



BM-windream

Compliant Data Management
for the Digital Age

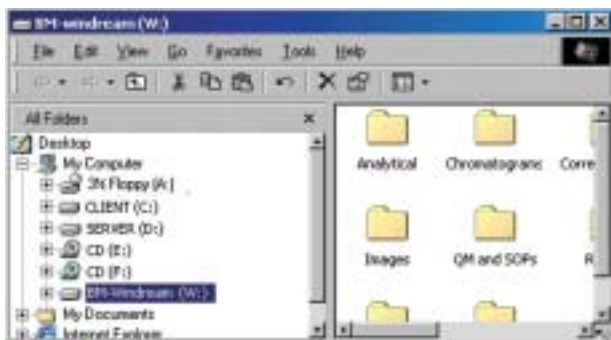
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BM-windream

What is BM-windream?

BM-windream is an advanced, 21 CFR part 11 compliant electronic data and document management system (EDMS). BM-windream is fully embedded within the Microsoft Windows operating system. Users do not need to start a separate application to work with the EDMS. The system can be intuitively operated by using standard Windows features. The EDMS is accessible via a virtual drive that appears on all client workstations. All Windows applications, which save data in any type of file format have access to this EDMS drive without any programming or adaptation.



The BM-windream drive as displayed in the Windows Explorer. It can be accessed from any program using the "Open" and "Save" commands.

Its seamless integration into Windows allows the control of BM-windream via the Windows Explorer – an interface all computer users are already familiar and comfortable with. All specialized EDMS features like audit trails, version control, indexing and electronic signature are directly accessible through extended Windows context menus. In addition to all general EDMS functions, BM-windream features a seamlessly integrated electronic archive system for secure, long-term archival on optical media (CD, DVD, WORM).

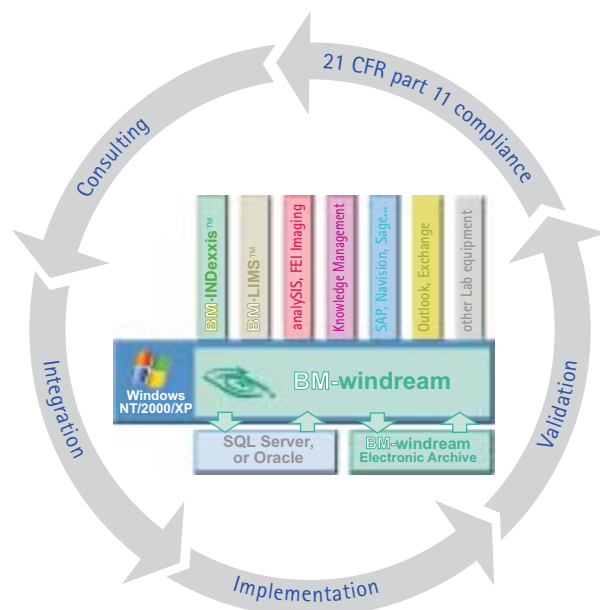
Designed for 21 CFR part 11 compliance.

BM-windream is the 21 CFR part 11 compliant version of the patented windream EDMS system with thousands of installed users in other industries. BioMedion is the exclusive worldwide supplier of windream technology for (GxP) regulated industries. BioMedion has extended and validated the system to comply with 21 CFR part 11 and other relevant regulations.

Advantages of BM-windream

The management perspective.

- BM-windream paves the way to company-wide 21 CFR part 11 compliance while cutting costs for document administration, retrieval and archival at the same time.
- Low total cost of ownership (TCO) through:
 - Seamless integration into your existing hardware and software landscape.
 - Limited project scale. BM-windream is quickly implemented as a compliant data-storage for rapid ROI and can be upgraded later step by step to a fully integrated corporate EDMS with knowledge management functionality and a web portal.
 - Very little user training needed by the use of the familiar Windows interface.
 - Comprehensive overall concept using industry standards and a transparent system architecture.
 - Rapid and easy integration of third party applications.



BM-windream is part of a suite of software solutions which BioMedion has developed for (GxP) regulated industries.

The objective is a seamless compliance with 21 CFR part 11 for all electronic data.

For details about this concept see our company brochure.

