Understanding Compliance: Moving from Cost to Value

Throughout the life sciences sector, the key trends of globalisation and digitalisation are providing new opportunities for growth and innovation. However, within development facilities, quality assurance, lab systems and scientific teams are feeling the impact of these transformations. Especially as their endeavors to ensure high levels of compliance meet the growing regulatory pressure within the industry.

With an increasingly digital and connected lab infrastructure, failing to navigate the challenges of global regulatory requirements can be costly. As such, any compliance and validation processes must be designed to meet the needs of multiple geographies, business activities, and functions.

Taking action to identify, analyse, and reduce compliance risks requires a high level of resource and expertise. However, in a fast-paced, scientific environment, researchers are already stretched thin. This brings an added risk of slowing down productivity in even the best-run laboratories if compliance is not strategically managed.

To overcome these challenges, lab managers are increasingly turning to external partners who have expertise in qualification, requalification, risk management, and remediation. By transforming their compliance processes, scientists are then free to concentrate on research and discovery and meet the evolving demands of a more digital and connected lab.

Here, we speak with Joshua McWilliams, Product Manager, GxP Validation Services at PerkinElmer Inc., to learn more about the rising need in the pharma industry for compliance expertise and support.

Hi Josh, before we dive into compliance best practices can you tell us more about how your role drives and inspires you?

Sure. I lead the GxP Validation Service team as part of PerkinElmer's OneSource strategic services group. I'm inspired by how we collaborate closely with our clients so we can determine their unique needs and help them further their science while creating or maintaining safe and compliant processes.

For me, it's exciting to see first-hand how trends and global drivers play out in the lab and affect compliance. For example, in the late 90s to early 2000s, we saw an exciting shift towards digitising labs. However, this more online route came with new challenges and required a different level of validation. As more labs move towards advanced digitalisation and cloud-based data management, they need to look at compliance in a more collaborative and connected way and share information securely and accurately.

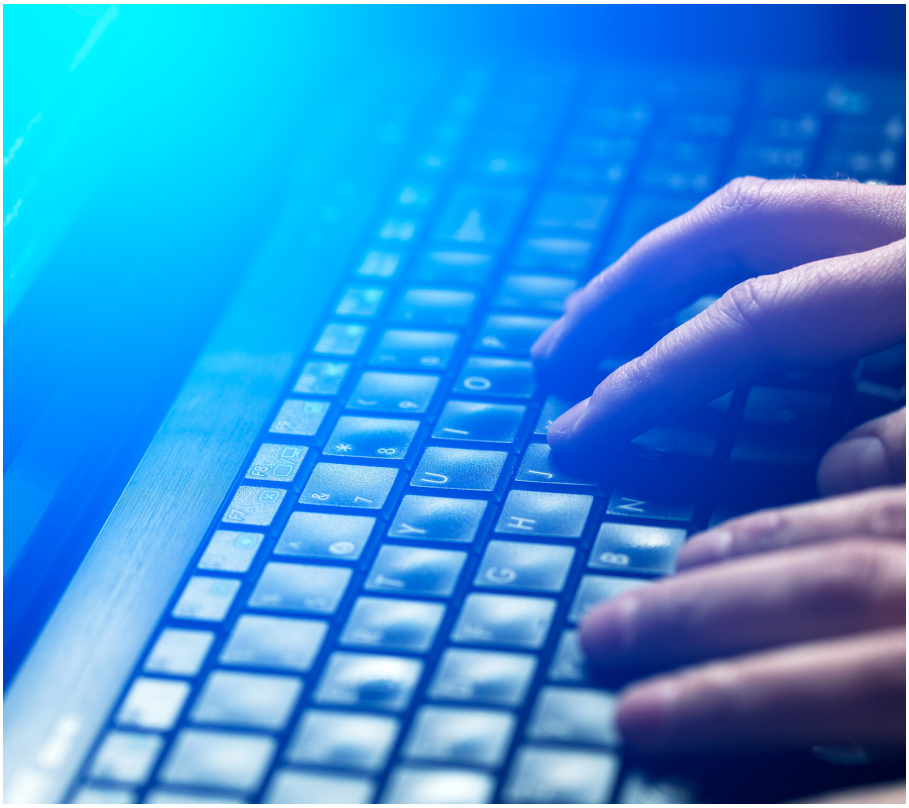
Lab managers and scientists are experts in their field but finding dedicated compliance expertise in-house can be a real challenge. I started my career as a bench chemist, so I know all too well how difficult it can be to manage your own time in the lab let alone handle compliance needs. This direct insight allows me to help labs define the difficult and non-core compliance tasks that are getting in the way of their vital research and key scientific tasks.

Ultimately, the biggest driver for me and my team is to give time back to science, so researchers and lab professionals can focus on discovering better therapeutic candidates vs. getting bogged down in compliance execution and monitoring.

What do you consider to be the top best practice approach for compliance or a framework to work from?

Industry best practice involves following a risk-based approach for patient safety and quality. We work to GAMP 5 guidelines, which build in quality checks throughout the entire production process and enable us to meet the unique needs of a company and particularly its computerised systems.

The first step is creating a comprehensive requirements document, which includes how a



system is supposed to operate and its intended uses. A validation plan can then be drawn up that should outline the strategy – which policies and procedures will be followed, any functional configuration specifications and design specifications as needed.

