Data Integrity treating in home working involving GLP

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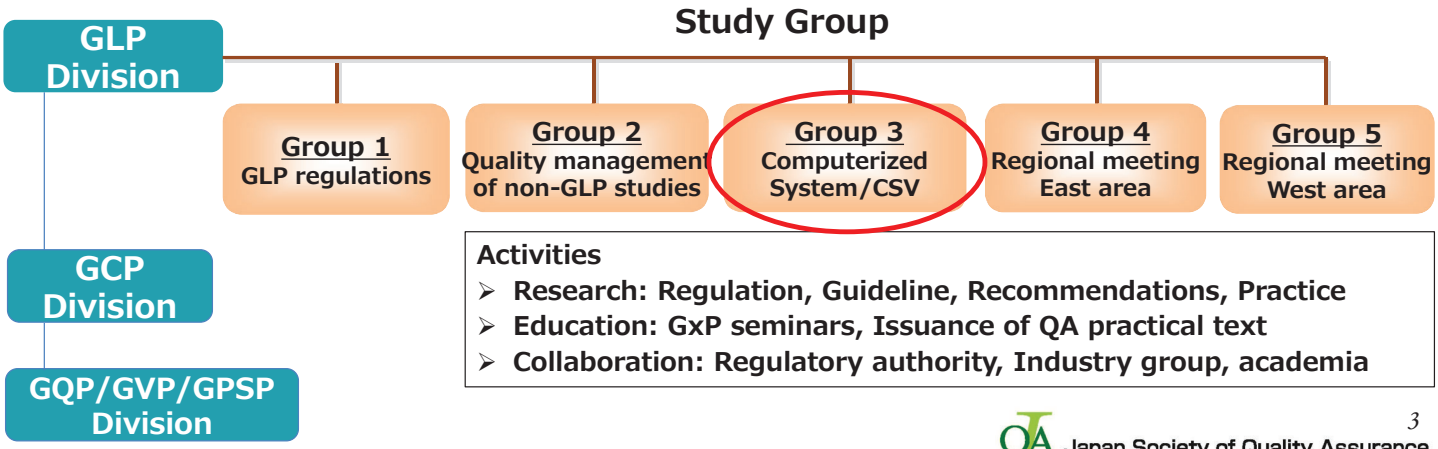
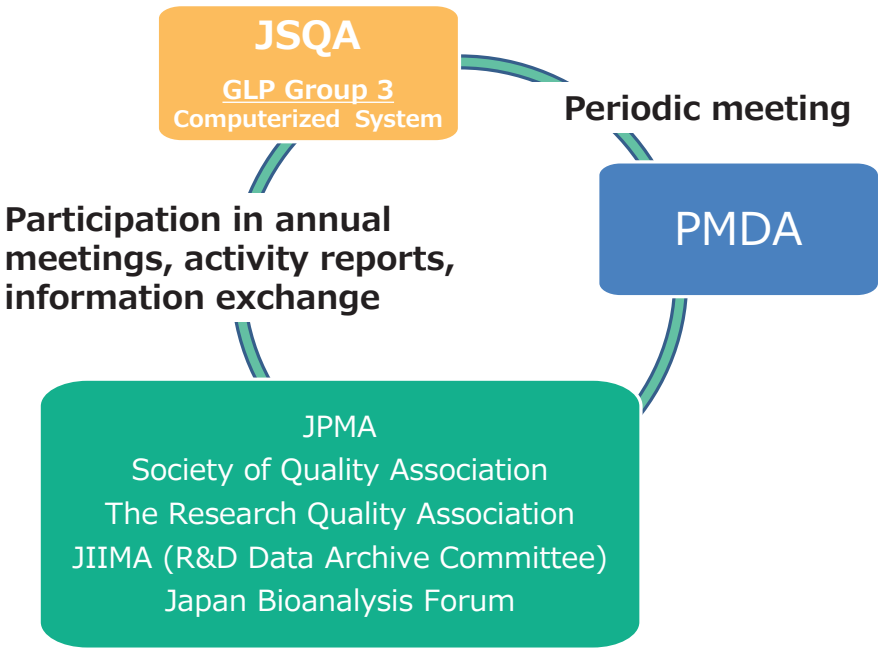
Introduction of JSQA

Vision
Contributing to the improvement of people's health and welfare through information dissemination, human resource development and professional proposals related to reliability assurance of pharmaceuticals, medical devices, regenerative medicine products, agricultural chemicals, chemical substances, etc.



