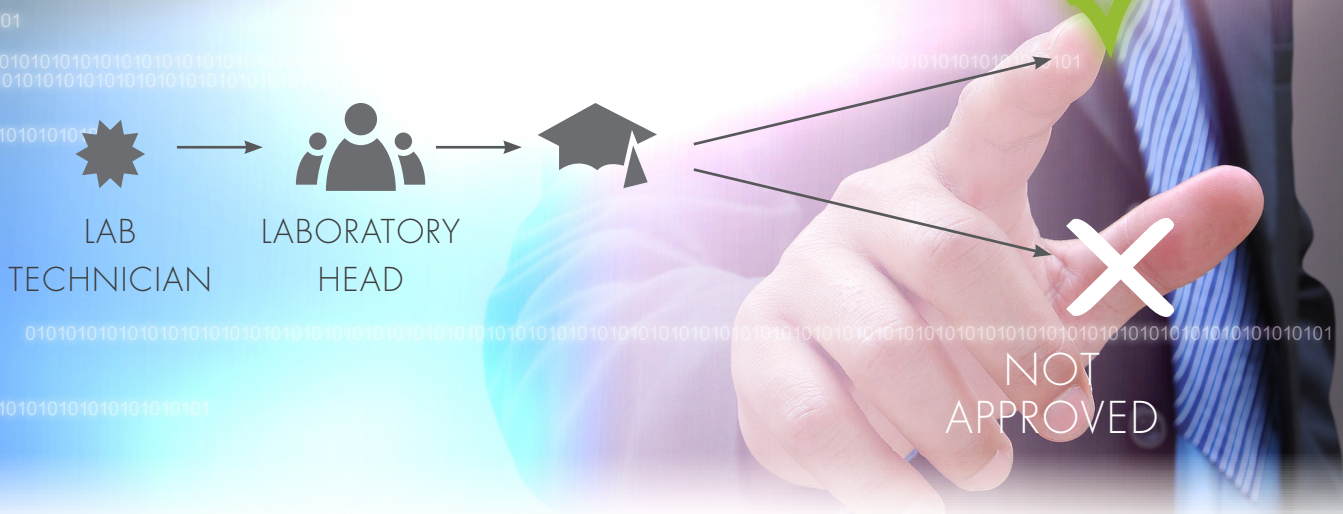
Workflows can be freely designed with the integrated Workflow-Designer.

This covers sequences, data entry forms as well as user roles and reports.

START  
WORKFLOW

CARRY OUT  
REVIEW

APPROVED



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