Lab instrument qualification historically would have meant simply purchasing, installing and bringing the new piece of equipment into service. Today's regulatory requirements mean that planning and development should occur before purchase to ensure the instrument is fit-for-purpose. After which, qualification continues with Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ). This isn't just a question of verifying the vendor's hardware and software qualifications. Everything should be checked against the requirements document for its specific use at the manufacturing site. Documents such as standard operating procedures also need to be created, and staff must be trained to follow them for all instrument usage, including administration and calibration as well as operation.

Ideally, validated instrumentation needs to be maintained across multiple sites and lab spaces by a team of specialised on-site validation experts. Here, a multivendor approach can save precious lab time, by harmonising protocols under a single Universal Operational Qualification framework. Allowing lab managers to streamline processes across all major models of laboratory instrumentation and scientists to concentrate on research and discovery.

Nowadays, regulators are probing how data is generated, reported, archived, and retrieved. Therefore, data integrity should play an essential role throughout the validation process. For example, regulations such as FDA 21 CFR Part 11 must be built into the requirements, to ensure the security of electronic records. Data relating to formulations, clinical trials and any other sensitive areas must be tightly controlled.

Compliance is a continual process: thorough documentation must be kept day-to-day to provide evidence that the policies and procedures set out in the validation plan are being carried out to meet the validation requirements. Centralised monitoring and continual improvements enable labs to pursue science with integrity and help keep staff and lab inspection ready.

When it comes to the conversation around compliance pressures in the modern-day pharma lab, where are the gaps in people's knowledge and understanding?

Within labs, there is often a lack of deep compliance knowledge. Although lab teams will be trained on compliance steps for individual instruments and tasks, they may not have a wider knowledge of compliance systems and processes as well as trends or new regulations that are evolving. There is also a challenge for facility IT teams, who may not have a real-time or full understanding of the specific compliance needs within highly regulated industries like pharma or food. Labs that don't have the expertise or procedures in place to prove their increasingly connected data is accurate and their instruments are fit-for-purpose may risk non-compliance which slows their R&D cycles.

These knowledge gaps are compounded as teams are unable to fully understand the benefits that investing in rigorous validation methodology can bring. Our OneSource validation and compliance team utilises industry best practices, keeping up with changing regulations on a daily basis. One recent trend we see is the regulatory focus on data integrity. However, accurate and reliable data has always been the foundation of successful basic research, it just takes on different meanings and needs around security, sharing and validation in cloud-based environments.

What are the key challenges labs face when navigating today's compliance environment?

One of the biggest challenges is ensuring that lab efficiency does not suffer at the hands of compliance. Events such as the purchase of new equipment, company acquisitions, relocations, and audit findings can all contribute to increased validation needs and workloads and need to be proactively vs. reactively factored in. Plus, the increased focus on Computer Systems Validation (CSV) and data integrity is driving a need for larger validation budgets and resources.

Like data integrity, CSV is a broad concept that affects virtually every dimension of pre-clinical research and drug discovery. Departments such as IT will be needed to help with the configurations, permissions, and necessary settings. Without a dedicated validation team, general lab or IT resources may not have the appropriate skill set or bandwidth and can become overwhelmed. Furthermore, as the industry looks to adopt new digital tools and innovations like eValidation, staying current with the latest software versions may require additional validation to be completed.

It's important to understand the impact that updates can have on your validated systems. As such, it's clear that CSV is an ongoing process, not a one-time activity. It will extend all the way through to the eventual decommissioning of the given instrument or application. Its time-consuming nature may require outsourcing and expert assistance to keep the process on track.

How can strategic approaches to outsourcing help support labs looking to meet their compliance demands while also enabling scientific innovation?

While compliance endeavours can seem daunting, they are ultimately critical to the scientific integrity of the pharmaceutical industry and, down the line, to the safety and well-being of patients. Companies can achieve the most effective regulatory defensible position for computerised instrument and analysis systems using a standardised delivery framework. This requires compliance and scientific expertise.

By partnering with a third-party expert, lab teams can receive unbiased recommendations from specialists that engage with the needs and demands of regulatory compliance all day, every day.

Integrating successful validation and QC procedures into the lab results in more streamlined and efficient workflows. Furthermore, external solutions help put both data integrity and the closely associated CSV on sustainable trajectories.

Lab managers may want to avoid investing more in-house or with a compliance service provider, but the costs of non-compliance are often much greater. Strategically partnering with an expert supplier can be more cost-effective and enables labs to stay focused on their core R&D activities.

From your point of view, what do you think the future of compliance looks like for pharma and life science labs?

I think we'll continue to see the trend of incorporating digital tools for cloud-based data capture, visualisation and sharing that is part of Pharma 4.0, as well as further validation of enterprise systems versus stand-alone equipment. Labs are starting to move data to the cloud, and with that comes the regulatory focus on validating to intended use and following a risk-based management approach.

I'm also expecting to see an increasing number of companies choosing strategic partnerships to understand and overcome the latest compliance needs and challenges. External service providers can leverage learnings and insight from across the industry. As such, they can help streamline lab workflows and boost scientific productivity with data integrity assessment and methods to establish quality control procedures that support reliable research data. With an experienced partner, you're not just getting the resource to do the work. You're also getting the breadth of experience across all professional services to support you through the continued digital revolution.

Josh McWilliams

Josh McWilliams is GxP Validation Services Product Manager for PerkinElmer's OneSource strategic services and has 25 years of experience working in the pharma industry. Josh currently oversees the development of the OneSource GxP Validation Services product roadmap, as well as product innovation and oversight, including; Stand-alone and Enterprise Computer Systems Validations, Data Integrity projects, Method Validation, Process Validation and CQV. Before joining OneSource, Josh developed his skills and experience working as a senior scientist at Watson Laboratories and as a validation specialist at PPD.