



DATA INTEGRITY IN PHARMA WHY IT MATTERS AND HOW TO IMPROVE IT

First published by Pharmaceutical Technology.

Maintaining exceptional data integrity is essential for the smooth running of an organization, particularly in the pharmaceutical sector. Ensuring the accuracy and consistency of datasets as they are produced, processed and published not only guarantees an efficient internal process, but also keeps companies on the right side of the law when it comes to data integrity in pharma.

Since 2010, when the U.S. Food and Drug Administration (FDA) incorporated data integrity into its primary inspection objectives, the number of data integrity warning letters issued in the pharma industry has increased substantially. A higher level of scrutiny will no doubt lead to more errors being detected, but nearly a decade later many companies still struggle to comply with these regulations.

NSF International conducted extensive research into this issue, reviewing 154 warning letters issued between 2005 and 2017.

The company found incomplete and missing records to be the key culprit, cited in 67% of the letters. This was followed by incidences of access control deficiencies, which clocked in at 32%, and reintegration, reprocessing and inappropriate manual integration, cited in 39% of the letters.

NSF has now identified four key factors leading to these kinds of breaches and how to overcome them.

FOUR CAUSES OF DATA INTEGRITY ISSUES IN PHARMA

IGNORANCE AND DISENGAGEMENT

Pharmaceutical employees can often fail to understand the importance of systems set out to maintain data integrity. They therefore feel disengaged from the process and fall into a pattern of mindless box ticking and failing to thoroughly assess whether or not data integrity has been maintained.

As a result, it's vital for staff training sessions on data integrity to highlight the consequences, should the FDA find that data integrity has not been maintained. This can range from a formal warning to criminal prosecution and ought not to be taken lightly.

COMPANY CULTURE

Data integrity lapses can also occur as a result of poor corporate morale. A company culture where employees feel unable to come forward and admit their mistakes can often lead to an increase in errors made. If colleagues feel pressured to generate perfect data documents this can, ironically, lead to data integrity issues as they disregard factors such as authenticity, accuracy and timeliness in favor of surface-level record keeping.

This can be mitigated through a working environment of openness and transparency. Logistical errors which could lead to data integrity breaches ought to be addressed as opportunities for learning and improvement, rather than punishment.

HUMAN ERROR

The human element, of course, can be hard to overcome. Even the most diligent employees can offer only the best they can with the resources they have available. Stress, fatigue and distraction can all lead to errors and thus data integrity issues.



The best way to work around this is to once more encourage a positive working environment, where employees feel valued both as members of an organization and as human beings. Happy workers will consistently deliver higher standards, not only in terms of data integrity but in all areas.

INEFFICIENT SYSTEMS

Finally, it's important to note that needlessly complex data integrity systems will magnify the risk of problems in this area. Standard operating procedures should be simple and easy to navigate so that they remain fit for purpose yet avoid falling into the trap of implementing any well-intentioned shortcuts which could allow data integrity breaches to slip through the net.

This is a delicate balance for any pharmaceutical company to strike and will be quite unique to each organization. As such, it is important senior staff members take the time to ensure their systems of data integrity are at once rigorous and efficient, to ensure high standards across the board.

NSF International has pulled together a brief questionnaire which pharmaceutical employees can complete on behalf of their companies to assess their own data integrity compliance. Employees should [use it to see where and how NSF can be of help in supporting their enterprise.](#)



Watch this video from NSF integrity expert and ex-MHRA Inspector [Rachel Carmichael](#) where she takes a high-level look at why data integrity matters so much.

ABOUT RACHEL CARMICHAEL



Rachel has over 20 years' experience of pharmaceutical manufacture, control and quality management including nearly 11 years as a GMDP Inspector for the UK Competent Authority, the MHRA. This includes serving as the lead inspector representative within the MHRA for the transition from the Medicines Act to the Human Medicines Regulation, SI 2012 1916. Ms.

Carmichael is eligible to act as a Qualified Person under the provisions of EU Directives and is a member of the Royal Society of Biology. She has wide-ranging experience of inspecting against European Good Distribution Practice and Good Manufacturing Practice requirements in the UK, China, India and the U.S. to meet the associated quality standards for medicines (non-sterile and aseptic production, including radio pharmaceuticals) and the blood industry.

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Cite as: NSF International. October 2019. Data Integrity in Pharma: Why It Matters and How to Improve It. NSF: York, UK.

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