



WHY AREN'T ENOUGH PEOPLE TALKING ABOUT DATA INTEGRITY FOR IVDS?

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Whether as a sophisticated test to identify cancer markers or a cost-effective method of detecting malaria in a low or middle-income country, in-vitro diagnostic devices (IVDs) are an essential component of making a diagnosis and choosing a safe and effective treatment. They represent a key platform in the delivery of health care and disease prevention globally.

An often-overlooked issue with these important products is data integrity. Many misconceptions are held, especially by IVD manufacturers who have often missed the ongoing scrutiny of premarket assessment for CE marking. The new EU IVD Regulation 2017/746 emphasizes comprehensive and competent notified body premarket assessment that will require approximately 80% of all IVDs to be CE marked. It will also require notified bodies to carry out annual inspections of manufacturing sites. The quality and integrity of your technical data is what will bring conformity. Many IVD manufacturing sites and technical files will be facing tough scrutiny for the first time – so make sure the culture of quality is strong, and your data is attributable, legible, contemporaneous, original and accurate.



DEFINITION OF DATA INTEGRITY AND THE ALCOA PRINCIPLES

According to the WHO, “Data integrity is the degree to which data are complete, consistent, accurate, trustworthy and reliable and that these characteristics of the data are maintained throughout the data lifecycle. The data should be collected and maintained in a secure manner, such that they are attributable, legible, contemporaneously recorded, original or a true copy and accurate.”¹

ALCOA is the commonly used acronym for “attributable, legible, contemporaneous, original and accurate.”

The ALCOA principles have been acknowledged as fundamental for maintaining data integrity. Implicit in these principles is the need that data are also complete, consistent, enduring and available.

Here are some common attitudes to data integrity. Fact or myth? What do you think?

Q1) Data integrity refers to falsified data in the pharma industry.

When we talk about data integrity, people tend to think about falsified data associated with the pharma industry. This of course is a criminal activity, but it is not the only way in which data integrity can be compromised. Data integrity is more frequently inadvertently breached in day-to-day activities. So, the statement is true, but the issue is not exclusive to the pharma industry or to the falsification of data.

Q2) Data integrity is a new requirement.

False. Data integrity is a requirement of the quality management system standard ISO 13485. Section 4.2.5 describes the need to have records that remain legible, identifiable and retrievable. Likewise, similar emphasis is placed on documents in Section 4.2.4.

¹ Fiftieth report of the WHO Expert Committee on specifications for pharmaceutical preparations. Annex 5 Guidance on good data and record management practices (WHO technical report series; no. 996 annex 5) ISBN 978 92 4 120996 0

Q3) *Data integrity issues are found primarily in certain jurisdictions.*

False. Intentional and accidental breaches to data integrity are discovered internationally. Incidents in high-income countries are reported by every regulator, for all types of products assessed, and in every country inspected.

WHAT DO I NEED TO DO TO MAINTAIN DATA INTEGRITY?

According to the WHO guidance, *"Assuring data integrity requires appropriate quality and risk management systems, including adherence to sound scientific principles and good documentation practices."*

As with many quality practices, it is important that senior management are engaged and ensure that an effective data management system is in place. Data integrity principles apply throughout the whole product lifecycle, impacting both paper and electronic records. It is normal to think that strong scientific principles will ensure data integrity, but these also are insufficient. The onus falls again on senior management to create a culture of quality that embraces the ALCOA principles.

Data integrity is a very important part of doing business, and the most important step is getting ready NOW. Be aware, do what is required and remain vigilant!

ABOUT THE AUTHORS



Robyn Meurant has more than 30 years of experience in the field of IVDs, as a laboratory scientist and as a regulator with the Australian Therapeutic Goods Administration (TGA) and with World Health Organization (WHO) Prequalification. Ms. Meurant began her career working in several large diagnostic laboratories in the role of senior scientist. In her position at TGA, Ms. Meurant assisted in developing the new regulatory framework for IVDs. With WHO, she served as the lead technical officer for application evaluation and dossier assessment, and as lead for the development of guidance and technical specifications for IVDs in the scope of WHO Prequalification. In addition, she has contributed to standards development and has been a source of expert advice to the Australian government on IVDs. In 2009 she was awarded the Distinguished Service Award by the Australian Society for Microbiology.



Howard Broadbridge has more than 35 years of experience in the medical device industry, covering a range of specialties including pharma, surgical instruments, surgical gloves, operating microscopes, primary care, patient monitoring, ECG/defibrillation, endoscopy and ophthalmology. His roles have been in international sales, marketing and general management. Prior to entering regulatory and quality consultancy, Mr. Broadbridge served as Vice President of Strategic Marketing at Optos plc, a manufacturer of innovative, ultra-widefield retinal imaging devices. In addition to sales and marketing, Mr. Broadbridge has extensive experience of product development, having led several multi-functional development teams in diverse companies such as Johnson & Johnson and Welch Allyn. He also played a key role in the expansion of powder-free surgical gloves in major world markets, including the USA, Japan and Australia.

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