

Data Integrity in Pharmaceutical Manufacturing: ALCOA+ Principles, Regulatory Expectations and Strategies for Effective Data Governance

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Abstract

Data integrity is a fundamental component of pharmaceutical quality systems because product quality, patient safety and regulatory decisions depend on reliable and trustworthy data. Digital transformation has expanded the use of computerized systems, laboratory information management systems, electronic batch records, cloud platforms, process analytical technology and artificial intelligence in pharmaceutical development and manufacturing. These technologies improve traceability and efficiency but also create new risks related to unauthorized access, inappropriate data modification, incomplete metadata, inadequate audit trails, system validation and cyber-security. The ALCOA+ framework—Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring and Available—provides a practical basis for evaluating data integrity across the data life cycle.

This review synthesizes regulatory guidance and recent literature on data governance, computerized systems, audit trails, Industry 4.0, cloud computing, artificial intelligence and digital pharmaceutical manufacturing. Regulatory expectations from the US Food and Drug Administration (FDA), Medicines and Healthcare products Regulatory Agency (MHRA), World Health Organization (WHO), Pharmaceutical Inspection Co-operation Scheme (PIC/S) and European Union (EU) GMP are compared. Common data integrity observations and corresponding CAPA strategies are also summarized. The review concludes that effective data integrity requires an integrated quality culture supported by risk-based governance, validated computerized systems, access control, audit-trail review, secure archival, personnel training and continuous monitoring. Emerging AI-enabled and cloud-based environments will require life cycle-based governance, explainable, traceability and human oversight.

Keywords: Data integrity; ALCOA+; pharmaceutical manufacturing; GMP; data governance; audit trail; computerized systems; artificial intelligence; Industry 4.0; quality assurance.

Introduction

Pharmaceutical manufacturing is fundamentally dependent on data. Raw-material testing, process monitoring, environmental monitoring, analytical testing, batch release, stability studies, equipment qualification and quality investigations all rely on records that must be accurate and trustworthy.

Data integrity therefore represents more than a documentation requirement; it is a critical component of the pharmaceutical quality system and a direct support for patient safety.

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The digitalization of pharmaceutical operations has substantially increased the volume and complexity of data. Laboratory information management systems, chromatography data systems, manufacturing execution systems, distributed control systems, electronic batch records, cloud applications, automated equipment and advanced analytics now coexist with traditional paper records. This environment improves efficiency and traceability, but it also creates vulnerabilities such as shared accounts, inappropriate privileges, deletion or overwriting of raw data, weak audit-trail review, inadequate backup, uncontrolled spreadsheets and insufficient system validation. [1,2,4–6,15].

The US FDA states that data used to demonstrate compliance with CGMP should be reliable and accurate and recommends meaningful, effective and risk-based strategies to prevent and detect data-integrity problems [1]. MHRA guidance similarly places data integrity within a broader data-governance framework and emphasizes lifecycle controls [2]. WHO and PIC/S have developed guidance covering good data and record management, while EU GMP Annex 11 establishes expectations for computerized systems [3-6].

The ALCOA concept has become a widely used framework for evaluating data integrity. The original principles—Attributable, Legible, Contemporaneous, Original and Accurate—are commonly extended to Complete, Consistent, Enduring and Available, forming ALCOA+. The present review integrates these principles with regulatory expectations and recent literature on digital and AI-enabled pharmaceutical manufacturing. [1–4,7].

Review Methodology

A PRISMA-style literature-search methodology was used to structure the evidence identification and screening process. Because the present article is a narrative regulatory review rather than a quantitative systematic review or meta-analysis, PRISMA was used as a transparent reporting framework rather than as a claim of formal systematic-review registration.[8,9,15]

Information Sources

Literature was searched using PubMed/MEDLINE and broad scholarly web searches, together with primary regulatory sources

from FDA, MHRA, WHO, PIC/S, the European Commission, ICH and ISPE. Searches covered publications and regulatory documents available through August 2026.[10,11,12]

Search Strategy

Representative search terms included: (“data integrity” OR ALCOA+ OR data governance) AND (pharmaceutical OR biopharmaceutical OR GMP); (audit trail AND pharmaceutical); (computerized systems AND GMP AND data integrity); (cloud computing AND pharmaceutical manufacturing); (artificial intelligence AND pharmaceutical manufacturing AND GxP); and (Industry 4.0 AND data integrity AND biopharmaceutical manufacturing). Reference lists of relevant reviews and regulatory documents were additionally screened.[13,14]

Eligibility Criteria

Included sources were peer-reviewed articles, authoritative regulatory guidance, international GMP standards and relevant technical guidance addressing pharmaceutical data integrity, computerized systems, data governance, audit trails, digital manufacturing, AI or related GxP technologies. Sources without a clear pharmaceutical, biopharmaceutical, regulatory or data-governance relevance were excluded. Foundational regulatory documents were retained regardless of publication year because they remain directly applicable to the regulatory framework.[12,14-16]