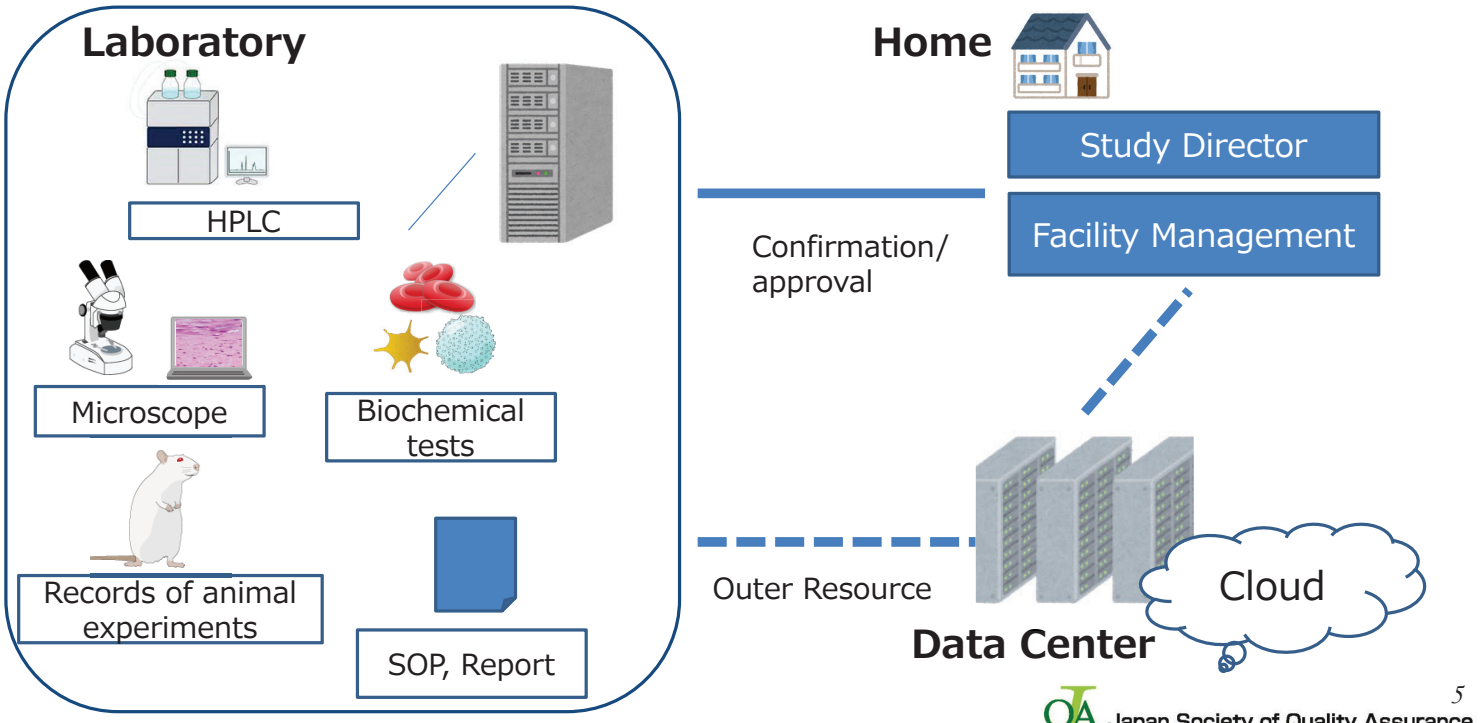
External collaboration of computerized system study group



Topics

- Data Integrity
- Cloud computing
- System retirement
- E-learning
- Electronic Signature
- New technology
  - Blockchain
  - Digital watermark
  - AI

Home working in GLP



ALCOA (+CCEA)

- **Both paper data and electronic data are commonly required to manage under the data integrity**
  - Attributable
  - Legible
  - Contemporaneous
  - Original
  - Accurate
  - Complete
  - Consistence
  - Endurance
  - Available

Approval of data and records in home working

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Approval of data and records in home working

- **Electronic data and records**
  - e.g. document management systems, toxicology testing systems, archiving systems, third-party electronic signature systems
  - It is relatively easy to ensure data integrity by using an appropriate system to manage data.
- **Paper documents (with wet ink signature)**
  - e.g. scanning of documents and signatures, approvals via email,
  - When these methods are used, attention should be paid to data integrity issues.

