



Case Study

Swift implementation of tailored enterprise software solutions for MS-based analysis of novel biotherapeutics

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Background

Comprehensive characterization and efficient quality monitoring are key factors to ensure safety and efficacy of novel biotherapeutics while reducing their development costs.

Providing information at the molecular-level and delivering high analytical throughput, mass spectrometry is increasingly being used across the biopharma industry to supplement and replace established analytical techniques that cannot address the inherent structural complexity of biotherapeutics.

To keep pace with the increasing demand for MS-based analyses, we expanded our lab's capacity and capabilities by acquiring two new instruments and developing novel protocols for intact mass analysis and peptide mapping. Implementing these applications proved challenging, with data processing and analysis constituting the most critical bottlenecks. We therefore established a partnership with Genedata to overcome these challenges and worked together to evaluate our analytical processes and develop unique solutions to maximize our lab's productivity that met our specific business and technical needs.



About Bayer Pharmaceuticals
Bayer Pharmaceuticals focuses on researching, developing, and marketing specialty-focused innovative medicines that provide significant clinical benefit and value.

Industry
Biopharmaceuticals

Website
www.pharma.bayer.com

Key Challenges
Establishing new MS-based analytical capabilities for novel biotherapeutics, increasing productivity by speeding data analysis and generating custom reports

Solution
Automated MS data processing using Genedata Expressionist®

Results
Swift implementation of a platform that delivered high-quality results and six-fold reduction in processing time

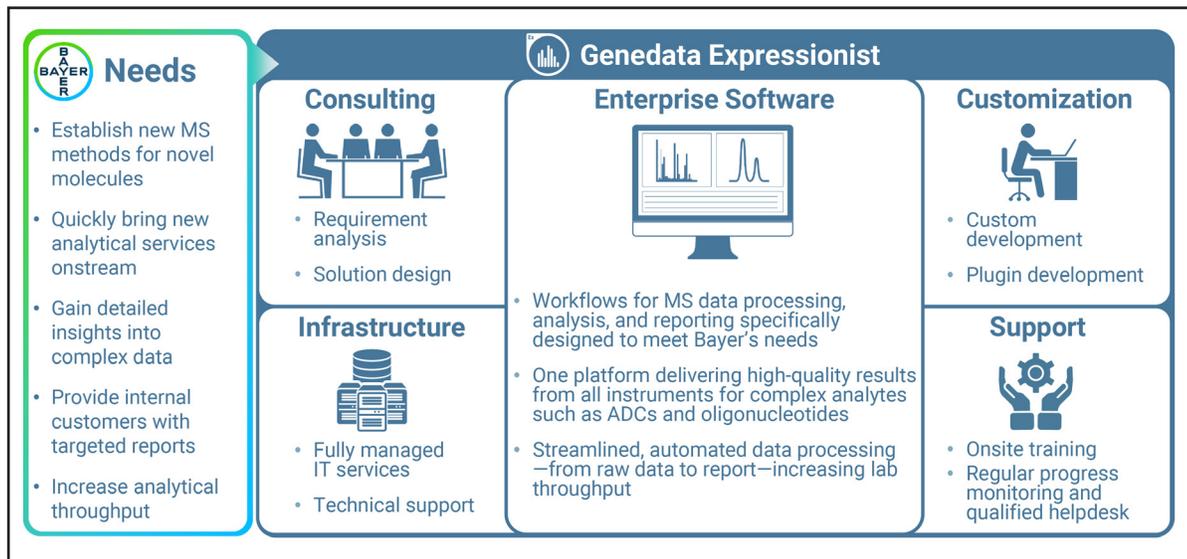


Figure 1: How the Genedata Expressionist platform meets the needs of the Analytical Development laboratory at Bayer Pharmaceuticals.

Main Challenges

Developing new methods to characterize novel classes of biopharmaceuticals

The challenge of establishing new analytical capabilities was compounded by the novel nature of the analytes, for which no established MS-based protocols were available. Interpreting results and iteratively optimizing experimental and analytical methods for such molecules requires a significant amount of area expertise in MS-based characterization of biotherapeutics.