- Fast track to compliance by BioMedion's expertise in implementing and validating 21 CFR part 11 compliant solutions.
- Competitive advantage by using the full potential of advanced IT-technology.
- We strive to tailor our solutions to your
 - business
 - scientific
 - regulatory
 - and technological
 objectives, both from a strategic and operational point of view.

The user perspective.

- Users continue to work within the familiar environment. No time-consuming learning curve to master another new application.



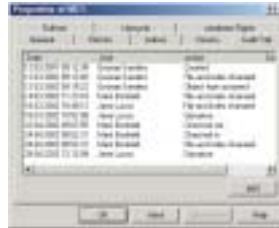
- Instant access to all needed data and information by powerful search and retrieval mechanisms.
- All data accessible by one system – Lab journals, LIMS, images, clinical data, production, packaging, manuals, SOPs, correspondence, e-mails...
- Data from diverse sources (file servers, SAN, optical archive, etc.) can be accessed in mixed-modes without change of systems or applications. No need for the user to know where a data file is actually stored, in order to find and use it.
- System can be directly accessed from all Windows applications by standard "Open" and "Save" menu functions.
- High speed full-text search and retrieval. More than 270 file formats are automatically screened and indexed for text searches.
- Comfortable but highly secure system access and digital signature by use of smart card technology.

BM-windream features

Some of the important features that BM-windream adds to Windows are:

Audit trail

BM-windream's audit trail function fulfills the FDA requirements for electronic records. Each transaction like creating, changing or deleting a document or data file is automatically recorded with date and time stamp, user name and type of transaction. Optionally a comment for each change can be entered by the user. Audit trails are secured against changes or manipulation by users.



Version control

BM-windream supports the creation and management of successive versions of files and documents. The version-menu keeps track of all previous versions, which are automatically locked for subsequent changes, once a new version of a document is created. This version history allows the tracking and inspection of all changes that have been made to any file or document during its life cycle.

Indexing

The index function allows the attachment of meta-information to any file or document. This highly enhances the ability to classify, identify, manage, and retrieve files and records. Index fields and document types can be easily created by administrators using the visual drag & drop object generator of the management console.



Index search

The index search facilitates the instant retrieval of required documents which have been previously indexed automatically or by users. With the index search even large

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features continued

network storages and electronic archives can be scanned in a matter of seconds and the requested information retrieved.

Full-text search

BM-windream extracts and automatically indexes text information from over 270 different file formats. The full-text search allows the finding of information quickly even if no index information is available.

Access control

BM-windream uses a sophisticated access control hierarchy which is based on Windows NT user accounts and groups. With BM-windream you can control exactly who is allowed to see, change or alter data and documents, files or folders.

Digital Signatures

BM-windream supports FDA compliant digital signatures based on SmartCard technology. BM-windream digital signatures are interoperable, that means the validity of these signatures can be checked not only in BM-windream but also in third party applications (e.g. Outlook, Notes, etc.).

Document life cycle management

The integrated life cycle management allows the automation of archival, retention and eventual deletion (after a pre-set retention period) of documents and data. This function automatically transfers files to the optical long-term archive system without the need of user interference. Nonetheless all archived data remain accessible through the usual search and retrieve functions.

Administration via the Microsoft management console

BM-windream is administered via the Management console of Windows NT/2000. A snap-in integrates the entire administration of BM-windream directly into the Microsoft management console. Thus system administrators feel instantly at home and need minimal training to manage and maintain BM-windream.



System requirements Server

Software

Windows NT 4
or Windows 2000 Server

SQL Server 2000
or SQL Server 7.0
or Oracle 8.1.7

Hardware

min. Pentium 400 MHz, preferably more
min. 500 MB RAM
hard disk: Min. 8 GB (program, temporary files, filestream-pools, etc.), plus data

Jukebox, preferably JVC or Plasmon.

System requirements Client

Software

BM-windream supports the following client operating systems:

Windows 95
Windows Me
Windows NT 4.0
Windows 2000
Windows XP
Internet Explorer 5.01 and up with Active Desktop

Other operating systems can access the system through a web-portal client.

Hardware

Min. Pentium 133 MHz
(recommended: 266 MHz)
Min. 64 MB RAM
Free disk space: 20 MB
(recommended: 50 MB)
SVGA with 1024 * 768 resolution.



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