MHRA guidance

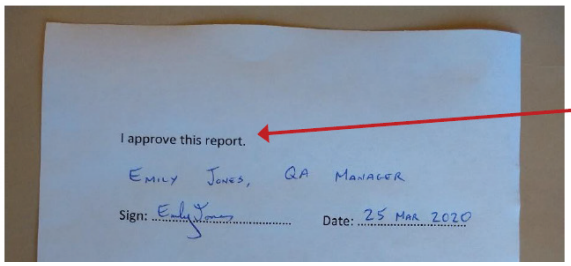
Approval of GxP documents when working from home during the coronavirus (COVID-19) outbreak
Published 9 April 2020

Points to consider when approving remotely

- The scope of the approval is clearly stated.
- It should be detected if a document was changed after approval.
- The security of the electronic signature, so that it can only be applied by the "owner" of the signature
- When approving remotely, all necessary information should be available to the approver.

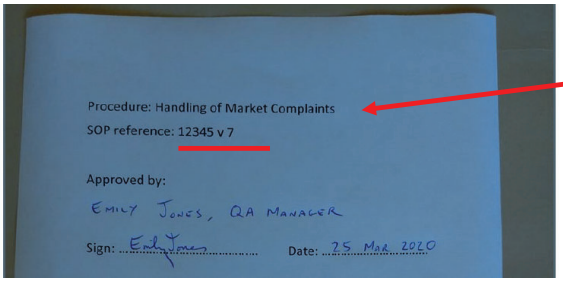
Examples to consider when performing remote approval

Example1 Document number/version not included on the approval page



It is ambiguous what document is being referred to.

Example2 document number/version included



the scope of the approval is described with the document title, reference and version included on the approval page.

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/879021/Examples_of_issues_with_remote_approval_-_April_2020.pdf

Examples to consider when performing remote approval

Example3 Inserting signature images to documents

- Is the signature image under control?
- Is the timestamp accurate?
- Is an electronic signature system used?
  - Part 11 compliant document management system

This is inappropriate as it can be difficult to control who can do this and therefore how the signature is attributable to the individual. This is not compliant with good documentation or data integrity principles.

Examples to consider when performing remote approval

- Approval by email
  - In general, for more critical signatures, reliance on only an email to record document approval does not provide adequate control.
  - For low risk approvals, e.g. to record that an update to an internal procedure has been reviewed and approved.
- Approved documents stored in a shared folder
  - It is important that there are adequate controls to avoid uncontrolled document changes.
  - There should be access control to the folder.
  - It should be detected if a document was changed after approval.

Using external IT resources

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General requirements for using external archive in GLP

1	Clarification of the responsibilities of the facility management, the archivist, and the person in charge of the contractor
2	Understanding by the contractor of the SOPs in place and their revision status in relation to GLP data storage
3	Confirmation of the status of environmental monitoring at facilities and areas where the contractor's data is stored
4	Appropriate QA inspections by entrustor (sponsor)
5	Obtaining information on access restrictions and procedures to the facility
6	Check the status of GLP-related education and training for staff
7	Identifying and responding to abnormalities

GLP guidebook 2014

Points to note on GLP when using external IT resources

Guidance

- **OECD GLP FAQ**

  https://www.oecd.org/chemicalsafety/testing/glp-frequently-asked-questions.htm

- **OECD GLP No.17(Application of GLP Principles to Computerised Systems)**

  https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2016)13&doclanguage=en

- **MHRA Data Integrity Guidance**

  https://www.gov.uk/government/news/mhra-gxp-data-integrity-definitions-and-guidance-for-industry

