

# 20|20 VISION A NEW FRONTIER?

## CALL FOR POSTERS WINNER

JSQA GLP Division, Study Group 3, Subgroup 2  
Akira Yamazaki (Kyowa Kirin Co., Ltd.), Hiroe Takeshima (Taiho Pharmaceutical Co., Ltd.), Noriaki  
Katanosaka (Sekisui Medical Co. Ltd.), Masaki Aota (Astellas Pharma Inc.), Masako Takayama  
(Mitsubishi Tanabe Pharma Corporation), Norihiro Omae (FUJIFILM Corporation)

for their poster

**QUALITY ASSURANCE WHEN INTRODUCING NEW  
INFORMATION COMMUNICATION TECHNOLOGY**

## 2020 RQA INTERNATIONAL QA CONFERENCE

10TH - 12TH NOVEMBER 2020

A VIRTUAL EVENT



Anthony Wilkinson  
Director of Operations, RQA

## RQA 2020 INTERNATIONAL QA CONFERENCE: CALL FOR POSTERS WINNER

Although many things were different about this year's RQA conference, one thing was familiar – our popular Call For Posters competition still took place. Our winners this year was an entry from the JSQA GLP Division, Study Group 3, Subgroup 2 (led by Mr. Akira Yamazaki) titled **“Quality Assurance when introducing New Information Communication Technology”**.

We appreciate the hard work that went into the poster and hope to see more entries from JSQA members at our EU Symposium (May 2021) and 2021 RQA Annual Conference (November 2021), which will both be delivered virtually.

### Quality Assurance when introducing New Information Communication Technology

JSQA GLP Division, Study Group 3, Subgroup 2  
Akira Yamazaki (Kyowa Kirin Co., Ltd.), Hiroe Takeshima (TAIHO PHARMACEUTICAL CO., LTD.), Noriaki Katanosaka (SEKISUI MEDICAL CO., LTD.), Masaki Aota (Astellas Pharma Inc.), Masako Takayama (Mitsubishi Tanabe Pharma Corporation), Norihiro Omae (FUJIFILM Corporation)

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#### Introduction

With recent technological innovation, computer systems using new technologies are being developed. For example, the Internet of things (IoT), which provides measurement and control via the Internet, is being introduced into home appliances and analytical equipment, and in addition, Computer Vision that aims to help machines make sense of images is also being developed. However, these new technologies are not yet widely used in GLP facilities in Japan. Therefore, in order to promote the use of new technologies in GLP facilities in Japan, we examined what new technologies can be used in each process of GLP study.

#### New ICT systems related to study processes

Plan	Conduct	Report	Archive
Preparation of Experiment	Material Ordering Equipment Record of Raw Data Analysis and Evaluation Result Table Data QC Change Management (Amendment)	Deviation Management	Change Management (Amendment)

★ Examples of New ICT Systems on GLP

ICT	Expected System	Phase	Expected Usage
RPA	Study Support System	Material Ordering	A system that can automatically order materials necessary for experiments, such as laboratory animals and reagents.
IoT	Chromatographic Equipment Management System	Experiment to Analysis and Evaluation	The chromatographic equipment can be monitored and controlled by the mobile terminal.
Computer Vision	Handwritten Records Digitizing System	Record of Raw Data to Deviation Management	System for digitizing handwritten characters through a camera and interpreting handwritten records.
AI	Pathological Evaluation System	Analysis and Evaluation	A system that has completed AI learning on pathological evaluation.

#### IoT (Internet of Things)

[e.g.: Chromatographic Equipment Management System]

#### Computer Vision

[e.g.: Handwritten Records Digitizing System]

<Principle>

<Example>

Ophthalmology  
Annual No. 303  
Timing: week 4  
Finding: normal capacity  
\* description error  
01 Apr. 2020  
(Signature)

→

OCR Data  
Annual No. 303  
Timing: week 4  
Finding: normal capacity  
\* description error  
01 Apr. 2020

→

True copy (electronic data)  
Electric data  
Annual No. 303  
Timing: week 4  
Finding: normal capacity  
\* Audit trail  
Due to description error, this finding was changed from No Finding to Consent Opacity on 03 April 2020 by Aline Yamazaki.

#### Items to be verified on CSV

<b>Concept</b>	<ul style="list-style-type: none"> <li>• When using a measurement device that can control a mobile device, the mobile device and the measurement device should not be validated separately, but they should be validated as one computerized system.</li> <li>• Requirements for that system include, but are not limited to:                             <ul style="list-style-type: none"> <li>→No access by unauthorized person during control using wireless communications</li> <li>→Data should not be stored in the mobile device.</li> <li>→It is not interfered with by other applications in the mobile device.</li> </ul> </li> </ul>
<b>Project: Verification</b>	<ul style="list-style-type: none"> <li>• It should be verified that the measurement equipment is controlled by an authorized user and not by an unauthorized user.</li> </ul>
<b>Operation: Change control</b>	<ul style="list-style-type: none"> <li>• Changes in the model of the mobile device that controls the measurement equipment should be handled in accordance with the change control procedure.</li> <li>• When installing a new application on that mobile, it should be verified that it is not affected by the change control procedure.</li> </ul>
<b>Points to be checked by QA personnel</b>	<ul style="list-style-type: none"> <li>• Control of mobiles for ensuring security</li> <li>• Change control procedures, including process for changing mobile device models or installing new applications</li> <li>• Confirmation of the operation according to the procedure</li> </ul>

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#### Items to be verified on CSV

<b>Concept</b>	<ul style="list-style-type: none"> <li>• Computer vision is used to convert the content recorded on paper into electronic data to create a true copy.</li> <li>• Corrected records containing a single or double line, will be converted into an audit trail.</li> <li>• After obtaining a true copy, the original paper records are discarded.</li> </ul>
<b>Project: Configuration and/or Coding in supplier</b>	<ul style="list-style-type: none"> <li>• After the handwritten records are collected and scanned, it is confirmed that the system can recognize letters to the same degree as a person.</li> <li>• If corrected on a single or double line, the original entry is legible and corrected entry is converted into an audit trail.</li> <li>• The types of available scanners should be identified.</li> </ul>
<b>Project: Verification</b>	<ul style="list-style-type: none"> <li>• It should be verified that the system provides adequate character recognition and audit trail creation when using the company's scanners.</li> </ul>
<b>Operation / Retirement</b>	<ul style="list-style-type: none"> <li>• Before the original paper records are discarded, QC checks should be made to ensure that the true copy is equivalent to the paper record. QC checks should be performed in accordance with the risk-based approach. For example, it may be possible to omit checking the handwritten records of preparers for whom authentic copies have been properly obtained in the past.</li> </ul>
<b>Points to be checked by QA personnel</b>	<ul style="list-style-type: none"> <li>• CSV records during project phase as well as those during operation and retirement phase</li> <li>• The risk-based QC checks before the original paper records are discarded</li> </ul>

#### Conclusions

We examined the applicability of the new ICTs to the GLP studies and the expected validation method. It was concluded that even a system using new ICTs would be validated by the conventional method in principle. However, there are some differences:

- For IoT-based systems, it is important to ensure security during wireless communications. In addition, it should be ensured that change control related to mobile devices is appropriate.
- Computer vision-based systems should be checked to ensure that true copies are properly made so that the original paper records can be discarded. This includes verifying that QC checks are properly performed at the time the original paper records are discarded.