BIOVIA

3DEXPERIENCE®

FROM COMPLIANCE BACKLOG TO PROACTIVE CONTROL

HOW THERMO FISHER SCIENTIFIC TRANSFORMED CPV REPORTING WITH BIOVIA DISCOVERANT

Use Case

DASSAULT SYSTEMES

Challenge:
Manual, labor-intensive data processes resulting in backlog of regulatory reports

Solution:
BIOVIA Discoverant for automated, faster and accurate Continued Process Verification (CPV) reports and Annual Product Reviews (APR)

Results:

- **100% On-Time Reporting at Most Sites:** Previously overdue reports are now current
- **14 Sites Live:** Deployment has scaled successfully across the network
- **746 Registered Users:** A growing community of active data users
- **50+ Data Sources:** Connecting diverse systems into a single source of truth
- **237 Products Configured:** Handling complex hierarchies across biologics and small molecules
- **1–3 FTE Reduction:** Creating CPV reports
- **~ 4,000 FTE Hours Saved Annually:** During equipment monitoring

CUSTOMER: A CDMO LEADER IN THE PHARMACEUTICAL INDUSTRY

Thermo Fisher Scientific is the world leader in the CDMO pharmaceutical industry, operating at the forefront of life sciences. With a vast network of manufacturing sites and a diverse portfolio ranging from small molecules and biologics to viral vectors and oral solid doses, the company's operational scale is immense. In an industry where regulatory compliance and product quality are non-negotiable, the ability to monitor manufacturing processes with precision and speed is a critical competitive differentiator.

As manufacturing complexity grew, Thermo Fisher Scientific recognized the need to transition from reactive data compilation to proactive, automated process control to ensure operational excellence and maintain their leadership position.

By implementing BIOVIA Discoverant, the company not only resolved its compliance reporting backlog but also established a new paradigm of data-driven process intelligence, achieving measurable gains in efficiency and operational control.

CHALLENGE: OVERDUE REPORTS AND INACCESSIBLE DATA

With a large and diverse product portfolio, Thermo Fisher Scientific's manufacturing division was struggling with the immense burden of generating Continued Process Verification (CPV) reports and Annual Product Reviews (APRs). The reliance on manual data aggregation using tools like Excel and Minitab was unsustainable. This process was not only labor-intensive and prone to error, but it also created a critical compliance bottleneck.

The consequences were significant. At some sites, the backlog grew to over 30 overdue reports, posing a serious compliance risk and straining valuable scientific resources. The manual effort required to produce these reports was immense; one assessment revealed that staffing for weekly CPV reporting at a single site would have required an additional 20 full-time employees (FTEs). Furthermore, critical process data remained siloed in disparate systems, hindering proactive analysis and forcing teams into a reactive troubleshooting cycle. A more automated, unified, and compliant solution was necessary to support strategic growth.

THE SOLUTION: BIOVIA DISCOVERANT - AUTOMATED, VALIDATED, AND SECURE

Thermo Fisher Scientific selected Discoverant to centralize data aggregation and automate reporting. A key factor in this decision was Discoverant's on-premise architecture, which aligned with Thermo Fisher Scientific's stringent cybersecurity policies by allowing direct, secure connectivity to internal data systems without exposing them to external networks. Discoverant stood out as the only solution capable of providing comprehensive data aggregation, contextualization, and analysis wrapped in full 21 CFR Part 11 compliance.

Secure Connectivity and Validation

Discoverant's on-premise hosting capability ensured data remained within Thermo Fisher Scientific's secure network, satisfying cybersecurity requirements. The system connected to approximately 50 different data sources—including ERP, Shop Floor Automation, IPC Testing, and LIMS—allowing for seamless data aggregation without compromising security. This allowed Thermo Fisher Scientific to create 237 product process maps across 14 sites, building end-to-end process genealogies from raw materials through to final packaging. Today, the system supports 746 registered users, providing widespread access to validated data.

