

GLP施設におけるテレワーク導入の可能性

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Possibility to utilize telework in the GLP test facility

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Introduction

Can we apply telework to the operation in GLP test facilities ?

Is it applicable?

- Study tasks (such as, blood sampling, examination) ... Seems impossible
- Meeting, designation, document preparation (including draft) ... Seems possible

What can QA contribute?

Order of Consideration

1. Understanding telework  
• Exploration of implementation status results\*  
\* Reports by others
2. Survey on the implementation of telework in our Group  
• Sorting out the work of GLP facilities
3. Summary

1 What is telework?

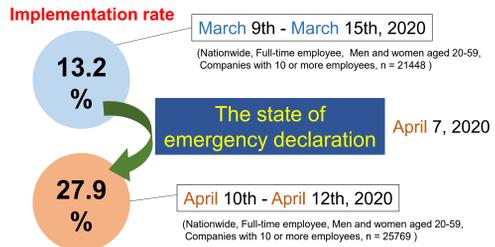
It refers to a variety of work styles that make effective use of time and space through the use of information and communication technology (ICT).

Telework means working from a place other than the office such as a home, cafe, or a rental space.



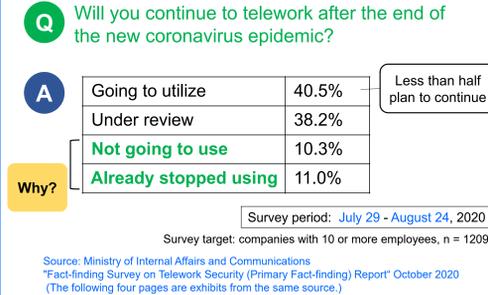
Need to digitize daily work

Telework implementation rate doubled due to the coronavirus (COVID-19) outbreak



Source: PERSOL RESEARCH AND CONSULTING CO., LTD. "Urgent investigation on the impact of new coronavirus measures on telework" 2nd survey

Signs that telework will not take root



Reasons for "Not going to use" or "already stopped using" (Multiple answers allowed)

1. Because it is difficult to proceed.	59.1%
2. Because there is no suitable job for telework.	46.7%
3. Because it interferes with internal communication.	33.9%
4. Security concerns such as information leakage.	30.7%
5. Because it interferes with external correspondence with customers, etc.	29.6%
6. It's a burden on the people around a teleworker.	21.8%
7. Because of the lack of digitization of documents.	20.6%
8. Because it is difficult to evaluate employees.	16.7%

For the top three reasons, we checked the composition of employee size and business type. n = 257

Employee size of companies that "Not going to use" or "already stopped using"

Employee size	10~19	20~29	30~49	50~99	100~199	200~299	> 300
Actual count (Total 257)	89	41	46	43	25	6	7
Difficult to proceed (%)	70.8	51.2	56.5	48.8	52.0	66.7	57.1
No suitable job (%)	48.3	34.1	50.0	48.8	40.0	66.7	71.4
Interference communication (%)	32.6	41.5	26.1	23.3	52.0	66.7	28.6

No significant trend was observed.

Business type of companies that "Not going to use" or "already stopped using"

Business type	Construction industry	Manufacturing industry	Transportation / postal business	Wholesale / retail	Finance / insurance business	Real estate business	Information and communication industry	Service industry / others
Actual count (Total 257)	27	42	14	68	2	6	15	83
Difficult to proceed (%)	74.1	52.4	42.9	55.9	50.0	33.3	60.0	65.1
No suitable job (%)	44.4	45.2	85.7	41.2	50.0	66.7	-	53.0
Interference communication (%)	48.1	40.5	28.6	32.4	50.0	33.3	60.0	22.9

Not so high in the manufacturing industry. Same category as Test facility

Why telework does not take root?

Because it is difficult to proceed.

There is resistance at first, but it may get used to it after a few times.

Because there is no suitable job for telework.

We may just not be able to extract the tasks that can be carried out by teleworking.

2 GLP Test Facility

- Good Laboratory Practice is a regulation regarding the organization and operations required for facilities that conduct safety tests.
  - "Who must do what" and "How each task must be performed" are clearly defined. (SOP)
- Since business procedures are extracted individually, it is easy to determine whether telework can be applied or not.

Jobs in the GLP test facility are compatible with telework.

Questionnaire to group members(JSQA L-5-1)

\* Subgroup 1, Study Group 5 of GLP Division, Japan Society of Quality Assurance

Q: Is telework being implemented?	A: Yes. 13/13 (100%)
Q: What kind of work do you apply telework to?	A: Office work that does not involve practical operation.
Application to experiment related work is 0%.	
Examples of telework implementation	
<ul style="list-style-type: none"> <li>• Participation in meetings</li> <li>• Attending education</li> <li>• Create educational materials</li> <li>• Preparation of draft SOP</li> <li>• Drafting of plans and reports</li> </ul>	

Q: What did you notice after implementing telework?	A: It is necessary to digitize the entire process of work. Some work could only be done at the facility.
Efficiency will not increase unless the entire process is digitized. (Including digitization of past data)	
Q: Is there a time limit set for the application of telework?	A: Yes. 3/13 (23%) Only during the state of emergency declaration
Not all facilities are necessarily proactive.	

Q: Do you apply telework to your internal audit?	A: Yes. 2/13 (15%)
<ul style="list-style-type: none"> <li>• It takes time to scan paper records and convert them to PDF.</li> <li>• There are some data that can only be viewed using specific terminals in the facility.</li> <li>• To keep paper records of the inspection, there are needs to come to facility to keep records.</li> <li>• It made me realize the importance of information obtained through non-verbal communication.</li> </ul>	

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Q: Do you have experience in conducting remote audit of contracted facilities?	A: Yes. 4/13 (31%)
<ul style="list-style-type: none"> <li>• Combination of site-inspection and remote audit 3/13 (23%)</li> <li>• Obtain and inspect document files and work recording files 1/13 (8%)</li> </ul>	

Q: Have you ever had an inspection in a remote audit?	A: Yes. 4/13 (31%)
<ul style="list-style-type: none"> <li>• We submitted the necessary documents in advance and had a question and answer session at a web conference.</li> <li>• Documents that are difficult to read with a Web camera were presented as PDF on the spot.</li> <li>• After remote audit, received on-site inspection.</li> </ul>	

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3 Summary

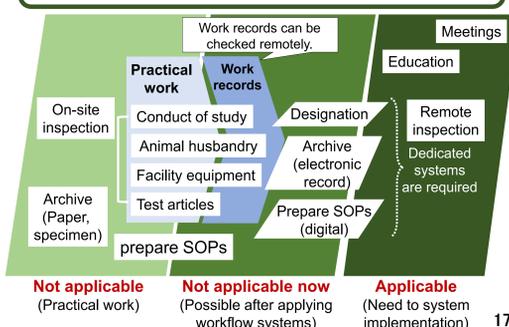
- ◆ Although the rate of adoption of telework was high, the process of conducting studies had not yet been applied in any facilities.
- ◆ Start with the parts of the operations that can be digitized and optimize the system step by step.

This method is similar to preparing SOPs.

The experience of preparing SOPs should be useful in implementing telework.

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Possibility of applying Telework in GLP test facilities



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- ◆ If we can establish a workflow system that covers the entire operations of test facility, it will also help improve the reliability of records.

for example  
Electronic lab notebook  
Laboratory information management system  
Materials (animal, test article, personnel) management system

What QA can contribute

Ensuring system reliability

- for example
- Ensure that all operational risks are managed.
- Reliability of electronic data is ensured.
- Confirm that the communication security is secured.

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