

Data Integrity is at the Heart of Laboratory Compliance



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"Prove It," Regulators Say

Walter Deming, the legendary physicist and management consultant, once described research this way: "Uncertainty makes research predictable, but you still need proof to satisfy everyone else¹." In one sentence, Deming perfectly describes why compliance management in government regulated industries is now so dependent upon metrology, or the science of measurement. When it comes to manufacturing products that can affect public health, scientists need to prove the integrity of their data or risk having their laboratories cited - or even shut down.

Thanks to evolving and oftentimes complex guidelines at global regulatory agencies such as the U.S. Food and Drug Administration (FDA), the UK's Medicines and Healthcare Products Regulatory Agency (MHRA), and the European Medicines Agency (EMA), analytical laboratories are encountering a whole new regulatory mindset during the audit process.

In recent years for instance, the FDA reviewed thousands of analytical reports, conducted hundreds of on-site inspections, and took action against more than 200 out-of-compliance companies for a variety of reasons². According to one industry expert, the preparations that labs have traditionally taken in preparing for these audits are no longer adequate. The focus is increasingly shifting beyond the validation of procedures, instruments, and personnel training and towards the integrity of data. The "who," "what," "when," and "where" of that data's development, throughout its lifecycle, are increasingly important indicators to regulators of potential fraud or insufficient system management practices³.

Defining "Current"

If general audit preparation seems a bit intimidating, things can certainly become even more complicated if FDA inspectors believe a lab is out of Current Good Manufacturing Practices (cGMP) compliance. In many respects, good compliance actually all starts with the "c" in cGMP. The FDA says it stands for 'current' and requires companies "to use technologies and systems that are up-to-date in order to comply with the regulations⁴." As we know, what was state-of-the-art only a few years ago may now be inadequate by today's standards. There are differing interpretations of what "current" really means and there are no definitive resources available to settle the inevitable disputes⁵.

Events and information recorded on paper vs electronically generated data and information are a perfect example. Over the past few years, regulatory agencies have determined that electronic data is more secure and less likely to be manipulated when tracking the lifecycle of products and processes. On the other hand, it may be simpler to print out chromatograms to paper, but these are no longer considered by the FDA as a "true copy" or "exact and complete" record of the entire electronic raw data, since it does not capture all the required raw data and metadata⁶.

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Data Integrity Steps Into the Spotlight

In a continuing effort to refine and improve, 'new' guidance comes to the rescue. In April 2016, the FDA issued 'Data Integrity and Compliance With cGMP Guidance for Industry'⁷, a Q/A style document that provides deeper insight into FDA thinking and depicts the growing importance of Data Integrity in the industry. According to a supplemental document⁸, 21 out of the 28 warning letters issued between January 2015 and May 2016 involved data security lapses in drug manufacturing. From the guidance itself, 'In recent years, FDA has increasingly observed cGMP violations involving data integrity during 39 cGMP inspections. These data integrity-related cGMP violations have led to numerous regulatory actions, including warning letters, import alerts, and consent decrees.'

While appropriate and necessary, remediation from such an event is likely to be costly, time consuming and have significant impact on productivity and morale. As per the guidance the FDA encourages companies to demonstrate that problems have been effectively remedied by:

- Hiring a third party auditor,
- Determining the scope of the problem,
- Implementing a corrective action plan (globally), and
- Removing at all levels individuals responsible for problems from cGMP positions⁹.

So What's My Problem?

The problem for companies right now is:

- The ability to move fast enough. How to keep pace with ever advancing compliance regulations?
- How to manage and contain the cost for compliance?
- Who has the global capability to staff across all labs?
- In a space fraught with complexity of systems, how do you understand the specific needs of the lab to arrive at the right solution?

There is no question that managing Data Integrity associated with IT platforms is enormous and the complexity of the problem encourages industry to adopt a wait-and-see approach. This reactive approach typically results in:

- Inefficiency – costly time and resources spent on Corrective Action Preventative Action (CAPA) and temporary fixes
- An inability to plan – companies are so busy with remediation, they cannot address their environment holistically
- Needing to regularly expend precious resources on emergency or high priority situations - always having to perform in Firefighter mode.