> "The fact that it is validated is one of the biggest reasons why Thermo Fisher Scientific chose Discoverant. There is simply just no other solution out there that does all of this that can be wrapped in 21CFR Part 11 compliance. The control charts, the validation, and the automation are a huge win."
>
> — Sam Watson
> Senior Manager Data Engineering Data Architecture

Automated Process Monitoring

Most importantly, Discoverant provides a fully validated environment compliant with 21 CFR Part 11 regulations. This out-of-the-box compliance, combined with powerful statistical tools and automated control charting, equipped Thermo Fisher Scientific with a scalable and defensible solution for process monitoring and reporting. Discoverant allowed them to build data sets for thousands of parameters and instantly generate control charts, assessing them for out-of-spec or out-of-trend data.

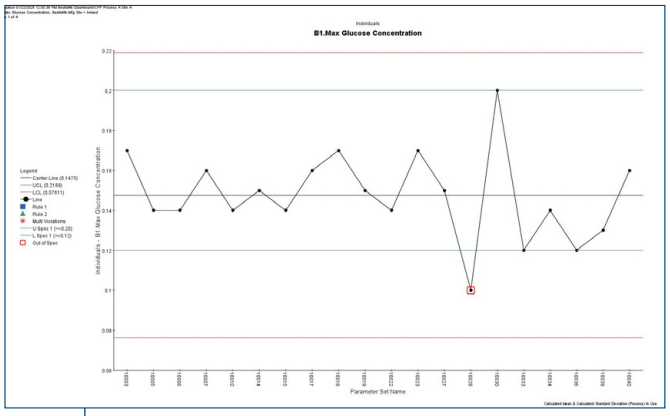

Figure 1: Automated control charts monitoring Critical Process Parameters (CPPs) of biologics manufacturing

End-to-End Genealogy

A critical feature for their biologics and viral vector workflows was Discoverant's genealogical power. The platform enabled the team to build 145 process maps for products tracing all the way from raw materials to the finished therapeutic. For their gel manufacturing site, the process is identical, so one process map captured 45 product families. This provided a holistic view of the manufacturing process that manual tools simply could not replicate.

RESULTS: MEASURABLE GAINS IN COMPLIANCE, EFFICIENCY, AND INSIGHT

The deployment of Discoverant has yielded significant operational improvements, driving efficiency, compliance, and cost savings across the organization.

On-Time Compliance Reporting

Sites with ~30 overdue reports successfully reduced that number near zero, bringing all CPV and APR reporting into full compliance.

Massive Gains in Operational Efficiency

The automation of report generation saved 1000's of hours, eliminating the need for 20 additional FTEs at a single high-frequency reporting site.

Enhanced Data Democratization

With 746 registered users, scientists and engineers are now empowered to perform their own ad-hoc analyses, drastically reducing the time spent waiting for data retrieval and accelerating the pace of investigation.

Time and cost savings

1–3 FTE reduction for CPV and approximately 4,000 FTE hours saved annually for equipment monitoring, with overall impact dependent on the number of reports, batches, and products per site.

Thermo Fisher Scientific's partnership with BIOVIA has transformed their approach to reporting. By moving away from reactive, manual reporting to a validated, automated environment, they have secured regulatory compliance and unlocked significant operational efficiencies.

Looking ahead, Thermo Fisher Scientific is expanding the scope of Discoverant. The company plans to move the deployment to the AWS cloud to leverage data lakes and is exploring the integration of artificial intelligence (AI) with Large Language Models (LLMs) to further automate the summarization of complex report outputs.

Most importantly, they are shifting their focus from pure reporting to proactive Statistical Process Control (SPC), utilizing daily monitoring to prevent batch loss and improve "Right First Time" metrics.

CONCLUSION

Thermo Fisher Scientific's adoption of Discoverant illustrates a successful digital transformation journey. By automating manual processes and unifying data within a validated framework, the organization eliminated significant compliance risks, unlocked substantial operational efficiencies, and empowered its scientific teams with direct access to actionable data. This foundation enables Thermo Fisher Scientific to not only meet today's regulatory demands but also to drive future innovation and operational excellence in a competitive global market.

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