Delivering productive output in a timely manner

To meet the needs of our internal customers involved in time-critical projects and maximize Bayer's return on investment in new infrastructure, it was important that new protocols were optimized and made productive as quickly as possible.

Obtaining a complete overview of data to facilitate resolution of complex process issues

The novel nature of our analytes and protocols and the limitations of the available software made interpretation of results far from straightforward. When troubleshooting a complex process issue, it is extremely helpful to have not only domain expertise, but also to have a comprehensive and unbiased overview of all data at all stages of processing.

Keeping pace with an increasing number of samples and projects

Any solution that we implemented had to be scalable and able to handle high sample throughputs. Using the available software, data processing and the production of targeted reports were laborious and time-consuming processes that required frequent manual interventions.

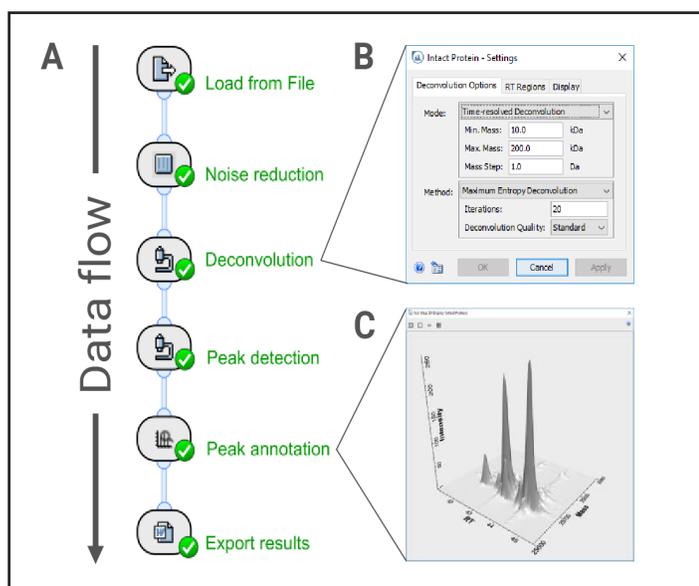


Figure 2: (A) Genedata Expressionist workflow. (B) Each processing step can be precisely controlled. (C) Intuitive visualizations aid interpretation at every step.

The Solution

In-depth business- and technical-needs analysis

Our partnership with Genedata began with their scientific consultants visiting our site and carrying out a comprehensive analysis of our entire MS data acquisition and processing workflow. Through careful consultation with our scientists, Genedata identified our current and future needs for an MS data processing platform (Figure 1).

An understanding of the status quo

Thanks to the intuitive and unique visualizations provided by Genedata Expressionist, we immediately obtained a comprehensive, consolidated overview of all our existing MS data and gained new insights into our sample preparation, instrument setup, and data analysis procedures.

Design of tailored solutions

Working in close collaboration with Genedata experts, we evaluated the results, designed an optimized end-to-end MS analysis strategy—from sample preparation to result reporting—and planned an implementation timeline that addressed and prioritized our needs.

Rapid rollout with industry-leading scientific support

During the implementation phase, Genedata consultants provided extensive on-site training, regularly visited our site to monitor progress, and reacted very quickly to all our requests for support.

Solutions that address current and future needs

After successfully applying the intact mass analysis workflow in our lab, we were able to quickly develop and implement additional solutions for peptide mapping and oligonucleotide analysis, and we are currently developing more workflows.

At the heart of Genedata Expressionist is a unique workflow-based approach (Figure 2) that uses a sequence of highly configurable off-the-shelf building blocks to provide custom-built data processing solutions; not only for our target application of intact mass analysis of ADCs, but for any MS-based characterization or monitoring process for any biotherapeutic format.

Efficient IT setup and operation

We benefitted from Genedata expertise in planning, setting up, installing, and configuring a dedicated Genedata Expressionist server and integrating it into our existing IT landscape. To ensure stable daily operation we implemented Genedata managed IT services; which include Service Level Agreements guaranteeing a fast response, lifecycle management for new releases and patches, and health checks for infrastructure and configuration. Using managed services provides direct access to specialized single point of access support and means that we are not reliant on internal IT resources for application management.