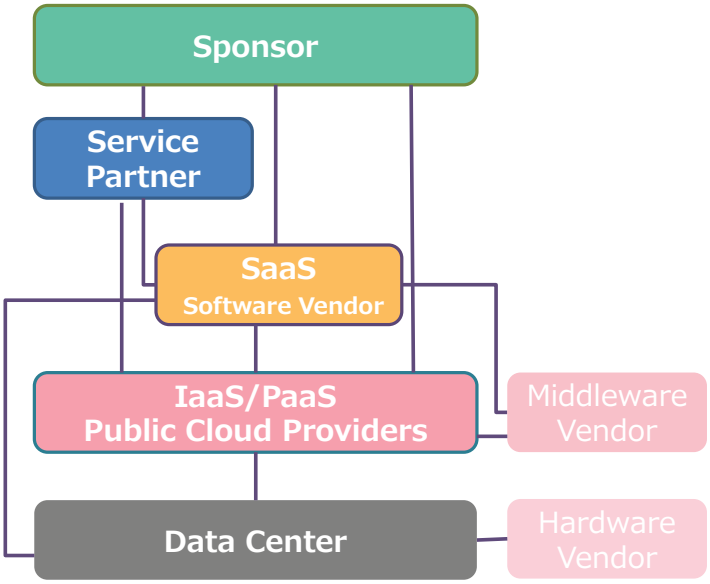
OECD GLP (FAQ)

IT Issues

Q : How should hosted services (“cloud” computing) and the retention of electronic data be treated in the context of GLP.

A : Hosted services (cloud services, e.g. platform, software, data storage, archiving, backup or processes as a service) should be treated like any other supplier service and **require written agreements describing the roles and responsibilities of each party**. It is **the responsibility of test facility management to evaluate the relevant service and to estimate risks to data integrity and data availability.** Test facility management should be aware of potential risks resulting from the uncontrolled use of hosted services. Written agreements (contracts) should exist between the test facility and the supplier. **These agreements should include clear statements outlining the responsibilities of the supplier as well as clear statements about data ownership**. (Posted on 28 February 2018)

Flow of using cloud services and contracts



Type of industry	
Sponsor	Users of the service, IT departments, user departments, etc.
Service Partner	Agents, system integrators
Software Vendor	Software developer, SaaS Provider
Public Cloud Providers	AWS、Microsoft Azure、Google Cloud etc.
Data Center Services	Service providers of data centers
Middleware Vendor	Manufacturers of databases, virtualization products, etc.
Hardware Vendor	Manufacturers of servers, storage, networks, etc.

Depending on the services to be used, the contracting process should be fully understood and a risk assessment should be conducted.

Issues in using public clouds with GLP

- **Appropriate Computerized System Validation(CSV) for cloud computing, including change management for software upgrades, etc.**
  - It is important that facilities determine the impact on data archive and system operation in accordance with GLP.
  - JSQA is examining the risks of cloud computing and appropriate CSV in GLP.
- **Information such as the location of the data center is not disclosed.**
  - The OECD GLP working group is discussing this issue.

Utilization and issues of remote inspection

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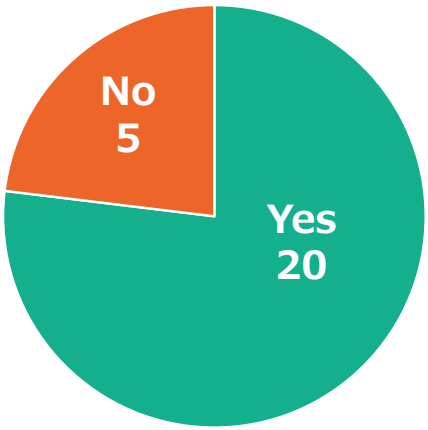
Utilization and issues of remote inspection

Experience of remote inspection

Do you have experience in remote inspection?



