# バイオアナリシスにおける監査の課題に関する検討
## Discussion on the Issues of Audit Activities for the Bioanalysis

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## Background and Objectives

### Background

- Japan Society of Quality Assurance (JSQA) has been considering the topic of 'Audit methodologies for clinical trial at laboratories' in the Joint Special Project Group 2 (KT-2). We have conducted surveys through a questionnaire for bioanalysis of clinical samples.
- The questionnaire results conducted by KT-2 were presented at the 7th, 8th and 9th JBF symposium.

### Objectives

- We conducted the questionnaire for the members of KT-2 to confirm current situation and audit correspondence in measuring pharmacokinetics (PK) and biomarker (BM) in clinical studies.
- In addition, the questionnaire covered for validation studies as well. Based on these results, we could see some challenges concerning audit of bioanalysis.

## Questionnaire Outline

- Target group: JSQA KT-2 (20 members)
- Period: October 23rd to December 4th in 2018
- Method: e-mail
- Answerer: 15 members
  (GCP division 8, GLP division 6, GQP/GVP/GPSP division 1)
- Question examples (see handout written in Japanese):
  - -Is PK study performed in-house or under contract
  - -Select important items to be checked in audit
  - -Select an audit method to check the items
  - -Select an audit section for PK or BM studies
  - -Select a section in charge of GCP training for analysts
  - -What is needed for the GCP training

## 1. Audit Viewpoints (1)

Question: Please select three important items to be checked in audit.

| Three or more counts in both PK and BM | PK | BM |
|---|---|---|
| • Analytical report (including validation report) | 8 | 6 |
| • Measurements (pretreatment, (re)analysis, calibration curve, QC, etc.) | 7 | 5 |
| • Analytical plan (preparation, amendment, deviation, etc.) | 3 | 4 |
| • Data analysis (peak treatment, calibration curve, accuracy, concentration, etc.) | 3 | 3 |

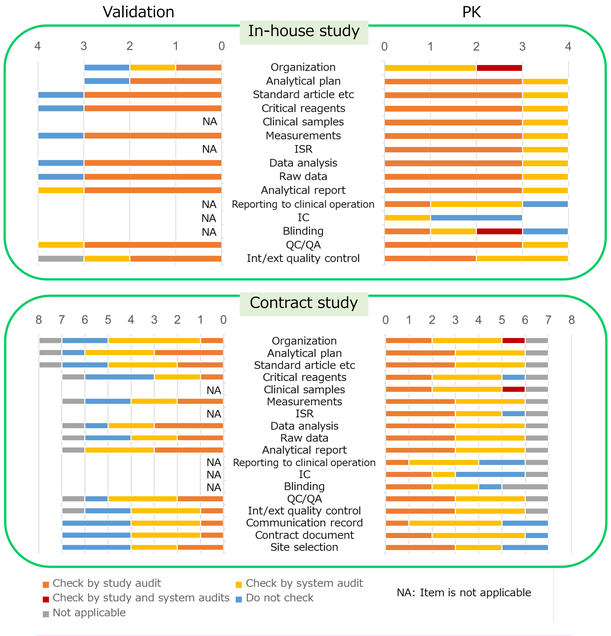
| Two or less counts in PK or BM | PK | BM |
|---|---|---|
| • Raw data (date, sign, correction, archive, etc.) | 7 | 1 |
| • Organization (designation of responsible personnel, training, etc.) | 5 | 2 |
| • Clinical samples (transport, storage, discard, stable period, etc.) | 2 | 2 |
| • Self QC, third-party QC, and QA | 2 | 0 |
| • Int/ext quality control (result of GLP inspection, check of equipment, etc.) | 1 | 2 |
| • Communication record with sponsor* | 1 | 0 |
| • Critical reagents (lot of antibody, etc.) | 0 | 2 |
| • Standard article etc. (transport, storage, discard, stability, etc.) | 0 | 0 |
| • ISR (process and result) | 0 | 0 |
| • Reporting to clinical operation | 0 | 0 |
| • Informed consent | 0 | 0 |
| • Blinding in double-blind study | 0 | 0 |
| • Contract document (contract period, personal information protection, etc.) | 0 | 0 |
| • Site selection* | 0 | 0 |

Count is total of in-house and contract studies
* Contract study

Important items were analytical report, measurements, analytical plan and data analysis.

