

Using a SaaS system at a Japanese Facility in GLP Studies

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Background

Since the pandemic, remote clinical trials and R & D have become necessary, supplement 1 of OECD Document No. 17 was published in 2023, and cloud services are being considered and introduced in Japan. In the use of cloud services, it is considered important not only to have a relationship with the service provider, but also with distributors and subcontractors. This poster will explain the unique aspects of cloud adoption in Japan.



Figure 1 Relationship of user, distributor and service provider. Distributors play an important role in CSV activities.



Figure 2. Consideration of Points to use cloud service. This diagram illustrates the SQA CVIC and JSQA Sub-committee#3 collaborative achievements. (Volume 41.1 of Quality Matters, SQA Technical Article 2025-1)

Japanese Facilities typically go through distributors

In Japan, when a GLP facility introduces a computerized system — particularly one provided by a vendor outside Japan — it is typical for the user to enter a contract through the vendor’s local distributor, rather than directly with the overseas system vendor.

Language and Support Considerations

When contracting directly with an overseas vendor, all documents, training, and support must be conducted in English, which can create operational and audit-related difficulties. Therefore, it is common practice to use a domestic distributor who can provide Japanese-language documentation and technical support.

Legal and Contractual Alignment

Japan’s GLP requirements (as stipulated by MHLW Ordinance No. 21, etc.) emphasize accountability, quality assurance, and data integrity. Direct contracts with foreign vendors may obscure the allocation of legal responsibility or warranty coverage. Hence, contracts are generally made with a Japanese legal entity or authorized distributor, who assumes responsibility under Japanese law.

Support for Computerized System Validation (CSV)

Under GLP, computerized system validation is mandatory. Distributors typically provide localized validation templates and procedures that align with Japanese GLP expectations (e.g., PMDA guidelines). Standard documents from the overseas headquarters alone often do not fully satisfy Japan’s regulatory requirements.

Key Points of Using Cloud Services

It can be very difficult to conduct an appropriate risk-based assessment of the services that users want to use and proceed with CSV independently. Therefore, it is expected that an efficient and quality risk-based audit can be conducted by conducting an audit in cooperation with a distributor who has a good understanding of the contents of services and the service structure. Figure 2 shows the points to be considered in an audit. Audit team should evaluate these points on a risk-based approach.

Our Solution

Even if users employ distributors, PMDA (Monitoring Authority) insists that the implementation of CSV should be user-driven. In order to ensure the reliability of computer systems, IT, QA, and implementation departments should cooperate to implement risk-based CSV, and relationships with distributors and service providers are required.