Screening and Synthesis

Titles and abstracts were screened for relevance, followed by assessment of the full text or authoritative source where available. Evidence was organized into five themes: ALCOA+ principles; data lifecycle and governance; computerized-system and audit-trail controls; regulatory expectations; and emerging digital/AI technologies. The final synthesis emphasizes regulatory consistency and practical implementation in pharmaceutical manufacturing.[17,18]

Data Integrity: Concept and Scope

Data integrity is the degree to which data are complete, consistent, accurate, reliable and trustworthy throughout their lifecycle. In a GMP environment, integrity applies to both paper and electronic records. It encompasses data creation,

processing, review, reporting, storage, archival, retrieval and destruction. Data may include raw analytical results, instrument files, manufacturing parameters, environmental monitoring results, batch records, calculations, metadata, audit trails, electronic signatures, deviations, investigations, stability records and quality-control documentation. [1–5,8,10].

Data governance provides the organizational framework through which data are controlled. It assigns ownership and responsibilities, defines criticality, establishes access and review controls, manages risks and ensures that data remain fit for intended use throughout their lifecycle. Importantly, data integrity is not solely an information-technology responsibility. QA, QC, manufacturing, engineering, validation, IT, regulatory affairs and senior management all contribute to effective governance. [2–5,19].

ALCOA+ Principles [15,18,20-22]

5. Pharmaceutical Data Lifecycle

ALCOA+ element	Meaning	Example control
Attributable	Data can be traced to the person or system responsible for generating or modifying them.	Unique user accounts, electronic signatures and controlled attribution.
Legible	Data remain readable and understandable throughout the retention period.	Permanent paper records and accessible electronic formats.
Contemporaneous	Data are recorded when the activity is performed.	Real-time recording and time-stamped electronic records.
Original	The original record or a verified true copy is retained.	Raw data plus relevant metadata.
Accurate	Data are truthful, correct and free from inappropriate manipulation.	Validated methods, controlled calculations and review.
Complete	Relevant data are retained without inappropriate omission.	Include failed, atypical and suspect results where applicable.
Consistent	Data follow logical chronological and procedural relationships.	Controlled dates, sequences and standardized processes.
Enduring	Records remain preserved for the required retention period.	Secure storage, archival and migration controls.
Available	Authorized users can retrieve data when needed.	Accessible records for review, investigation and inspection.

Pharmaceutical Data Lifecycle

Pharmaceutical Data Lifecycle

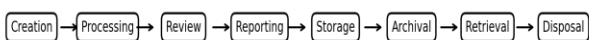


Figure 1. Data lifecycle from creation through controlled disposal.

Integrity controls should be applied throughout the lifecycle rather than only at the point of final review. At creation, validated instruments, approved procedures and trained personnel are required. During processing, calculations and transformations should remain traceable. Review should assess completeness, accuracy and relevant audit trails. Storage and archival should protect records against loss or unauthorized alteration, while retrieval should preserve readability and contextual metadata. Disposal should occur only under approved retention and destruction procedures. [1,5,23].

Data Governance and Risk Management

A mature data-governance program should define data owners, system owners, process owners and quality oversight. It should include data classification, criticality assessment, risk assessment, access management, audit-trail review, computerized-system validation, backup and recovery, change control, deviation management, CAPA, supplier oversight and periodic review. [2–5,8,9,13].

Risk-based management is particularly important because organizations generate very large quantities of data. Controls should be proportionate to data criticality, vulnerability and potential impact on product quality and patient safety. Critical analytical results used for batch release, sterility testing, environmental monitoring, stability testing and critical process parameters generally require stronger governance than non-GMP administrative information. [8,11,25].

Paper and Electronic Records

Data integrity requirements apply irrespective of media. Paper-record risks include backdating, uncontrolled forms, illegible entries, inappropriate corrections, missing signatures and use of unofficial notebooks. Corrections should preserve the original entry, identify the person making the correction, include the date where appropriate and provide a reason when required by procedure. [11,24,26].

Electronic systems introduce additional risks, including shared accounts, excessive administrator privileges, deletion or overwriting of records, disabled audit trails, inadequate

backup, uncontrolled software changes, unauthorized remote access and incomplete metadata. EU GMP Annex 11 provides a specific framework for computerized systems used in GMP environments [5].

Computerized Systems and Audit Trails

Computerized-system controls should include unique user identification, role-based access, appropriate segregation of duties, validated functionality, audit trails, electronic signatures, secure backups, recovery testing and controlled changes. System configuration should prevent users from altering or deleting records outside approved workflows. [1,5,6,13].

