

ALCOA++ History:

ALCOA stands for five key principles of data integrity: **Attributable, Legible, Contemporaneous, Original and Accurate**. It was introduced by the US FDA in the 1990s to help evaluate data quality especially in regulated fields like pharmaceuticals. **ALCOA+** expands the original ALCOA principles to cover broader data integrity needs. It was formally introduced in the European Medicines Agency's (EMA) 2010 reflection paper on electronic source data. This added four new principles—**Complete, Consistent, Enduring and Available** to the original five: **Attributable, Legible, Contemporaneous, Original and Accurate**

In 2023, European regulators further expanded ALCOA+ **to ALCOA++** by adding **"traceable"** as the tenth principle. This ensures audit trails and complete data lineage in electronic systems, addressing modern data integrity needs. The change was formalized in the EMA's 2023 guideline on computerized systems in clinical trials in chapter 4. Principles and definition of key concepts – 4.5. ALCOA++ principles. ALCOA++ principles are now the universally accepted standard, offering clear and legally binding definitions for all ten elements of data integrity.