Transformation through Managed Services and Strategic Partnership

It is possible to turn the situation around through a mature, effective Managed Service program that is tailored to the needs of an organization. A PerkinElmer Managed Service engagement will bring:

- Experienced teams – necessary to avoid the wasted time and effort through Trial and Error scenarios
- A Mature Platform Operating Model – an established business process model means rapid results through proven methodologies
- Effective Program Execution – PerkinElmer has successfully worked with many large clients across the industry on transformational initiatives

The Managed Services programs at PerkinElmer are founded on established methodologies to deliver proven results and the programs are built upon the principles of Lean Six Sigma, Change Execution Management (CEM), Information Technology Infrastructure Library (ITIL) and Capability Maturity Model Integration (CMMI).

At the outset of an engagement, PerkinElmer employs a proven assessment process which looks at all dimensions of an organization resulting in a Compliance Strategy and Action Plan that puts an organization on the path to compliance confidence. All aspects of the organization are examined from technical considerations such as the complexity of shared accounts in a shared development process and how they relate to 21 Code of Federal Regulations (CFR) Part 11, to business processes such as how Data Integrity is governed, a notable callout in the Medicines and Healthcare products Regulatory Agency (MHRA) Draft Guidance¹⁰.

Adopting a Risk-based Approach to Compliance

Industry leaders are no longer leaving compliance to chance. Increasingly, they are turning to companies such as PerkinElmer OneSource Laboratory Services to lead the way. While some companies offer pieces of the solution, PerkinElmer stands alone in their ability to offer a mature, comprehensive solution that works across all of your vendor applications, which includes:

- Computer System Validation based on 21 CFR Part 11 and Good Automated Manufacturing Practice, v5 (GAMP5)
- Fully-automated qualifications for temperature mapping and dissolution
- Harmonized Instrument/Technology agnostic protocols through our Universal Operational Qualification (UOQ) product
- Performing instrument repair and calibration services
- Maintaining efficiency and effectiveness of lab applications
- Developing traditional protocols
- Conducting expert training
- Providing turnkey services that enhance scientific workflows all the while implementing high quality compliance practices and processes.

In the lab, it might be as simple as introducing electronic recordkeeping, automatically affixing data time stamps, or validating analytical instruments, computer systems, and software¹¹. On the enterprise level it could also lead the way to a more productive and profitable approach to doing business. This requires the adoption of a global, comprehensive risk-based approach to compliance that builds quality into procedures and products rather than “inspect” them in later. Successful laboratories with strong Quality and Compliance programs continually operate with confidence under “inspection readiness”.

As the world of drug development and manufacturing becomes more complex, it raises new challenges in the oversight process involving such variables as personnel, practices, treatments, and geographic dispersion. With the expertise of OneSource, companies are deploying proven solutions to mitigate and prevent risk as they streamline their compliance strategy and approach to be in line with global guidance. Staff scientists no longer need to tinker with hardware, software, or validation procedures in hopes of remaining compliant. That is part of the OneSource solution. It is based on centralized monitoring activities and continuous improvement processes that allow scientists to do what they do best – pursue science with integrity¹².

The Solution: An Effective, Global Program for Managing Data Integrity

Getting ahead of the problem is the only solution and working with PerkinElmer's OneSource Laboratory Services team delivers results. The right investment in a proactive solution means:

- Improved Compliance - Correct issue before they arise during inspection
- Stabilized costs – Know what you're spending, avoid costly, ballooning remediation scenarios
- Plan your resources – Exercise control over your staff's time spent on compliance.

Working with OneSource as a partner, our experts can assess an environment, develop a strategy and plan to respond, implement and manage the necessities of compliance.

PerkinElmer will be the difference in your organization.

Contact them today for a consultation at www.perkinelmer.com/onesource.

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To learn more about the complete portfolio of OneSource Laboratory Services please visit www.perkinelmer.com/OneSource

To schedule a consultation for your laboratory contact PerkinElmer OneSource Laboratory Services at www.perkinelmer.com/onesource/contact or call 1.800.762.4000

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