An audit trail should allow reconstruction of significant activities affecting electronic GMP data. Relevant information may include the user, date and time, original value, modified value and reason for change where required. Audit-trail review should be risk-based and incorporated into approved procedures. It should not be treated as a purely technical exercise; QA and process owners should understand what events are significant for product quality and data reliability. [1–5,11,13].

Research on data integrity in biopharmaceutical manufacturing has emphasized the interaction between ALCOA+, validated computerized systems, Industry 4.0, data analytics and cloud platforms [15]. A 2022 review of pharmaceutical data-integrity issues similarly identified organizational behavior, quality culture, processes and technology as interconnected causes of deficiencies [16].

Regulatory Expectations: Comparative Review[10,12,15,32,36]

Framework	Key data-integrity expectations	Primary reference
FDA	Reliable and accurate data; risk-based controls; complete CGMP records; computerized-system controls; audit trails; investigation of DI issues.	Data Integrity and Compliance With Drug CGMP Q&A [1].

MHRA	Data governance across the lifecycle; ALCOA principles; risk management; audit trails; organizational culture and oversight.	GxP Data Integrity Guidance [2].
WHO	Good data and record management; lifecycle approach; risk-based governance; appropriate controls for paper/electronic data.	WHO TRS 996, Annex 5 [3].
PIC/S	Good data management and integrity practices; risk-based controls; computerized systems; inspection-oriented expectations.	PI 041-1 [4]. [4].
EU GMP	Documentation controls and computerized-system requirements; validation; access; audit trails; signatures; backup and continuity.	EU GMP Chapter 4 and Annex 11 [5,6].

Common Data-Integrity Observations and CAPA [8,12,25,28,29]

Observation	Risk	Typical CAPA
Shared user accounts	Loss of attribution; inability to reconstruct actions.	Disable shared accounts; issue unique IDs; review access; train users; periodic access audit.

Excessive privileges	Users can modify/delete data beyond their role.	Role-based access; least privilege; segregation of duties; periodic review.
Audit trail disabled or not reviewed	Changes may not be reconstructable or detected.	Enable validated audit trails; define review frequency; QA oversight; documented review.
Deleted/overwritten raw data	Original evidence is lost.	Technical controls preventing deletion; backup; retention; investigation and impact assessment.
Unreported failed or suspect results	Selective reporting can bias quality decisions.	Retain all relevant data; SOP controls; independent review; investigation and CAPA.
Backdating / late entries	Unclear timing and sequence of activity.	Contemporaneous recording controls; training; electronic timestamps; deviation assessment.
Uncontrolled spreadsheets	Formula changes and version confusion.	Spreadsheet inventory; validation based on risk; access/version control; change control.
Inadequate backup/recovery	Permanent loss of critical records.	Validated backup strategy; restore testing; disaster

		recovery; periodic verification.
Poor system validation	System behavior may not reliably support intended use.	Risk-based validation; URS; testing; traceability; periodic review.
Inadequate data-integrity training	Human error and inappropriate practices persist.	Role-based training; competency assessment; refresher training; quality-culture programs.
Uncontrolled remote/vendor access	Unauthorized changes or weak traceability.	Controlled remote access; logging; vendor qualification; contractual responsibilities; periodic review.
Inadequate investigation of DI events	Root causes and affected batches may remain unidentified.	Documented investigation, scope assessment, root-cause analysis, CAPA and effectiveness checks.

Data Integrity in Quality Control Laboratories

QC laboratories are high-risk environments because they generate large volumes of electronic raw data from HPLC, GC, UV-visible, FTIR, dissolution, TOC, microbiological and other systems. Risks include trial injections, inappropriate reprocessing, deletion of chromatographic runs, uncontrolled integration changes, manual transcription and inadequate audit-trail review.

FDA laboratory guidance emphasizes that laboratory records should include complete data derived from all tests and should not selectively

retain only passing results [27]. Laboratory controls should therefore address instrument configuration, user access, audit trails, raw-data retention, method version control and review of atypical or failing results.

Industry 4.0, Cloud Systems and Digital Manufacturing

Industry 4.0 technologies connect manufacturing equipment, sensors, laboratory systems, data platforms and analytics. These systems can increase process visibility and support real-time monitoring, but data may move across multiple interfaces and vendors. Integrity controls must therefore cover interfaces, metadata, time synchronization, user access, data transfer, storage and cybersecurity. [15,18–21].

The literature on biopharmaceutical Industry 4.0 highlights cloud platforms, data analytics and automated manufacturing as areas where data-integrity controls must evolve alongside digital transformation [15]. Cloud adoption additionally requires clear ownership of data, validated configuration, backup and recovery, access controls, supplier qualification, business continuity and appropriate contractual responsibilities.

