PROPHARMA GROUP®

Improving Patient Health and Safety

# A Guide for Efficacious Data Integrity During COVID-19

In a recent conversation, an MHRA inspector explained: "Now that we are dealing with the COVID-19 pandemic, data integrity (DI) is even more important than it ever has been before in the pharmaceutical industry." DI issues can cause business-critical problems including unsafe products and damaged reputation.

With the current COVID-19 pandemic creating schedule delays, interrupting supply chains, and reducing margins, it's more important than ever that companies are able to trust their data for better quality decision making.

This whitepaper will define DI, outline which steps to take to find and address DI gaps, as well as explain the important role company culture plays in ensuring systems and processes are compliant.

## Addressing Data Integrity Through Culture

The inspector explained that when assessing a company, he has a feel for the organization's data integrity maturity level within the first five minutes. In that short amount of time, he can determine whether this company is able to deal with upscaling or changing processes in a compliant way, or if they are not able to do this and will struggle to survive.

As he starts, the inspector is not looking for procedures or batch records, nor for orphan labels, signatures or other typical documentation. Instead, he talks with the people at the site. He asks if people enjoy their job, if there is adequate communication between departments, and if there is time enough to do their job. And most importantly, he asks if their managers treat them with respect.

This story underlines the importance of company culture. The culture is key in dealing with the changes required by the COVID-19 situation. During these times of fast adjustments and on-the-fly decision-making, we get to know our real culture and processes. How well have you been able to deal with the changes and how quickly were you back in control of all your data? Have your ways of data handling changed since the beginning of the crisis? This tells you exactly how well your culture is dealing with data integrity.

In March 2018, the MHRA released guidance on DI and culture

Data integrity is the overall accuracy, completeness, and consistency (validity) of data over its lifecycle. In March 2018, the MHRA released a guidance on DI in which company culture and behavior are foundational pillars. It is the role of senior management to drive this culture, not only by establishing performance indicators and quality objectives, but most importantly by leading by example.

Data integrity should start at senior management, but it is everyone's responsibility. We have seen many catch-22 situations, where team members say, "We need time and orders from management to improve data integrity," while senior management says, "We hired you to do your job." DI is a way of working, a reasoning which everyone in a pharmaceutical company should follow. While operators may have a more detailed level of knowledge, all team members – from analysts to managers to IT staff – should understand and follow the organization's DI processes.

Culture and behavior are not the only pillars. Systems and processes should be designed to facilitate compliance with the principles of DI and act as enablers of the desired behavior and, ultimately, data integrity. This includes access control, accessibility of records at certain locations, provision of a work environment that permits performance of the tasks, reconciliation of controlled printouts, and sufficient training.

# Tips to Identify and Address DI Gaps

During our DI training, we cover thinking critically about one's work and daily routines. Questions such as, "Can I throw away handwritten notes?" or "Should we buy a shredder?" that seem easy to answer, will be placed in the context of processes and systems. We teach teams to develop objective-analysis and problem-solving skills related to the data involved in their daily work.

These four basic questions are an excellent starting point for this:

1. What is the process which generates data?
2. Is the data generated from this process raw data?
3. What quality decisions do you (or someone on your team) make with this data, if any?
4. Are you still able to reconstruct the process in five years?

To know whether you have treated your data correctly, we use the acronym "ALCOA" to provide a framework for important next questions to ask:

## A: Attributable

- Do you know who created the data, on paper and in systems? Do you have a personal login on the system? Do you capture audit trails?

## L: Legible

- Can you read your data all the time? Do ink and labels fade away? Can you still read data after a major system upgrade?

## C: Contemporaneous

- Do you write down your data immediately after the action? What do you do when a system fails and writing on paper is the only option left? What do you do when you hand over material to another department, but there is nobody to receive the material?

## O: Original

- When is your data raw data (ie, original)? Can you make a printout of your computer system? Is your data your first recording? Can you store a scan of a printed paper? What do you do with the calculation you did on a scrap paper?

## A: Accurate

- How many decimals are required? Do you consider all measurements? Does your machine measure accurately enough? How do you know?

By applying the four basic questions and ALCOA, you will better understand how you need to treat your data. However, employees often encounter practical hindrances to applying ALCOA properly, including: “We do not have enough space to add the calculation to a batch record”; “The system does not have specific user access”; “We need extra storage space”; etc.

Rome was not built in one day, nor is a data integrity culture. In times like the current COVID-19 pandemic, when we have to react quickly, we are able to discover vulnerabilities: How are we dealing with our data? What processes need to be adjusted to optimize as much as we can? The organizations that can best manage these changes are the ones with the best likelihood for success.

# A Guide for a Successful DI Journey

In addition to the above steps to find the gaps and the ALCOA principle, read the International Society for Pharmaceutical Engineering (ISPE) guideline on DI. It is a valuable resource. You will read about the three pillars of DI: governance & management; cultural & behavioral; and technical & procedural. These pillars will help prepare and set up a proper DI approach in 2 phases:

1. Phase 1:
   a. Develop sponsorship and stakeholder management
   b. Assess “good DI practice” at shop floor level (spot checks)
   c. Assess IT systems and procedures for DI
   d. Train employees in DI
   e. Develop a DI policy
2. Phase 2:
   a. Develop a formal governance structure
   b. Develop training for specific interest groups, such as managers and IT
   c. Extend the spot check program to other departments and integrate with other programs, such as audits and lean 5S
   d. Develop and execute a risk-based remediation program for IT systems
   e. Develop and execute a program for process and data mapping. Again, the ISPE guide is a valuable resource

## Conclusion

Yes, the road to a good data integrity practice could be lengthy and bumpy, but with these tips you will prepare yourself to set up the correct structure through improving culture, addressing the gaps, and preventing reputation damage, unsafe products, and unnecessary costs. If you need support on any of this, please feel free to contact us. And keep in mind, the MHRA inspector’s first steps are asking employees to:

- Think critically about the data and ALCOA and determine if they are well trained
- Explain the support they get from management
- Know exactly how systems support DI
- Know about quality and patient risk in their daily work

From

**Ir. Emmie Heeren**, Managing Consultant / **Marc Stegeman MSc**, Principal Consultant

## Data Integrity Expertise

ProPharma Group provides the data governance, lifecycle, and management expertise needed to ensure you are ready for inspections at any moment. We help companies develop and implement a robust DI framework to maintain control of the full lifecycle of data.

With our knowledgeable team of DI experts and successfully proven programs and solutions, we provide world-wide audits and/or gap assessments to quantify your strengths and identify areas of improvement.

## Improving Patient Health and Safety. **At Every Step.**

From early concept development through each clinical phase, product launch, and commercialization, we partner with pharmaceutical, biotechnology, and medical device clients to tackle complex challenges. We help to ensure regulatory expectations are met, business goals are achieved, and patient health and safety is improved.

Our team of experts brings a comprehensive portfolio of regulatory and compliance solutions to help solve complex challenges in a dynamic regulatory environment. With our mission to improve the health and safety of patients, we are focused on delivering the highest quality of services throughout the full product lifecycle.

Contact ProPharma Group today for a complete assessment and options to ensure your data's integrity.

www.ProPharmaGroup.com

Info@ProPharmaGroup.com

PROPHARMA GROUP®

Improving Patient Health and Safety