

**CLIENT
PROFILE:**

APOTEX

Canadian pharmaceutical company
serving a global healthcare market

Apotex Inc. was founded in 1974, and is the largest Canadian-owned pharmaceutical company, employing 7,500 people in research, development, manufacturing and distribution facilities world-wide. Based in Toronto, Ontario the company's pharmaceuticals can be found in virtually every pharmacy and healthcare facility in Canada and are exported to over 115 countries around the globe.

CHALLENGE: Improve and automate the validation lifecycle

The Systems Qualification & Compliance team at Apotex was looking for a computer system validation solution that was paperless, electronic and automated. Their existing process was paper-based and slowing the process of getting approvals, testing execution, and routing documents for signatures. For global organizations like Apotex, sending documents between globally disparate locations is costly and time consuming. Validating the many types of software used in the pharmaceutical industry requires a lot of dedicated resources – a challenge facing many organizations in the global life sciences industry.

Apotex Inc. began to search for an experienced software validation partner who could implement an automated system that would enhance and streamline the existing

robust and mature paper-based validation process. This included collection of user requirements, creation of all validation deliverables including validation plan, test plan, test procedures, traceability matrices, summary reports and document index. The requirement to workflow and electronically sign the deliverables electronically and globally was also crucial to significantly reduce the amount of time, and in-house resources needed to complete validation projects.

“We understood that implementing better technology would help us perform validation with greater ease, speed and efficiency.”

— *Esra Guven, Principal Consultant for the Systems Qualification & Compliance group.*

SOLUTION: Implementing a more efficient validation process using existing technology.

Compliance Associates offered a complete solution to help Apotex Inc. overcome their validation challenges.

Upon evaluation of the Compliance Associates validation software “Validator” an industry leading automated validation software Apotex determined that Validator met over 90% of their required functionality right off the shelf. It was also determined that the remaining functionality needed to meet the other Apotex-specific validation process tasks and activities could be fulfilled during the implementation and configuration of Validator.

In the first phase of the project Compliance Associates installed Validator at The Apotex facility in Ontario, Canada. The strategy for implementation was to install the system at a central location and allow other Apotex facilities around the globe to access the software over the internet. The software architecture of Validator facilitates this strategy as

it is a truly web-enabled application. The first phase of the project also had the Compliance Associates team working with Apotex to configure the Apotex specific validation templates and deliverables as well as the organization validation strategy. Configuration of the aforementioned items would allow for a standard and streamline approach to future projects across the organization. Comprehensive training manuals to train new users of the system were created by Apotex project team leads. The team also performed rounds of user- acceptance testing and led user-training sessions to ensure trouble free transition to the automated process.

“It was critical that we learn to use the system to its fullest potential and to understand the complete capabilities of the software”

— *Esra Guven, Principal Consultant for the Systems Qualification & Compliance group.*

The team at Compliance Associates worked closely with the Systems Qualification & Compliance group to educate them on the functionality of the Validator software and streamline the migration from their existing paper-based process.

During implementation, Validator was partially customized to meet specific requirements and requests outlined by Apotex. The software was customized to include design and functionality enhancements, such as application display options, workflow features, and custom configurations.

“The Systems Qualification & Compliance group gave input into how we wanted the system to work. The communication with Compliance Associates was open and they really understood the challenges we were facing in the industry.”

*— Esra Guven, Principal Consultant
for the Systems Qualification & Compliance group.*

The solution would include a service support component that would provide assistance after the launch of the Validator system. The product experts were available to resolve issues, offer additional training and best practice guides, and perform ongoing upgrades to the system as required. For example additional functionality sought by Apotex or feedback for required issues when fixes were required as a consequence of testing Apotex specific development.

After the implementation phase mentioned above the integration of Validator into Apotex's day-to-day validation process and methodology was complete. Through the diligent work of the Compliance Associates and Apotex project team, the software was successfully implemented, fully operational, and validated. Compliance Associates facilitated the validation of Validator by providing a comprehensive validation package. The validation package streamlined the implementation effort and allowed for quicker access to the technology in the production environment.

IMPACT: Using better technology for better results

Apotex's experience in working with Compliance Associates consultants and the Validator software has been very positive. Apotex describes Compliance Associates as a vendor that understood the unique challenges of their business and provided a technology solution that effectively automated their validation process, ultimately saving the company time and money.

THE KEY BUSINESS BENEFITS INCLUDE:

- A streamlined migration to a paperless automated solution
- Lower cost associated with Validation project execution, better use of resources as validation specialists can focus on the science versus the administrative activities typically associated with a paper process
- Easy, configurable / customizable business workflows for performing validations

- Dependable and ongoing customer support
- Standard approach to every validation project and project type
- Built-in enforcement of business rules and standards
- Complete traceability from Requirements to Test Plan to Test Procedures to Results to incidents
- True content management system allowing for quick creation and repurposing of data and or documents
- Centralized validation documentation for all systems
- Collaboration on projects across the enterprise over the internet

“Validator is helping us complete validation projects better than before”

*— Alok Varshney, Manager of the
Systems Qualification & Compliance group.*