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# The QC Lab of the Future

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## How Biogen optimized the Laboratory Asset Management Process

As more companies seek to modernize operations, it goes without saying that they are taking another look at existing practices. In 2015, Biogen's QC leadership developed a "Lab of the Future" vision for its laboratory operations with a goal to streamline and significantly automate the company's laboratory asset lifecycle management process. The first step entailed conducting an evaluation of its laboratory equipment processes for validation, associated status tracking, inspection audit preparedness and change impact assessment management.

A key element of their "Lab of the Future" vision involved streamlining, simplifying and automating laboratory business processes. By optimizing the use of assets, improving right-first-time operations and increasing productivity the company would deliver quality, reliability and fast support to operations. While Biogen already relied on advanced equipment and computer-based analytical systems, many of the laboratory recordkeeping processes remained manual and paper-based. The QC leadership recognized that migrating to a well defined electronic recordkeeping process offered the potential to significantly improve cycle time, productivity and compliance assurance.

In addition, Biogen forecast an increase in QC assets over the next few years due to the introduction of new products, expansion of test methods and labs, and implementation of new equipment.

## Setting the Stage for a Future State

Driven by the "Lab of the Future" vision, a cross-site team began the process of analyzing the existing asset lifecycle management process. This clarified the challenges and, consequently, defined the key outcomes for the project:

- Conversion of the analytical instrument validation (AIV) process from paper-based to fully electronic, complete with integrated test execution and reporting
- Cross-site standardization of the asset lifecycle management process
- Cross-site standardization of the lab equipment selection process
- Reduction in "onboarding" cycle time of new assets, from order to release for use
- Central management of laboratory asset records for quick access and retrieval
- Maintenance of an easy-to-use, real-time register of all global lab assets
- Real-time visibility into validation, periodic review status and other records by management for all global assets
- Minimization of potential data integrity issues
- Minimization of downtime for laboratory assets related to asset lifecycle management activities
- Elimination of nonvalue-added process activities such as manual review and approval, redundant validation documents, redundant review and approvals, paper-based test execution, records archival and status reporting
- Improved productivity by reduction in laboratory resource efforts associated with asset lifecycle management
- Improvement of laboratory asset change control and change impact management

Biogen already used the Kneat Gx electronic platform across all sites to manage facilities, utilities and equipment validation, cleaning monitoring, production equipment changeovers and integrated commissioning and qualification. The cross-site team analyzed the system against the defined key outcomes and concluded that the platform could support the goals of the project. The key features included: flexibility to configure the system to the QC lab's new optimized process; potential to fully automate the end-to-end process and documentation, including all testing activities; ability to efficiently generate template protocols and reports; and availability of real-time access, visibility and control of information across all sites and for all aspects of the global process.

The project team focused on optimizing their AIV process as much as possible before recreating it electronically in the Kneat Gx tool for an initial pilot. This entailed streamlining workflows, removing excessive content and process requirements and eliminating redundant approvals. The team also designed a common workspace structure for an asset information repository as well as asset metadata requirements for use across all labs and lab equipment.

## Success Realized Within a Short Period

A cross-functional, cross-site team completed the effective global planning and mapping of the future process, and then initiated a pilot of the new process, identifying the following critical success factors:

- Common cross-site lab asset lifecycle management process
- Common system and repository for asset records
- Elimination of manual, paper-based asset lifecycle management process steps
- System-based leveraging and reuse of previous lab validation data
- System-based standardization of lab equipment selection
- Automation of test execution and generation of final report
- Effective records storage management (no scanning or PDF storage)
- QC equipment indexing and dashboard and reports of real-time validation status
- Positive user feedback on ease of use and functionality of the system
- Verifiable process productivity and cycle time improvement data

The pilot of the configured Kneat Gx system was successfully completed in approximately two months; all stakeholders gave the green light to deploy the new system across all laboratories based on achieving the critical success factors. The team deployed the new asset lifecycle management system—setting up the system and user accounts, providing formal training, updating SOPs and moving content to the production server. They also established a help desk to provide user support and feedback, which was cited as one of the factors behind the success of the deployment.

The new AIV system process was implemented in February 2017. The system went from pilot to release for use within six weeks and was considered a resounding success as it met all the key objectives, delivering the anticipated benefits in productivity, efficiency, compliance and data integrity.

Only three months in operation is insufficient time to fully quantify actual savings from the asset lifecycle management system and process. High-level comparisons between the before and after process, however, demonstrate significant improvements from which the company estimates that:

- Productivity (more work completed with same resources) will improve by 100%
- Cycle times (end-to-end work completion time) will be reduced by 50%

During the planning process, the cross-site team had forecast an increase in lab asset lifecycle management workload due to the addition of new products, test methods, labs and equipment. In actuality, the new system allows the company to efficiently deal with the increased workload without additional resource cost and without project delays.

One example of significant productivity improvements observed is the number of validation documents being processed. The average number of lab validation documents processed between 2014 and 2016 was 160 per year; the number of validation documents processed using the new system reached 170 within its first three months. This increase can be attributed to system functionality that provides for parallel processing and dynamic data-sharing of common information across validation documents, including real-time generation of the validation summary report.

Creating a highly productive, simplified, cross-site standardization of the QC lab asset lifecycle management process was a major outcome of the company's efforts. The transformation covered all aspects of the process from equipment selection through onboarding, validation, change, periodic review and revalidation generating a number of business benefits:

- Global standardization of the laboratory asset lifecycle management process
- Simplified protocol generation, review, preapproval
- Simplified and paperless protocol execution and discrepancy management
- Simplified protocol post-execution review and approval
- Elimination of manually handling, managing, and storing documentation and the many steps to process it
- Fewer deviations, more right first time operations, greater GDP and ensured data integrity
- Improved audit preparedness
- Improved metrics visibility on all aspects of the process
- Improved information access to equipment index, dashboards and records with full visibility from any location
- Standardized protocol and report templates
- Faster onboarding and start of use cycle time of new assets
- Dynamic data-sharing across documents and automatic generation of validation summary reports

### Users Very Positive about New System

Another critical success factor involved feedback from users. All in all, user comments were universally positive. Lab staff were immediately impressed with the new system, finding that the globally standardized templates made it easy to use overall and, specifically, easier and quicker to create, review, approve, execute and close out validation documents.

The QC director also appreciates how the system provides global metrics on all systems, eliminating the need for spreadsheets. Senior leadership continues to be impressed with the streamlined nature of the system and how it fits Biogen's vision of the Lab of the Future.

### Conclusion

All stakeholders—from QC leadership to management, from lab staff to equipment vendors—remain happy with the significant improvements and the project team is delighted to have successfully delivered another piece of the Lab of the Future plan.

Optimization and standardization of the QC lab process has added significant value, enabling users to be both compliant and more productive in their daily efforts, providing efficient generation and comprehensive visibility of lab asset status information and all records, improving compliance assurance and audit readiness, and enabling faster onboarding of new equipment and shorter "release-for-use" cycle time.

[The authors wish to recognize Gretchen LaPan as a special key project contributor. She was the AIV Manager who provided leadership and support at the time of project execution.]

## About the Authors

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