Data Integrity Policy

JCR Pharmaceuticals Co., Ltd. and its subsidiaries and associates (hereinafter collectively, the "JCR Group" or "we") conducts the following activities to ensure the integrity (completeness, consistency, and accuracy) of research/clinical trial data and production data that form the basis of the reliability of pharmaceutical products.

1. ALCOA+

   The JCR Group adheres to the ALCOA+ principle for all data, including research, clinical trial, production, and testing, and ensures that the data is A (Attributable), L (Legible), C (Contemporaneous), O (Original), and A (Accurate), as well as C (Complete), C (Consistent), E (Enduring) and A (Available).

2. Management System

   The JCR Group establishes an appropriate management system to promote the systematization of data recording, verification, approval, and storage to ensure data integrity.

3. Measures

   The JCR Group takes organizational, personnel, physical and technical measures to ensure data integrity. In case of an incident, we will promptly investigate the cause and prevent recurrence.

4. Education and Training

   The JCR Group conducts regular training for all employees on the importance of compliance with GxP and other regulations, and on appropriate behavior in accordance with the JCR Compliance Policy, in order to ensure data integrity and strives to foster a workplace culture that is open and transparent.

5. Business Partners

   The JCR Group may require its business partners to ensure data integrity.

6. Continuous improvement

   The JCR Group continuously inspects, reviews, and makes necessary improvements to the efforts described in items 1 to 5 above.

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[References]

ALCOA

The five basic elements (see table below) that are important for ensuring data integrity, as described in the FDA (Food and Drug Administration) document “Guidance for Industry - Computerized Systems Used in Clinical Investigations” [1)].

These elements are generally called “ALCOA principles”, for initial letters of them.

A (Attributable)	Clear attribution/responsibility: The recorder of all data is clear. Observers, recorders, and those who made corrections can be identified and traced. ✓ Dates and creators (or sources) can be traced. ✓ Record the work performed to ensure traceability. ✓ Use registered signatures and seals for recording.
L (Legible)	Legible/understandable: All data can be read easily and without doubt by anyone. ✓ Record legibly and accurately. ✓ Record accurately and make it easy to understand correctly.
C (Contemporaneous)	Contemporaneous: Record as soon as possible after the data is created. ✓ Do not record retrospectively. ✓ Record at the same time as the work.
O (Original)	Original: First recorded version. Not a copy or transcription. Keep all originals. Record data on appropriate forms. ✓ Do not record results of activities in any other way except on officially approved forms. ✓ Do not use sticky notes or memo pads as part of the record. ✓ Do not use personal notebooks to record data or make calculations.
A (Accurate)	Accurate: No errors, complete. Comply with the protocol and other procedures. ✓ Create a procedure manual, work according to these procedures, and record the results. ✓ Strictly prohibit any fraudulent practices (falsification, tampering) regarding documents and records.

ALCOA+ (Plus)

EMA (European Medicines Agency) is requiring **ALCOA-CCEA**, which is added the following element CCEA (see the table below) to ALCOA,[2)] and they are generally called ALCOA+.

C (Complete)	Complete: ✓ In cases of electronic records being integrated from computerized systems into other systems (i.e., records are not maintained in the original system), metadata (including audit trails and digital signatures) should be transferred or archived with the electronic records.
C (Consistent)	Consistent: Not inconsistent with the records in the source documentation. Not inconsistent with other source documentation. ✓ All GMP documents and records should be handled in accordance with the appropriate data management standards. Records include electronic records/electronic signatures.
E (Enduring)	Enduring: Record with a writing instrument that cannot be erased. Store data for a specified period in an appropriate environment that minimizes loss, damage, and deterioration. For documents whose original print becomes faint over time, a certified copy (a copy that is guaranteed to be identical to the original) should be made and stored together with the original. ✓ Paper records must be recorded with permanent ink. ✓ Electronic records must be stored in a safe and validated process. ✓ Based on the document lifecycle, the document must be maintained in perfect condition until the storage period.
A (Available)	Available when needed: The records can be made available promptly when needed throughout the period of storage. ✓ Records that support batch records, and the status of batch quality shall be stored in a safe and reliable manner so that they can be searched within the specified period and so that it is possible to completely prepare the batch history. ✓ In the case of using a computerized system, ensure availability even when updating the system.

1) FDA: Guidance for Industry-Computerized Systems Used in Clinical Investigations, May 2007
2) GCP Inspectors Working Group/EMA: Reflection paper on expectations for electronic source data and data transcribed to electronic data collection tools in clinical trials, Jun 2010

Excerpt from the training materials “Data Integrity for practitioners” provided by the JPMA (Japan Pharmaceutical Manufacturers Association)