Status of Data Integrity (DI) Implementation at GLP Facilities in Various Countries

S. Harano, Y. Ono, S. Yamada, K. Tokoro, Y. Matsushita, T. Takahashi and K. Ikeda
GLP Subcommittee
Japan Society of Quality Assurance (JSQA)

INTRODUCTION

Data Integrity (DI) has become an increasingly important issue and a globally recognized concern in GLP settings as computerized systems continue to advance. Japan's GLP monitoring authorities—the Pharmaceuticals and Medical Devices Agency (PMDA) and the Food and Agricultural Materials Inspection Center (FAMIC)—likewise emphasize the reinforcement of DI. In 2024, they identified four DI-related priority areas, promoting transition to DI-compliant equipment and encouraging industry-wide implementation of DI practices. These priority areas include:

1.Transition to DI-compliant equipment (especially audit trail functionality)

2.Defining original (particularly dynamic) data as raw data

3.Automatic recording of weighing values

4.Management of blank forms

In response to this international context, we conducted a questionnaire survey to gain insight into how DI practices are being implemented internationally. The survey targeted QA organizations in countries that have signed a Memorandum of Understanding (MOU) with JSQA. Based on OECD GLP Advisory Document No. 22 (2021), and PMDA's four priority areas for DI (the four priority areas described above), with the aim of assessing DI-related measures and implementation status across countries.
The survey was conducted via a web-based platform and consisted of both multiple-choice and open-ended questions. Differences in the perception and implementation of DI among countries, as well as shared global challenges, emerged through the analysis of the responses. The aggregated survey data was shared with participating QA organizations in March 2026.

AIM

This survey was conducted to assess the current status of DI implementation in countries with which Japan has established Memoranda of Understanding (MOU), namely the United States, the United Kingdom, Germany, France, China, South Korea, Taiwan, Sweden, and Switzerland. This presentation aims to summarize response findings and highlight regional differences and common global challenges related to DI implementation, with the intention of providing insights that may support the development of DI strategies and inform decision-making regarding the international outsourcing of GLP studies.

For detailed information on the questionnaire and survey results, please visit:

https://jsqa.com/society/

METHOD

To assess each facility's data integrity (DI) implementation in relation to the four key topics identified by PMDA, we developed a questionnaire consisting of items on audit trails (up to six), electronic data handling (up to thirteen), automated recording of weighing values (up to two), and the management of blank forms (up to three). Responses were collected from QA organizations in Japan's Memoranda of Understanding (MOU) partner countries, including the United States, the United Kingdom, Germany, France, China, South Korea, Taiwan, Sweden, and Spain, and also from Switzerland, which is not an MOU partner country.

Survey Items (for GLP Studies)

Q1&Q2. Affiliation- Name of QA organization; response provided as an individual facility or as a QA association

Q3. Audit Trail- Presence/absence of audit trail functionality; handling or alternative approaches for non-compliant instruments; QA timing and review perspectives for computer systems; SOPs for audit trail review

Q4. Electronic Data Handling- Handling of dynamic data; response to OS end-of-support; Administrator settings and readability after study completion; Use of cloud services; supplier assessment; information security; Dynamic data in outsourced studies; requirements for electronic signatures; use of ELNs

Q5. Automated Recording of Weighing Values- Automated capture of balance readings; future measures for non-automated balances

Q6. Blank Forms- Control status; responsible personnel; preparation and control methods

Aggregation Method

- Responses are counted based on the number of affiliated QA organizations.
- Responses representing multiple organizations were divided proportionally (e.g., SQA, RQA and SPAQA three organizations → one response counted as 1/3 for each organization).
- Therefore, fractional values appear in graphs and tables.

Affiliation Distribution of Questionnaire Respondents (GLP / QA / Both)

	SQA (America)	SOFAQ (France)	KSQA (Korea)	GQMA (Germany)	RQA (United Kingdom)	SARQA (Sweden)	SPAQA (Switzerland)	TSQA (Taiwan)	Others	CSQA* (China)
Both GLP Facilities & Organizations	0.5	1	0.5	0	0	1	0	0	0	0
QA Organizations	0	1	0	0	0	1	0	0	0	10
GLP Facilities	14.3	12.5	10	9.5	6.3	1	0.8	0.5	2	44

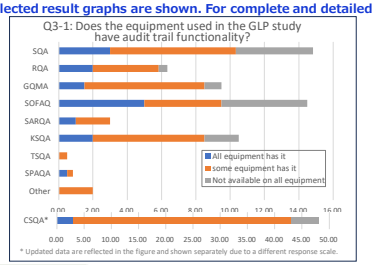
* Initially reported as a single aggregated response (n=1). Detailed data became available after the SQA Annual Meeting and are reflected in the figure.

