Compliance Associates

CASE STUDY

CLIENT PROFILE:

KIK CUSTOM PRODUCTS

One of North America's largest contract and private label manufacturers of consumer, institutional and industrial products

KIK Custom Products was founded in 1995 in Concord, Ontario as a producer of private label bleach products for small Canadian retailers. After going public in 2002 and two key acquisitions in 2005, KIK made the move into contract manufacturing for national brands, expanding their manufacturing capabilities to include personal care, salon, pharmaceuticals, pool additives, household and industrial cleaning products and medical device products. Through these acquisitions, KIK has been able to build on a successful legacy as a contract manufacturer that spans more than 50 years. Today, KIK Custom Products has over 3,000 employees and operates 17 manufacturing facilities strategically located in 14 different sites throughout Canada and the United States. The Company is now owned by Caxton-Iseman (KCP), L.P. and Caxton-Iseman (KCP) II, L.P., through an acquisition of all the assets of KCP Income Fund in May 2007.

CHALLENGE: Improve and automate the validation process to facilitate the implementation of business enabling technologies (LIMS, ECM)

Manufacturers like KIK use many types of software throughout their organizations, all of which must be validated in order to meet regulations set forth by then Food and Drug Administration (FDA) and Health Canada. A common challenge among these organizations is that validation requires a significant commitment of both financial and human resources. KIK's existing process was paper-based, slowing the process of getting approvals of key deliverables, testing execution, and routing documents for signatures. As a result, sending documents between its 17 manufacturing facilities and offices dispersed throughout Canada and the United States was costly and time consuming.

The IT Team and Quality Group at KIK were looking for a software package capable of automating the validation lifecycle. This was key as KIK had embarked on a major enterprise initiative to select, acquire and implement a new Laboratory Management System (LIMS) as well as a corporate Document Management system (DCM). KIK envisioned that to be successful in this endeavour they needed a partner with extensive industry expertise in all aspects of the business, including validation. The main objectives of the project were to select, implement and validate the right technology to meet the complex business and regulatory requirements of the laboratories and manufacturing areas. Additionally the chosen technologies were to be implemented simultaneously across multiple sites adopting best practices.

KIK began to search for a partner with a proven track record that could best meet their needs with a project of this magnitude. After considering several options, KIK found that Compliance Associates and their Validator software was the most suitable choice. Key to their decision was Compliance Associates industry recognised experience with LIMS, DCMs and the success of the Validator software in the life science industry. Time and efficiency were of the essence given the scope and timelines dictated by this initiative. To ensure adherence to the time constraints Compliance Associates initially provided KIK with a hosted model of the Validator software and later migrated them to an in-house setup. Compliance Associates also provided KIK with the necessary validation libraries, adding another dimension of efficiency as these are complete validation packages that can be used with minor revisions required. Comprehensive validation libraries for industries key systems are a unique and complementary offering to the Validator software. This strategy allowed KIK to commence project activities immediately.

Services provided by Compliance Associates for this engagement included collection of user requirements, evaluation of requirements against industry leading technologies, management of the implementation, and validation. Validation was performed using Validator to facilitate 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 critical in reducing the amount of time and in-house resources needed to complete validation projects.

"Compliance Associates helped us to understand that our existing software would not drive the necessary compliance requirements. They provided advice on what software would best fit our needs and get our systems into a validated state."

— Ilona Zadykowicz, Quality Assurance Manager

SOLUTION: Update existing software to optimize regulatory infrastructure

Compliance Associates (CA) offered a complete solution to help KIK overcome their implementation and validation challenges. Subsequent to extensive analysis by all project participants (CA, KIK, and IBM), the recommendation was to upgrade the existing LIMS system as it was not adequate in terms of driving the sought after compliance requirements dictated by KIK's evolving business strategies. The new LIMs system needed to support all aspects of KIK`s modern manufacturing operations from R&D to process testing, including data and workflow tracking, smart data exchange, and enterprise resource planning capabilities. The selected document management system had to span of the document lifecycle from inception to archiving, allowing for efficient organization of regulatory data.

Given Compliance Associates' extensive expertise with regulatory compliance requirements, and the systematic approach of the project team to arriving at a conclusion; KIK readily accepted the software recommendations, deciding to replace current software with Thermo Scientific`s LIMS system and implement a best-in-class document management system-NextDocs. Both of these software systems were selected based on the alignment between their key features and KIK`s compliance needs.

Upon software selection, the project team (KIK, Compliance Associates and Thermo Scientific) began implementation of the new systems using a rapid implementation approach and Validator, CA's innovative validation software that would optimize new regulatory infrastructure, so that KIK would be able to focus more time on core business activities. Implementation was carried out simultaneously with staggered go-live dates; NextDocs within the first year and LIMS a few months after. Typically, implementations of this nature suffer from extensive delays due to scope creep, inadequate technologies, or lacking resource commitment. It is not rare to see timelines of several years for similar projects. The chosen technologies, the project team and the automated validation approach worked in unison towards a successful implementation in record time

"Validator takes a systematic approach to the process of validation. With no ambiguities in the process audits are easy to defend and information is easily accessible."

— Han Duong, Director of Information Systems

Throughout the implementation process Compliance Associates worked closely with the IT Team and Quality Group to prepare documentation for validation and deliver validation reports to ensure expected results were consistently met. Validator was instrumental in facilitating these activities.

IMPACT: Streamlining the validation lifecycle for increased efficiency

KIK has had a very positive experience in working with Compliance Associates and the Validator software. KIK describes Compliance Associates as a highly responsive and knowledgeable vendor with extensive experience in the implementation of new technologies and the validation space, crediting Validator as a key asset in streamlining their validation process. When validation projects are efficient, implementation of new technologies or processes are not dependent on validation timelines.

THE KEY VALIDATOR BUSINESS BENEFITS INCLUDE:

- Seamless shift to an automated, paperless validation solution
- Easily accessible and organized storage of validation documents decreasing the time required to complete validation projects
- More efficient use of resources, leaving more time to focus on core business activities versus tedious administrative tasks associated with paper-based validation or other electronic validation systems.
- Electronic execution of audits and assessments, workflows and signatures all accessible via the internet
- Consistent and reliable customer support throughout the implementation process
- Collaboration across multiple sites.
- Expert advice and support on Validation requirements as needed

In addition, working with Compliance Associates we identified best practices which were provided to all team members to ensure use of LIMS and NextDocs run smoothly for future projects and all internal and external regulatory requirements are met.

"We had a great working relationship with Compliance Associates. They were responsive and supportive throughout the entire process – from consultation to implementation."

— Ilona Zadykowicz, Quality Assurance Manager