

CASE STUDY

# Successful Implementation of BM-Watcher and BM-windream at Formycon AG

**PROJECT COMPLETION**

April 2025

**CLIENT**

Formycon AG

**PARTNER**

biomedion GmbH

**SOLUTION DELIVERED**

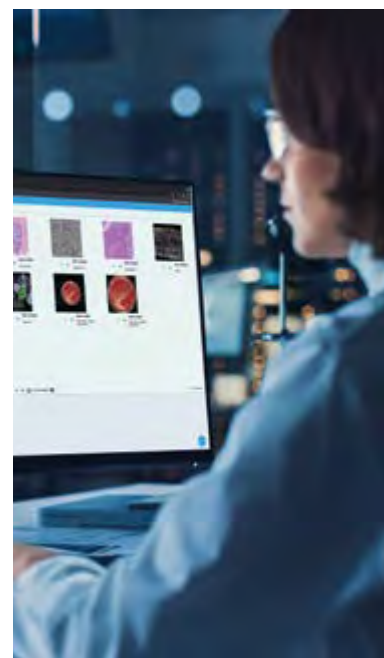
BM-Watcher 2.0.1.3  
BM-windream 7.0

# About the client



Formycon AG is a leading, independent developer of high-quality biosimilars, follow-on products of biopharmaceutical medicines. The company focuses on therapies in ophthalmology, immunology, immuno-oncology and other key disease areas, covering almost the entire value chain from technical development through clinical trials to approval by the regulatory authorities. For commercialization of its products, the company relies on strong, well-trusted and long-term partnerships worldwide. Formycon has already two biosimilars on the market. Another one has been approved and four further pipeline candidates are currently in development. With its biosimilars, Formycon is making an important contribution to providing as many patients as possible with access to highly effective and affordable medicines.

Formycon AG has partnered with biomedion GmbH to enhance their data integrity and process automation by implementing the BM-Watcher and BM-windream solutions across their laboratory environments. This project was driven by the need to meet stringent regulatory requirements, ensure seamless device integration, and establish a future-ready data management system.



## Business Needs

### > Enhancing Audit Readiness

The organization aimed to further optimize fast and structured access to critical data, proactively strengthening confidence and efficiency during FDA and EMA inspections.

### > Building Confidence in Compliance

By modernizing workflows, the team saw the chance to minimize errors and improve data security, reinforcing confidence in meeting regulatory expectations..

### > Improving Data Workflows

The organization recognized the opportunity to streamline data handling by reducing manual collation, paving the way for faster project execution.

### > Enabling Scalable Growth

The organization recognized the opportunity to enhance its infrastructure, ensuring seamless support for expansion across new locations and larger data volumes.

### > Streamlining Operations

Optimizing data validation and preparation processes offered the chance to minimize overhead and maximize the productivity of scientific teams.

### > Strengthening Data Integrity

The organization identified the opportunity to harmonize fragmented data management, reinforcing stakeholder trust in both quality and compliance.



# Objectives

- > **Deploy validated IT environments**  
for system operation.
- > **Connect laboratory instruments**  
to centralized data systems.
- > **Ensure Compliance**  
with regulatory standards and data integrity guidelines.
- > **Enable Future Scalability**  
through detailed validation and documentation.
- > **Empower Users**  
with comprehensive training and ongoing support.

## Project highlights



### Seamless Integration Across Lab Devices

- > 25 laboratory devices were targeted for integration.
- > 22 devices successfully connected to the new system, with the remaining planned for follow-up phases.
- > Custom modules developed to accommodate varying technical environments.



### Robust Validation & Compliance

- > Complete IQ, OQ, and UAT conducted, meeting Formycon's high standards.
- > Extensive risk assessment and supplier evaluation were performed.
- > All installation and configuration processes meticulously documented.



### Effective Collaboration

- > Joint Formycon–biomedion team ensured close coordination.
- > Weekly and bi-weekly project meetings kept progress on track.
- > Rapid issue resolution and transparent communication throughout the project lifecycle.



### Tailored Training & Knowledge Transfer

- > Detailed administrator and user training sessions delivered.
- > Training materials and recordings are made available for future reference.



## Results and benefits

- ✓ **Fully operational system**  
deployed within project scope.
- ✓ **Comprehensive project documentation**  
prepared for future scalability.
- ✓ **No open issues**  
or follow-up actions remaining.
- ✓ **Strengthened partnership**  
between Formycon AG and biomedion GmbH.
- ✓ **Enhanced regulatory compliance**  
and data integrity.

» The biomedion team showed strong commitment and flexibility during the project. Despite early challenges, their structured approach and collaborative efforts supported a smooth system implementation. The new system provides improved capabilities for managing our laboratory data.

— Ivan Avila | Sr. Director Information and Business Technology | Formycon AG



### Why biomedion?

Watcher 4.0 is the solution for end-to-end data integrity, uncompromising inspection readiness, and complete information lifecycle management. Professionals in the life sciences industry can trust Watcher 4.0 to help meet regulatory requirements and process compliance while ensuring archived data remains accessible for audits and inspections. Get the help you need to ensure your data is secure and compliant.

#### Raw-Data Transfer and Archiving

Raw data is an essential component of any research conducted by scientists. It is composed of raw information collected by various detection techniques, including, but not limited to, microscopy, chromatography, and spectroscopy.

#### For more information about Watcher solutions contact us:

[info@biomedion.com](mailto:info@biomedion.com) — [www.biomedion.com](http://www.biomedion.com)

