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Short communication

Controlled use of Artificial Intelligence (AI) in deviation reporting: ensuring ALCOA++ data integrity in GMP

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Introduction

Deviation reporting is a key element of pharmaceutical quality management systems (QMS), ensuring that unexpected events are detected, investigated, assessed and corrected through CAPA. In parallel, generative AI tools are increasingly used for drafting and data summarisation. However, deviation records are GxP-relevant and may directly influence regulatory decisions, meaning that any AI-assisted content must preserve data integrity and remain inspection-defensible. Recent EU GMP expectations emphasise data governance and risk-based control across the entire data lifecycle, rather than a document-focused approach.

This paper provides a practical framework for the controlled use of AI in deviation reporting, ensuring compliance with ALCOA++ principles and alignment with EU GMP Chapter 4 (draft), Annex 11 and Annex 22 expectations (European Commission, 2025).

Regulatory expectations translated into practice

The revised EU GMP Chapter 4 introduces a lifecycle-based approach to documentation, where all data, including metadata and record versions, must be controlled, traceable and protected based on risk (European Commission, 2025).

Annex 11 requires lifecycle management of computerised systems, including validation, audit trails and access control, ensuring traceability and data integrity of GxP records (European Commission, 2025).

Annex 22 establishes boundaries for AI use, distinguishing between critical and non-critical applications. Generative AI may be used only as a supporting tool under human oversight, while all GMP-critical decisions must remain under the responsibility of qualified personnel (European Commission, 2025).

Use of AI in deviation reporting

Deviation reporting typically includes event description, investigation, root cause analysis, impact assessment, CAPA definition and closure.

AI may support drafting, summarising evidence and organising investigation findings, but must not act as a decision-making system. Industry experience also shows that a significant portion of deviation management effort is spent on documentation rather than investigation, further supporting the use of AI as a controlled drafting support tool (Arora, 2025).

Acceptable use includes drafting deviation descriptions, summarising documentation and supporting trending, while source data remain the primary reference and outputs are fully verified.

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Non-acceptable use includes automated conclusions related to patient safety, regulatory compliance, or batch disposition, as these represent GMP-critical decisions.

Control model for ALCOA++ compliance

To ensure compliance, AI must be integrated into a controlled framework that preserves data integrity. Key principles include:

- Defined intended use: clear definition of permitted AI applications and limitations
- Human ownership: deviation owner remains fully accountable for content and conclusions
- Separation of draft and record: AI-generated text is treated as a draft, while the approved report remains the GMP record
- Traceability: actions must be attributable and, where applicable, supported by audit trails
- Risk-based approach: higher-risk deviations require stricter verification and documentation

This approach ensures alignment with ALCOA++ principles, particularly attribution, accuracy and completeness (Apotech Consulting, 2025).

Case study – practical driven

A case study may involve a deviation where an API used in a finished product batch originated from two individually approved manufacturers, raising traceability and regulatory compliance concerns at batch level. A structured risk assessment will be performed to evaluate potential impact on product quality, patient safety, data integrity and batch certification.

Available data confirmed that the batch was placed on distribution hold prior to market supply and all manufacturing and quality control results were within specification, indicating no impact on product quality. The primary concern was therefore related to regulatory compliance and traceability. The investigation identified a procedural gap, specifically the absence of a defined requirement restricting the use of API from more than one manufacturer within a single batch. Control measures were focused on improving detectability and preventing recurrence through procedural updates and potential system-based checks. A risk-based approach (FMEA, in line with ICH Q9) was applied to structure risks and define controls.

In this context, generative AI may support drafting structured deviation narratives, organising evidence and proposing consistent CAPA wording, provided that all outputs are verified against primary records and final conclusions remain human-approved. However, AI must not be used for GMP-critical decisions, such as assessing patient safety impact or determining batch disposition. In such cases, conclusions must remain under qualified human responsibility and fully controlled within the QMS, in line with EU GMP expectations.

Conclusion

AI can be effectively used in deviation reporting as a controlled support tool, primarily for drafting and structuring information. However, it must not replace human decision-making in GMP-critical activities.

Alignment with EU GMP Chapter 4, Annex 11 and Annex 22 requires a risk-based approach, clear definition of intended use, and strict preservation of ALCOA++ data integrity principles.

When implemented within a controlled framework, AI can improve efficiency and consistency of deviation reporting without compromising regulatory compliance.

References

European Commission, 2025. EU GMP Chapter 4 – Documentation (Draft).

European Commission, 2025. EU GMP Annex 11 – Computerised Systems (Draft).

European Commission, 2025. EU GMP Annex 22 – Artificial Intelligence (Draft).

ICH, 2005. ICH Q9 – Quality Risk Management.

ICH, 2008. ICH Q10 – Pharmaceutical Quality System.

Apotech Consulting, 2025. ALCOA+ Principles in Pharma.

PharmOut, 2026. Chapter 4 – GMP Documentation Changes.

Arora, A., 2025. AI in Deviation Management, ISPE Pharmaceutical Engineering.