Benefits

Fast implementation of a productive platform that addresses our specific needs

A key outcome of our collaboration with Genedata was the rapid implementation of MS data processing and analysis solutions that were tailored to our instrumentation and analytical requirements. Adopting a flexible workflow-based platform allowed us to streamline MS data analysis and quickly deliver productive output for different complex analytes such as mAbs and ADCs (Figure 3). This unique approach also provides unparalleled control and insightful overviews of the data at every stage of processing.

A single-software solution for all MS-based biopharma applications

Because it is a vendor independent platform, we can use Genedata Expressionist to process data acquired from all our MS instruments, and its workflows provide out-of-the-box data analysis for any biopharma application. Using a single software

standardizes our data analyses, increases reproducibility, and ultimately enables meaningful comparison of results. A common platform facilitates collaboration across our labs and eliminates costs for training and maintenance of multiple software packages.

A trusted partnership with the leading provider of enterprise software solutions for biopharma

We especially appreciated the high level of expertise and support provided by Genedata, which enabled us to optimize every stage of our MS-based analytical processes—while incorporating industry best practices—and quickly generate high-quality results. Our partnership also gives us the opportunity to address highly specific needs by including customized functionalities in the software. For example, the open architecture of Genedata Expressionist allows us to automatically create highly individualized reports that accelerate and facilitate decision-making by providing at-a-glance interpretation of results. Quickly identifying issues in this way can be invaluable in saving time and resources across the biotherapeutic development process.