RESULTS

Due to space limitations of the poster, only selected result graphs are shown. For complete and detailed data, please refer to the above QR code.

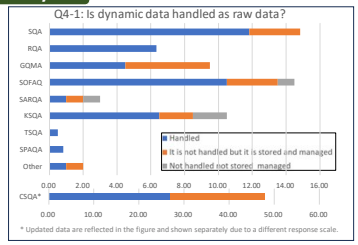
Audit Trail (Q3-1 to Q3-6) → Priority 1

- Audit trail functions were implemented on only some instruments, and most facilities have no plan to replace non-compliant equipment.
- QA audit trail review was most commonly conducted during study-based inspections, followed by facility- and process-based inspections.
- More than half of the respondents had established SOPs for audit trail review.
- Some facilities also reviewed audit trails during final report or raw data review.
- As alternative audit trail controls, many facilities combined usage records (user, start/end time) with access restrictions.



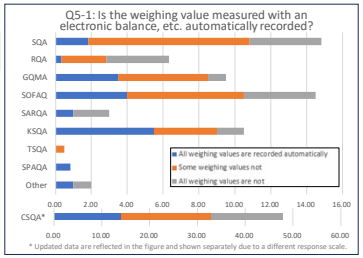
Handling of electronic data (Q4-1 to Q4-13) → Priority 2

- Systems for managing dynamic data were generally in place (Q4-1).
- Post-study data were mainly archived on on-site servers or removable media; cloud use was limited, though some cloud adoption was seen in SQA and RQA.
- Post-study preservation approaches varied by risk (stand-alone OS, virtualization, or OS update).
- Common measures included backups, format conversion, and long-term archiving strategies.
- In contract studies, CROs often maintained dynamic data after study completion.
- Electronic signatures were mainly supported under 21 CFR Part 11 in the U.S., OECD No.17/22 and EU eIDAS in Europe.
- Use of electronic laboratory notebooks in GLP studies remained limited, but usage was relatively higher within SQA and SOFAQ.



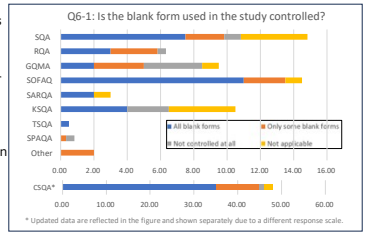
Automatic recording of weighing values (Q5-1 to Q5-2) → Priority 3

- Most facilities reported partial automation of weighing records (Q5-1).
- KSQA showed relatively higher rates of fully automated recording.
- Facilities using manual recording generally had no plan to introduce automation.



Blank forms (Q6-1 to Q6-5) → Priority 4

- Most facilities reported that all blank forms used in studies were controlled (Q6-1).
- Primary persons responsible for blank form management were the QAU, Study Director, and TFM.
- Blank forms were mainly created by the Study Director, or by document control department/QAU when standardized templates were used.
- Creation methods included standardized templates, assignment of control/version numbers and issuance dates, use of watermarked paper, and electronic forms registered in QMS or document management systems.
- Common management approaches were QMS-based control, SOP-based management, and electronic document control systems.



CONCLUSIONS

- **Summary of survey findings:** This international questionnaire survey provided an overview of the current status of data integrity (DI) implementation in GLP studies across MOU partner countries. While many facilities have introduced DI-related measures in line with regulatory expectations, full implementation across all systems and processes remains limited, with risk-based approaches commonly adopted.
- **Regional differences:** Clear regional differences were observed in the level of digitalization and regulatory references applied to DI practices. These differences were particularly evident in automation, use of electronic signatures, and adoption of cloud services and electronic laboratory notebooks, reflecting variations in regulatory environments and operational maturity.
- **Common global challenges:** Despite regional differences, common global challenges were identified, including partial implementation of audit trail functionality, continued reliance on legacy systems, and limited plans for system replacement. Many facilities rely on mitigation measures rather than immediate system upgrades due to cost, technical, and risk-based constraints.
- **Overall implication:** These findings indicate that DI implementation in GLP studies is progressing globally but remains in a transitional phase, providing useful insights for pragmatic DI strategy development and informed decision-making in international GLP outsourcing.