Quality – Data Integrity

Your Objectives:

At the end of this lesson, you should be able to use and know how to follow the ALCOA standard.

Firstly, watch this four-minute video: https://www.youtube.com/watch?v=PFO-SUmRnRM

What follows will shed some light on what lies behind ALCOA and on why the concept has gained recognition.

What is ALCOA?

The English mnemonic* ALCOA has been around since the 1990s and has now come to be invariably synonymous with data integrity. The principle behind it is used by GxP-regulated industries as a framework for ensuring data integrity and is therefore key to **good documentation practice** (GDP). ALCOA describes the requirements related to the integrity of data. In recent years, the term "data integrity" has received increased attention in GxP-regulated environments. Data integrity is equally critical for manufacturers, 'Notified Bodies', in Europe, (or 'Approved Bodies') as well as auditors.

*ALCOA refers to the following five characteristics:

- **Attributable**: An action can be ascribed to a person or a system.
- **Legible**: The legibility must be permanent
- **Contemporaneous**: The data is generated when it is created.
- **Original**: The storage takes place in original form or as a certified copy (true copy).
- **Accurate** (correct): The data must be error free and must not be subsequently edited unless changes are properly documented: omissions must be crossed out with a single line, and must include signature, date and written explanation from the original author).

What does 'data integrity' mean?

The British Medicines and Healthcare products Regulatory Agency (MHRA) defines data integrity as the extent to which data is complete, consistent, accurate, trustworthy and reliable. In addition, data integrity means that the attributes (listed above) are retained throughout the

entire data lifecycle, i.e. from its generation to final selling, deletion. According to the MHRA, the data should be collected and stored in a secure manner so that it is assignable, legible, timely, original (or in the form of a certified copy) and correct. To ensure this, adequate quality and risk management systems, including adherence to sound scientific principles and good documentation practices, are necessary.

This content (ALCOA) is by no means unknown. The ALCOA principle has been used for more than 20 years by regulated industries as part of good documentation practice (GDP). Various regulations, such as those stated in the Drug and Drug Manufacturing Ordinance (AMWHV), also includes requirements for the integrity and handling of (digitally) stored data. However, the term only achieved a certain “cult status” when the MHRA summarised the requirements in 2016 with the publication of the “GxP Data Integrity Definitions and Guidance for Industry” under the term “data integrity”. As a result, a number of guidelines, such as the “Data Integrity and Compliance with cGMP Guidance for Industry” (FDA, Draft 2016) and the “GAMP Guide: Records & Data Integrity” (ISPE, 2017), were published within a very short time.