

**CLIENT
PROFILE:****BIOGEN****Improving the Efficiency of Development
Translational Medicine at Biogen**

Biogen Idec (NASDAQ:BIIB) is the world's oldest independent biotechnology company. Biogen discovers, develops and delivers innovative therapies for the treatment of neurodegenerative diseases, hemophilia and autoimmune disorders. The Development Translational Medicine team at Biogen uses imaging and a wide variety of cutting edge technologies to establish translational strategies to improve the likelihood of drug development success in neurodegenerative, inflammatory and blood diseases. For this team, the ability to quickly and efficiently validate and qualify software and equipment is paramount because it speeds up time-to-market, reduces operations cost, and helps overall product quality. The company operates in locations worldwide; the North American corporate headquarters are located in Massachusetts, USA.

CHALLENGE: Improve the process and speed of equipment qualification and software validation

The Development Translational Medicine laboratories needed to streamline the process and delivery of its equipment and software validation. To do this, they required a vendor who could provide the right implementation methodology, had extensive knowledge of the life sciences industry, and an automated technology solution for validation that could seamlessly integrate into Biogen's complex delivery lifecycle. This included risk assessments, gathering user and functional requirements, generating plans, protocols and test scripts, tracking validation document approvals, and conducting the validation

testing. Lastly, the solution called for a vendor highly capable of adapting to frequent changes in timeline, understanding new equipment, and interacting with existing bio-analytical software (such as LightCycler, Analyst and Softmax Pro) at an expert level.

"Finding a partner that could handle the heavy lifting with minimal oversight was absolutely necessary for us."

— Eric David,
Director, Development Translational Medicine

SOLUTION: An integrated technology approach to lifecycle management

Biogen turned to Compliance Associates, a vendor with over 25 years of life science industry experience and a successful track record as an agile validation services provider. As the creators of Validator, they were confident Compliance Associates would be able to provide unparalleled technology expertise.

"We had the added benefit of working alongside the creators of the software. The product was so responsive to our needs that it was like having a custom tool built to fit the matrix of our business."

— Alexia Pico,
Supervisor, Development Translational Medicine

BIOGEN HAD IDENTIFIED TWO MAIN PROJECT OBJECTIVES:

- 1) Speed up the end to end validation lifecycle by expanding the use of Validator software

The web-based reporting interface allowed secure log in and instant access to critical data from any location; a key functionality for a global organization. Biogen was able to effectively streamline their process and delivery by implementing one end-to-end solution for its software and equipment validation.

- 2) Outsource all equipment and software validations to one vendor

Compliance Associates proposed a clear plan to perform both equipment qualification and software validation - from planning to execution to reporting. This included working closely with the Development Translational Medicine group onsite to complete validations for two to four pieces of new equipment and software per month while providing quarterly progress reports. The solution was thorough. Compliance

Associates provided expert knowledge and aptitude from start to finish, including:

- Capturing user and functional requirements, and producing documentation for new equipment and software
- Performing risk assessments
- Scheduling rounds of testing and dry runs
- Completing approvals using Validator

A critical component of the solution was the ability to work efficiently around tight schedules, with the flexibility to accommodate frequent changes to the timeline and scaling resource requirements. Compliance Associates was able to address the client's objectives using standard best practices and

proven methodologies without ever losing their focus on customer service.

With the confidence that high quality work was consistently being delivered on time and on budget, Biogen's internal resources could eliminate management costs and concentrate on their core business.

"We appreciate that they communicate and troubleshoot with our metrology team, SME's, scientists and IT personnel using their extensive knowledge of our business, our processes and our systems"

— Eric David,
Director, Development Translational Medicine at Biogen

IMPACT: A streamlined, cost effective validation process

Over the course of their 3 year partnership, Compliance Associates' Validator has helped Biogen qualify 2-3 pieces of equipment and software per month, in addition to a streamlined process and significant cost reduction.

A SMOOTHER, MORE COMPLETE VALIDATION AND QUALIFICATION PROCESS

Beyond the efficiency gains, the Development Translational Medicine group was also impressed with the easy functionality and accessibility of Validator. The seamless integration of the software into the validation lifecycle made it easier to route documents, send electronic signatures, automate steps in the validation process and track approvals with minimal effort.

"Validator is invaluable to us. With it, we have a far more efficient process overall".

DELIVERING COST-EFFECTIVE RESULTS

The partnership with Compliance Associates helped Biogen maintain a smaller core validations group, providing them with a cost-effective quality solution to meet their needs. Like many companies in the life sciences industry, Biogen had limited validation resources in-house. Without the cost-effective outsourced-vendor model provided by Compliance Associates, the Development Translational Medicine group at Biogen would simply not have been able to meet the demands and requirements of validation and qualification.

"Compliance Associates have consistently helped us accomplish our goals, delivering on timelines and handling a large amount of equipment qualifications and software validations every year".