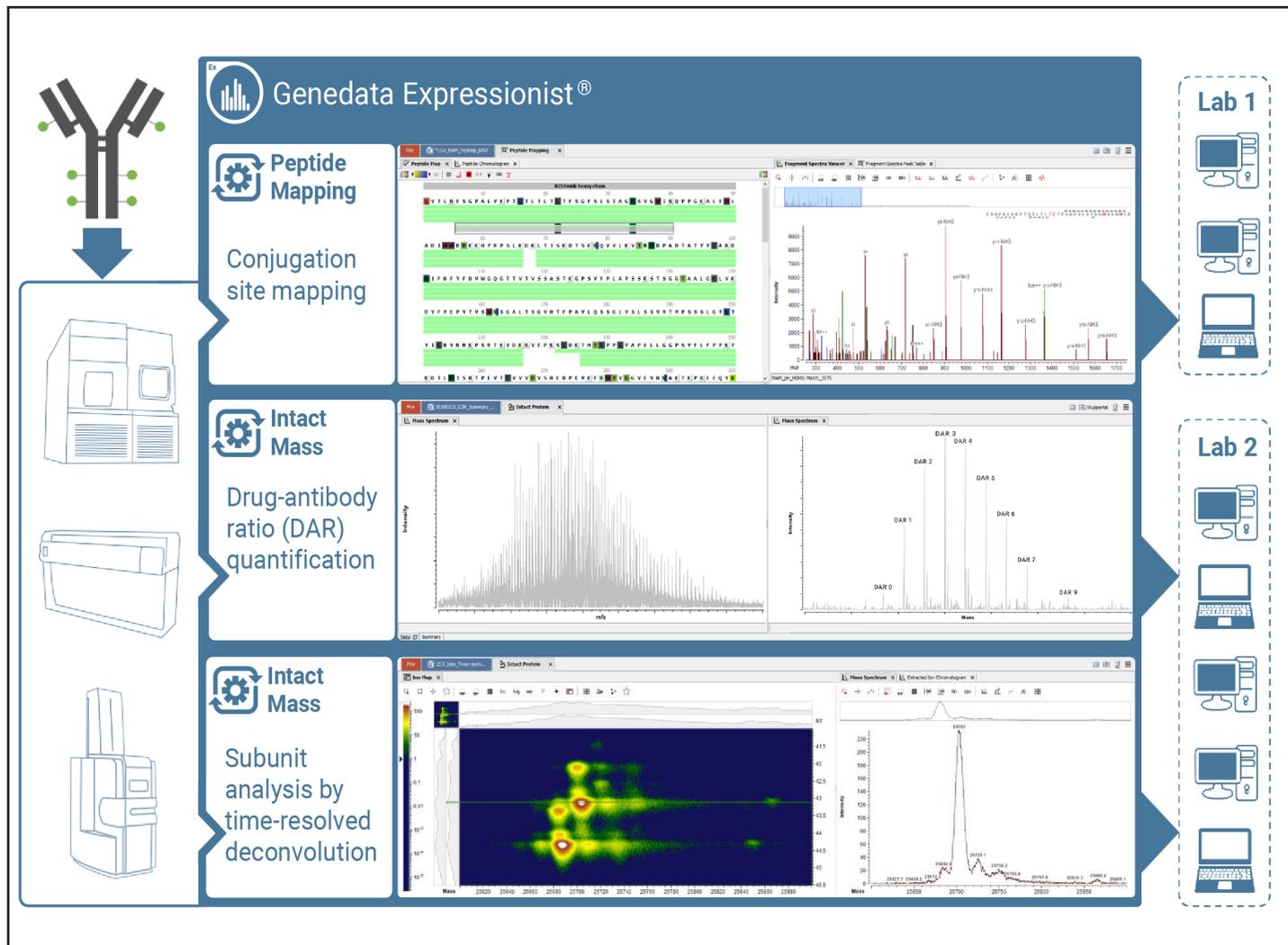


Figure 3: Genedata Expressionist offers a single platform for any MS-based analysis of biotherapeutics such as antibody-drug conjugates (ADCs).

Summary

Working with Genedata allows us to benefit from more than 20 years' experience in implementing configurable off-the-shelf biopharma data processing enterprise solutions for leading biopharma organizations. The high level of expertise and support provided by Genedata enabled us to design and apply best-in-class, end-to-end MS analysis strategies addressing our specific needs. Automated data analysis workflows for a range of applications and biotherapeutic formats were implemented within a very short timeframe. The flexibility and open architecture of the platform enables us to deliver highly individualized reports that accelerate and facilitate decision-making. The streamlining and automation of data processing provided by Genedata Expressionist enables us to keep pace with growing demands for MS-based analyses. This means that as our scientific and business needs evolve, we can be confident that we will be able to quickly adapt and continue to provide high-quality results to our internal customers in a timely manner.

Outlook

We are working together with Genedata to implement MS-based assays within a GxP framework. The enterprise nature of Genedata Expressionist and its ability to create "locked down" processing workflows enables us to streamline standard operating procedures (SOPs) and propagate them to colleagues working at other locations. The flexibility of the platform enables us to incorporate custom-designed system suitability tests (SSTs) for automated monitoring of instrument performance.



The Analytical Development laboratory at Bayer Pharmaceuticals in Wuppertal.

"We especially appreciated the high level of expertise and support provided by Genedata, which enabled us to optimize every stage of our analytical processes—while incorporating industry best practices—and quickly generate high-quality results."
"Automated data processing and report generation provide remarkable time-savings in all our MS-based biopharmaceutical characterization applications." Juliet Padden

About Genedata Expressionist

As a comprehensive software solution for transforming raw data from any mass spectrometry instrument into insights, Genedata Expressionist offers built-in functionalities that serve all MS applications for biopharmaceutical characterization, proteomics, and metabolomics in a single enterprise platform. Custom-built workflows address specific data processing, analysis, and reporting needs and enable harmonization and standardization between and across organizations. Complete automation, unbiased data interrogation with best-in-class algorithms and cutting-edge statistics, and intuitive visualizations deliver high-quality results with significant time and cost savings. Integrated data and project management enables organizations to streamline methods and efficiently manage data, results, and reports.

Genedata Expressionist is part of the Genedata Biopharma Platform for capturing, organizing, integrating, processing, and analyzing data to increase enterprise-wide productivity and R&D process efficiency.

To learn more about Genedata Expressionist and other customer case studies, visit www.genedata.com/products/expressionist

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Genedata transforms data into insights with innovative software solutions that support large-scale, experimental processes in life science research, and delivers enterprise solutions that streamline R&D workflows and improve research productivity.

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