## 1. Audit Viewpoints (2)

Question: Please select the closest method to check the following items in audit.




There was a trend that items checked by system audit or not checked increased in contract validation study.

## Considerations

### 1. Audit Viewpoints

- For PK, it focused on analytical report, measurements and raw data. This result was the same as the results in 2016 (at the 7th JBF symposium, in March 2016, PK, JSQA GLP division: 70 companies and JSQA GCP division:67 companies). As for the BM, it seemed to also focused on analytical report and measurements. However, the focus was not so much on the raw data.
- Regarding the audit items on the studies performed under contract, we could see the trend that the number of system audits and non-verifications were increasing compared to the studies performed internally. Besides, the important audit items were covered for all studies. In other word, it showed that it was conducted an audit for the items which focused on. This trend was same as on BM studies (refer to the poster P-28).

### 2. Audit Sections

- It looks like there are two types of audits in the studies performed under contract. One is to have division of labor (the auditing validation and clinical studies) between the nonclinical QA section and the GCP QA section. The other one is to collaborate with both sections on audit tasks. There is opportunity to improve efficiency of audit by investigating know-how about these audit structures.

### 3. GCP Training

- Multiple sections take charge of GCP training. The individual company has its own training and in some cases no trainings are conducted. The companies have different training policies for their analysts.

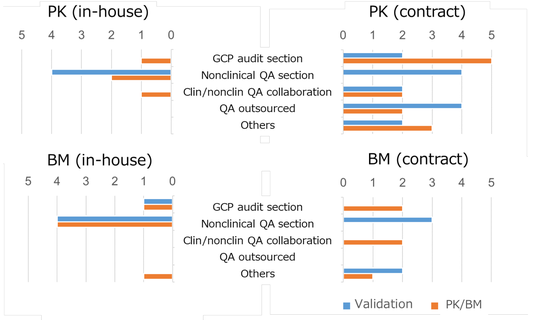
## ご協力ください！：ポスターアンケート

GCP教育について　どちらかひとつにシールを貼ってください
設問：分析担当者のみなさんにお尋ねします。
治験に関わるPKまたはBM測定を実施していて、GCP教育について勉強が不足していると感じたり、もっと教育をしてほしいと感じたことはありますか？

ある、YES　　ない、NO

## 2. Audit Sections

Question: Please select a section involved in audit for each study.




Nonclinical QA section was mainly involved in in-house study. In contract study, nonclinical QA section was involved in validation study and GCP audit section was involved in clinical study.

## 3. GCP Training

Question: Please select a section involved in GCP training for analysts. (multiple-choice allowed)

| Responsible sections | Count |
|---|---|
| Clinical section (also training CRA) | 2 |
| GCP audit section | 2 |
| Nonclinical QA section | 3 |
| Others (Nonclinical project management section, PK lab and the section responsible for other trainings , etc.) | 2 |
| Training is not done | 3 |
| Not applicable (having no analyst) | 3 |

Various sections were involved in GCP training for analysts.

Question: Please write down what is needed for analyst's GCP training. Key words are picked out from the answers and shown here.

- Human subject protection
- Informed consent
- Blinding
- Prohibition of use of clinical samples for other purpose
- Research ethics
- Outline of GCP ordinance
- Organization
- ALCOA
- Outline of ICH GCP (in a case of global study)
- Outsourcing contract
- Introduction/continuous training is needed

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https://www.jsqa.com/seikabutsu/society/

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