

The challenging world of **compliance**

Life sciences companies face an increasing level of compliance challenges and pressures as the complex web of regulations continues to multiply. How can an enterprise-wide approach to compliance help address these challenges? By **Kevin O’Leary**, QUMAS

Historically, organisations have treated compliance as independent silos scattered across businesses, functions and operations around the globe. The cost of compliance, and the exposure risk, grows with each new regulation. Instead of treating compliance as a series of silos that vary by department or stage in the product lifecycle, savvy life sciences companies are looking to build a sustainable, repeatable and cost-effective compliance system. An enterprise-wide approach allows them to integrate all their processes critical to regulatory compliance such as change control, audit, and customer complaints, with the tracking and management of their business and quality issues.

Separating regulatory and compliance issues

As the number of regulators and regulations increase, not only must companies deal with the traditional pharmaceutical issues around GMP or cGxP, they must also address the world of corporate governance and financial compliance as well as sales and marketing compliance within the same framework. Forward-thinking companies are taking a holistic view of compliance and risk to the extent of appointing a new role – Chief Compliance Officer – to oversee this approach. They are also applying a closed-loop approach to their compliance requirements across systems and functions to mitigate any compliance gaps.

Staying ahead of changing regulations

Our business was founded on providing a compliance-ready (from Day 1) product suite that is coded and validated against key regulations such as 21 CFR Part.11. We constantly monitor and assess evolving regulations, and of course, work with our clients to enhance the functionalities to their requirements.

Compliance and R&D

Preparing for a drug application is a complex and time-consuming process. In this

sphere, time is money – especially when you consider the profit window before patents expire. In their efforts to automate manual compliance processes, our customers have struggled with integrating and managing all the solution components they need to achieve their business goals. The QUMAS R&D Suite was developed to expedite the new drug application process with better quality submissions, and shortened review and approval cycles.

It is the first in a series of bundled solutions, which offer an integrated approach and one-stop solution with a services and support model to



Kevin O’Leary: “Forward-thinking companies are taking a holistic view of compliance and risk”

companies. We’ve essentially gone out and selected the best-in-breed components of a complete R&D strategy as listed below:

- A regulatory content management system
- A submissions management system for assembling and compiling compliant paper and electronic dossiers, based on the CTD standard
- Browser-based collaborative review and authoring solution

- eCTD authoring templates to simplify the process of automating and formatting guidance-compliance documents
- Bulk document loader used to import and export large collections of documents or file folders

We’ve then integrated these various components, so that they are optimised to work together, and to provide immediate value upon deployment. Finally, we’ve included the critical services and implementation accelerators such as test scripts and validation templates to ensure that clients can not only realise substantial savings, but also dramatically expedite their overall submissions process. ■

Kevin O’Leary has been with QUMAS since its inception and was responsible for the original design and development of the company’s first product release. Kevin has worked within regulated industries since 1987 and has extensive knowledge of regulatory compliance solutions. He established the company’s presence in the United States in 1997 and now serves as the company’s Chief Executive Officer and Chief Strategy Officer. Having originally majored in computer science, Kevin pursued further studies in industrial management and now works closely with regulators and industry organisations to ensure that QUMAS solutions meet the compliance needs of regulated companies.