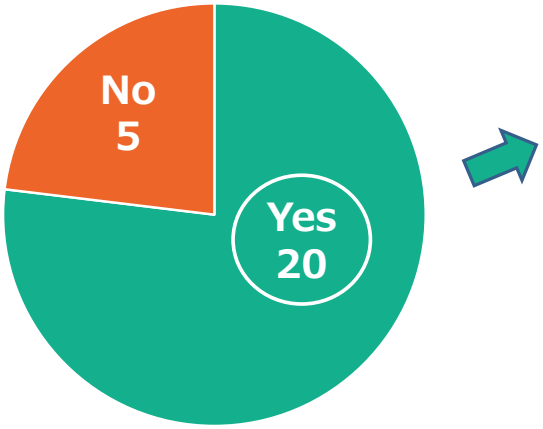
Questionnaire

- Target: JSQA GLP division Computerized System group
- Answer: 25/37 companies
  - Pharmaceutical and medical device companies : 18
  - CRO : 7

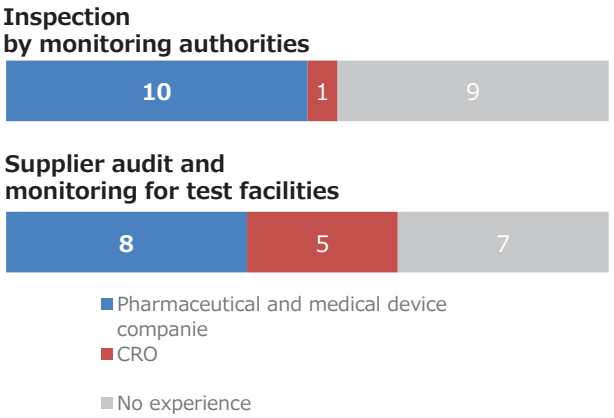
Utilization and issues of remote inspection

Experience of remote inspection

Do you have experience in remote inspection?



Details with remote inspection experience



Inspection by monitoring authorities

What is the type of inspection? (11companies)

*Application for partial changes (PMDA), GVP inspection (EMA) , GCP inspection (FDA) , Audit for CE mark (notified body)

- Currently, regulatory remote inspections are limited to document based audits.
- In document based inspections, file sharing systems such as Box or SharePoint are often used.
- In addition to sharing screens for presenting materials, document cameras are also used to present paper materials.
- It is an advantage to be able to receive back-up from Japan during audit of overseas offices.

Inspection by monitoring authorities

Advantages

- No need to move
- Shortening audit time
- Being able to participate in audits of overseas offices from Japan
- The concerns were presented in advance so that the audited could prepare for them. (Document - based Conformity Audit, GCP inspection)

Disadvantages

- Hard to prepare in advance
  - File sharing system preparation
  - Converting paper materials to PDF and uploading files
- Communication
  - difficult to see how the auditors are doing
  - Difficult to convey intentions
- Affected by the stability of the network connection

Supplier audit and monitoring for test facilities

Prior confirmation with the audited facility

- Types of web conferencing systems, which one will be the host
- Whether the documents and records are electronic or paper, and whether the paper records can be converted to PDF
- Method of document sharing: free browsing through a file sharing system or projection of paper documents using a document camera
- Period for viewing materials: Can it be before or after the audit date?
- Method of providing lab tour: live streaming via webcam or presentation with pre-taken videos and photos
- Prohibit recording: different ways to agree

Challenges of Remote Auditing

- **Digitization of documents and data**
  - It will be more efficient if the organization being audited is already digitized.
- **Improvement of IT infrastructure**
  - Stability of network communication
- **Ensuring integrity**
  - It may not be possible to review all data and records remotely.
- **Management of confidential information**
  - Prohibition of screenshots and recordings, acceptance or rejection of the use of file-sharing systems (the extent and method agreed upon varies from facility to facility)
- **Lab Tour**
  - Live Camera vs. Recorded Video → The key is how to use it.

Conclusion

- **After the end of the pandemic, teleworking and remote auditing will continue to be considered from the perspective of improving operational efficiency.**
- **For teleworking in GLP, it is essential to promote the digitization of documents and data from the perspective of ensuring data integrity.**
- **In order to promote the digitization of GLP operations, JSQA will study the reliability of guidance and new technologies in each country and propose best practices from the perspective of Quality Assurance.**