Artificial Intelligence and Data Integrity

AI is increasingly being applied to pharmaceutical development, manufacturing, quality control, predictive maintenance, process monitoring and decision support. AI systems create new data-integrity considerations because model performance depends on the integrity of input data, training datasets, preprocessing steps, model versions and generated outputs. [18–21].

Recent literature shows rapid growth in AI-enabled pharmaceutical manufacturing and emphasizes the need for GxP implementation controls, validation and governance [18-21]. A 2026 regulatory-focused industry survey reported increasing use of digital and AI-enabled models across pharmaceutical CMC activities while identifying regulatory barriers and governance priorities [18]. Another 2026 review specifically addressed AI applications, case studies and GxP implementation considerations in pharmaceutical manufacturing [19].

For AI-enabled GxP systems, governance should include dataset provenance, model version control, access control, change management, performance monitoring, validation of intended use, human oversight, traceability of decisions and procedures for handling model drift. AI should not be assumed to be compliant simply because the underlying software is technically functional. [18–21,35].

Recent Literature [15,16,18,19,20,21]

Year	Publication	Relevance
2022	Data integrity within the biopharmaceutical sector in the era of Industry 4.0	Industry 4.0, ALCOA+, cloud platforms, data analytics and smart manufacturing.
2023	Data integrity issues in pharmaceutical industry: Common observations, challenges and mitigations strategies	Regulatory observations, organizational causes and mitigation.
2026	Digital and AI-enabled models in pharmaceutical development and manufacturing: a regulatory-focused industry survey	Digital CMC, AI adoption and regulatory barriers.
2026	Artificial intelligence in pharmaceutical manufacturing: Applications, case studies, and GxP implementation considerations	AI applications and GxP implementation.
2026	A review on artificial intelligence in pharmaceutical sciences: opportunities and challenges	AI across pharmaceutical sciences, manufacturing and governance.
2026	AI-powered digital innovations in pharmaceuticals research & development: Current landscape and case examples	AI/ML, GenAI and digital innovation in pharmaceutical R&D.

15. Quality Assurance Role

QA provides the governance link between regulatory requirements and day-to-day data practices. QA responsibilities include approval of data-integrity policies and SOPs, risk assessments, oversight of computerized-system validation, review of audit-trail processes, internal audits, training, investigation of data-integrity incidents, CAPA, change control and management review. [2–5,8–10].

A mature quality culture should encourage employees to report errors and potential data-integrity concerns. Training should be role-specific and should address ALCOA+, GMP documentation, electronic systems, password security, audit trails, data correction and reporting obligations. [2,4,5,16].

Implementation Roadmap [16,20,21,28,35]

Step	Implementation focus
1. Establish policy	Define organizational expectations and responsibilities.
2. Inventory systems and data	Identify GMP systems, records, interfaces and data owners.
3. Classify	Identify data that can affect

criticality	product quality or patient safety.
4. Perform risk assessment	Assess vulnerabilities, controls and detectability.
5. Strengthen technical controls	Unique IDs, access, audit trails, backup and validation.
6. Strengthen procedures	SOPs for data review, audit trails, corrections, archival and incidents.
7. Train personnel	Role-based ALCOA+, GMP and computerized-system training.
8. Monitor and audit	Periodic review, internal audit, trending and management oversight.
9. CAPA and continuous improvement	Investigate failures and verify effectiveness of corrective actions.

Future Perspectives

The next stage of pharmaceutical data governance will involve increasing integration of AI, cloud platforms, industrial IoT, advanced analytics, digital twins and automated manufacturing. The 2026 literature indicates that digital and AI-enabled CMC tools are expanding while regulatory and governance questions remain active [18-21].

Future data-integrity programs are likely to use automated audit-trail monitoring, anomaly detection, continuous system monitoring and integrated quality-data platforms. However, automation should not replace quality oversight. Human accountability, validated intended use, traceability, cybersecurity and lifecycle governance will remain essential. [31-35].

Conclusion

Data integrity is a core requirement of pharmaceutical quality assurance and GMP compliance. ALCOA+ provides a practical framework for ensuring that records are attributable, legible, contemporaneous, original, accurate, complete, consistent, enduring and available. Regulatory frameworks from FDA, MHRA, WHO, PIC/S and the EU converge on the need for reliable data, risk-based governance, computerized-system controls, audit trails, access management, validation, backup, archival and effective quality oversight.

The transition toward Industry 4.0, cloud computing and AI-enabled manufacturing expands both the opportunities and risks associated with pharmaceutical data. Effective governance must therefore move beyond document control toward lifecycle-based data governance. Organizations that integrate technical controls with quality culture, personnel training, risk management and continuous monitoring will be better positioned to maintain trustworthy data and demonstrate inspection readiness.

Internal citation format: References are cited in square brackets using the numbered reference list below. Multiple sources are shown as ranges where appropriate [37–40].

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