



BioMedion

Bridging the gap between
Biomedical Science and Information Technology

BioMed



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About BioMedion

BioMedion develops and implements advanced IT-solutions for (GxP) regulated industries. We focus on pharma, biotechnology, medical devices and related industries (cosmetics, food etc.). Our core competencies are 21 CFR part 11 compliant solutions for data- and document management, knowledge management, laboratory management (LIMS) and quality management.

We enable our customers to manage, organize, analyze and archive their growing electronic data pools in compliance



with regulatory requirements such as GxP, 21 CFR part 11 and Annex 11.

For the selection and integration of our products we rely on leading (best of breed) technologies. Our primary design objectives are ease of use, fast implementation and seamless integration into the existing IT and equipment infrastructure of our clients. This results in a low total cost of ownership (TCO) and rapid return on investment. Our solutions are scalable from a few users in a single lab or department to thousands of users in large corporate networks.



We support the implementation of our software products by a comprehensive portfolio of services which extends from training about regulatory requirements via system planning, implementation, validation to drawing up SOPs and auxiliary documentation.

The BioMedion philosophy

We regard ourselves as partners for our customers. For this, we engage in ongoing research about the demands which the market and regulatory authorities impose on GxP regulated organizations. Our aim is to gain a competitive advantage for our customers through cost reduction and process optimization in R&D, production and quality management.

We listen to you.

Before suggesting any solutions, we want to understand our customers' goals, aspirations and requirements. Nobody knows your business like you do! This is why we first take the time to listen to you very carefully. In our opinion, this mutual understanding is the basis of a successful business partnership.

We speak your language.

Our team consists of professionals with years of experience in pharmaceutical R&D, production, process analysis, software technology and business administration. Thus we do not only understand the process-side of your work but also your scientific, regulatory and business objectives. This leads to solutions which are practical and tightly integrated into your way of working.

Economical solutions.

Investments need to fit the size of your business, your budget and deliver a return on investment within a foreseeable timeframe. We understand the economic pressures – especially of smaller and growing companies. The sustained economic success of our customers is the basis of our own success.

Open standards.

Our solutions rely on open formats and industry standards. Instead of creating just another "proprietary island", our solutions are transparent and open for integration with third party software and equipment.

Long term customer relationships.

We strive for long term customer relationships. In regulated industries, more than anywhere else, an IT-solution has to be considered in view of its entire life cycle. We accompany this life cycle and keep you and our products up to date with current technical and regulatory developments.

Our products

Designed for compliance™.

Based on technologically leading software components, BioMedion has developed its own suite of data and document management applications for regulated industries. All applications were developed to meet the requirement specifications of FDA's rule 21 CFR part 11, electronic records and electronic signatures. This does not only cover the features and functions of our products but also the quality management of the development process. Documentation and validation of all functions are the basis for optimal support of our customers in their own validation of the installed systems (IQ, OQ, PQ).

Our product family facilitates the implementation of a comprehensive 21 CFR part 11 compliant IT-infrastructure which allows easy integration of our customers' existing and future third party applications.

The basis of our product family is the electronic data and document management system BM-windream. By virtue of its open architecture and integrated long-term electronic archive, BM-windream is the ideal 21 CFR part 11 compliant corporate data management and archive backbone for all electronic data files.

Based on this "compliant data management backbone", BioMedion offers a steadily growing family of 21 CFR part 11 compliant solutions, which are seamlessly integrated into BM-windream. This is possible due to the unparalleled and patented integration of BM-windream into the Microsoft Windows operating system and network environment. Thus any existing or future file-based application which runs under Windows is automatically integrated into our system – without any programming or special interfaces.

BM-windream

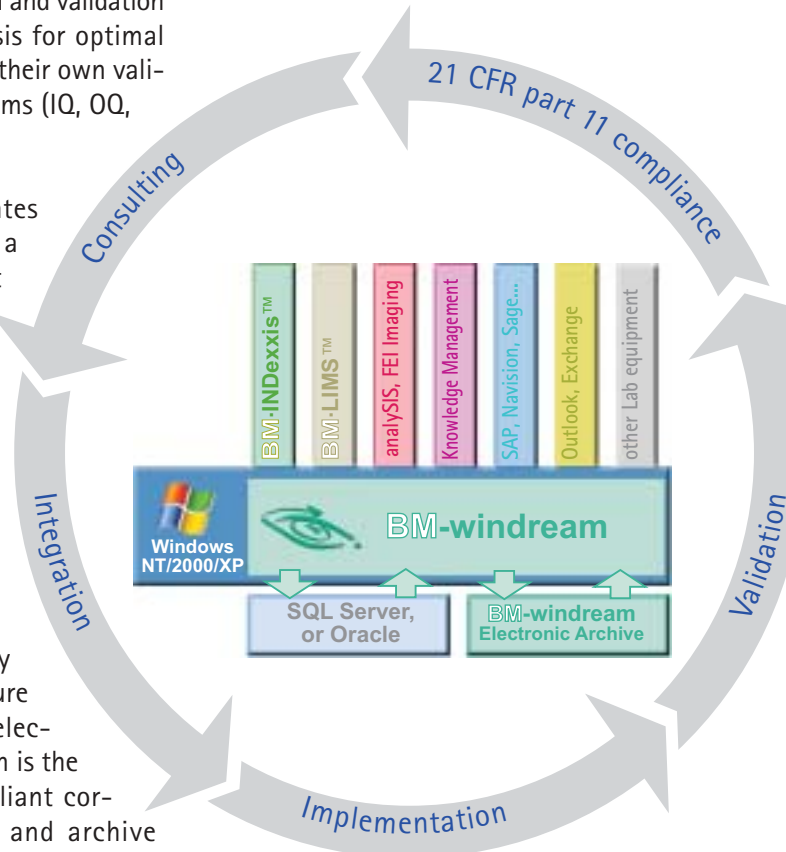
Compliant Data Management for the Digital Age

The 21 CFR part 11 compliant data management and archive system for (GxP and FDA) regulated industries.

BM-LIMS™

Boosting productivity for compliant laboratories

Data capture, data analysis, sample management, workflow, method management, orders, billing and more. 21 CFR part 11 compliant, seamless integration with BM-windream. Flexible and easily customizable.



Each BM-application is part of a comprehensive 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 individual applications, please refer to our respective brochures.

BM-INDexxis™

See things your way

Structured, customized file and folder views for display and organization of all data. Each user can create an individual view and data structure of all server and archive data without moving or duplicating any original data.

BM Partner solutions

- 21 CFR part 11 compliant integration of the scientific imaging software analysis (Soft Imaging System) with BM-windream.
- 21 CFR part 11 compliant integration of FEI Company electron microscopes (Quanta SEM series) with BM-windream.



Services

We base all our services on your business objectives. When planning and implementing solutions, we take the technical, economic and regulatory framework of our customers into close account .

We offer support for all phases of planning, implementation and integration of our solutions with the goal of a comprehensive validation and compliance, especially with GxP and FDA 21 CFR part 11.

Based on your individual needs, we assist in requirements analysis, risk analysis, system selection, implementation, integration of legacy systems, data migration, validation, training and ongoing life cycle management of your compliant systems.



Workshops

BioMedion offers dedicated training seminars and customer workshops dealing with the technical, regulatory and organizational aspects of electronic data management. We



offer these workshops in the form of in-house seminars at your premises or at any venue of your choice. For details please inquire on our homepage or directly at BioMedion.



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