Data Reliability of QC-Lab.

Japan Pharmaceutical Manufacturers Association (JPMA)
Quality & Technology Committee
Hiroshi Fujie

JPMA Activity for Data Integrity

GMP Discussion Forum (2017)

- Role and Responsibility of QC-Lab.
  - Laboratory control including Data Integrity -

GMP Case Study Seminar

- Current topics and Case study of JPMA member company for Data Integrity (2016)
- Case study of Data Integrity activity at JPMA member's manufacturing plant (2017)

Data Integrity Working Team (2017-)

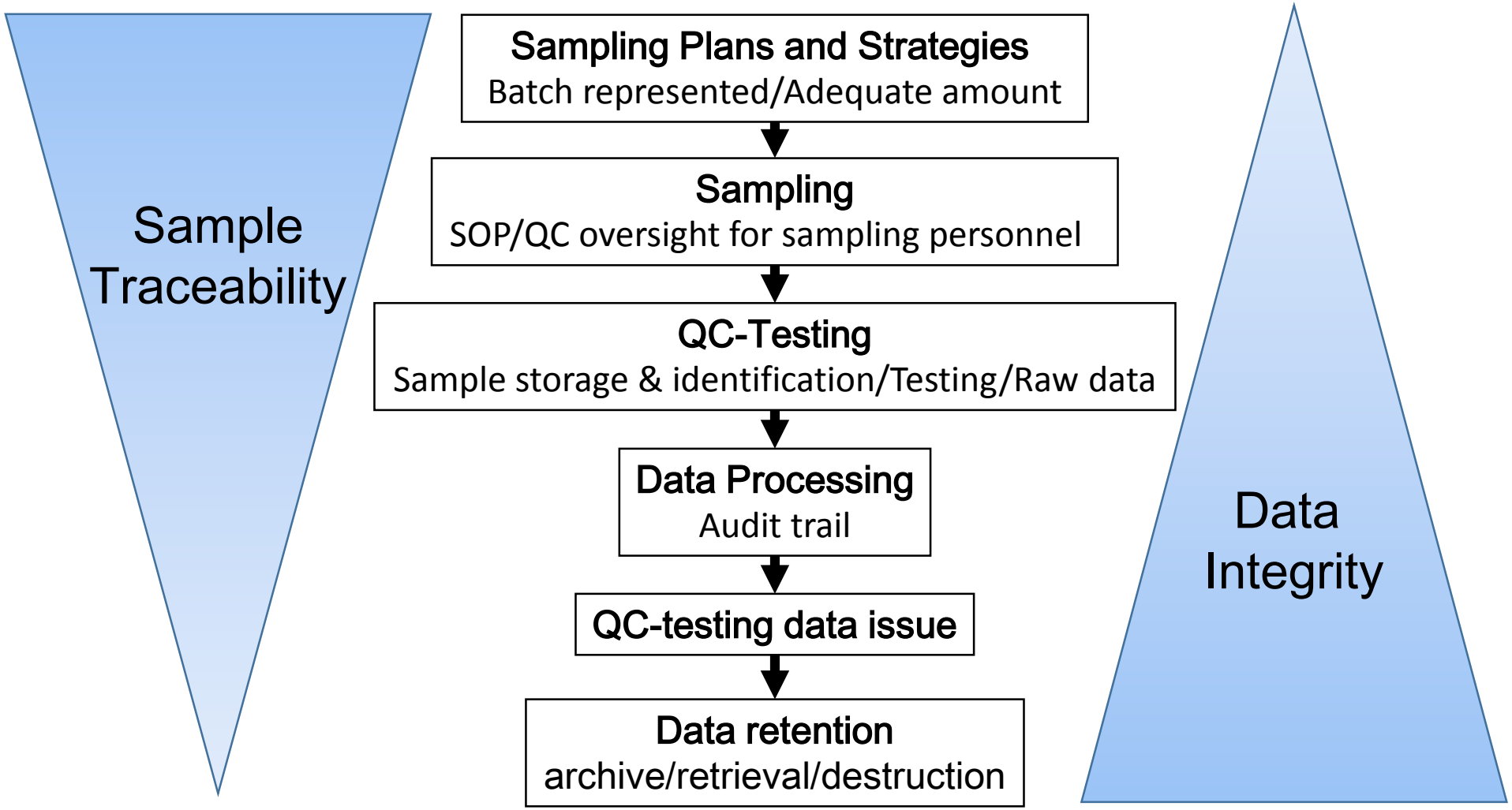
- 15 members are participating on the team to discuss how to implement Data Integrity at Japanese manufacturing sites

*1

- MHRA: GxP Data Integrity Definitions and Guidance for Industry
- WHO: Guidance On Good Data And Record Management Practices
- US FDA: Data Integrity And Compliance With cGMP
- PIC/S: Good Practices for Data Management and Integrity in regulated GMP/GDP Environments
- EMA: Q&A Data Integrity

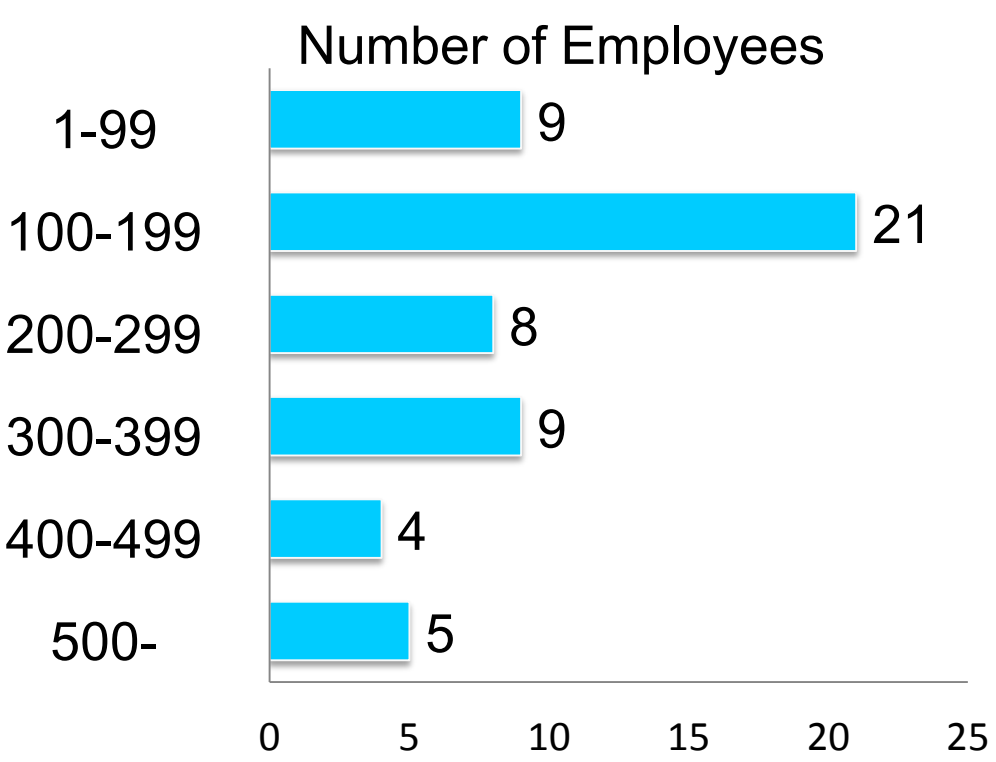
*1: GMP News, Vol.117, 2017, JPMA

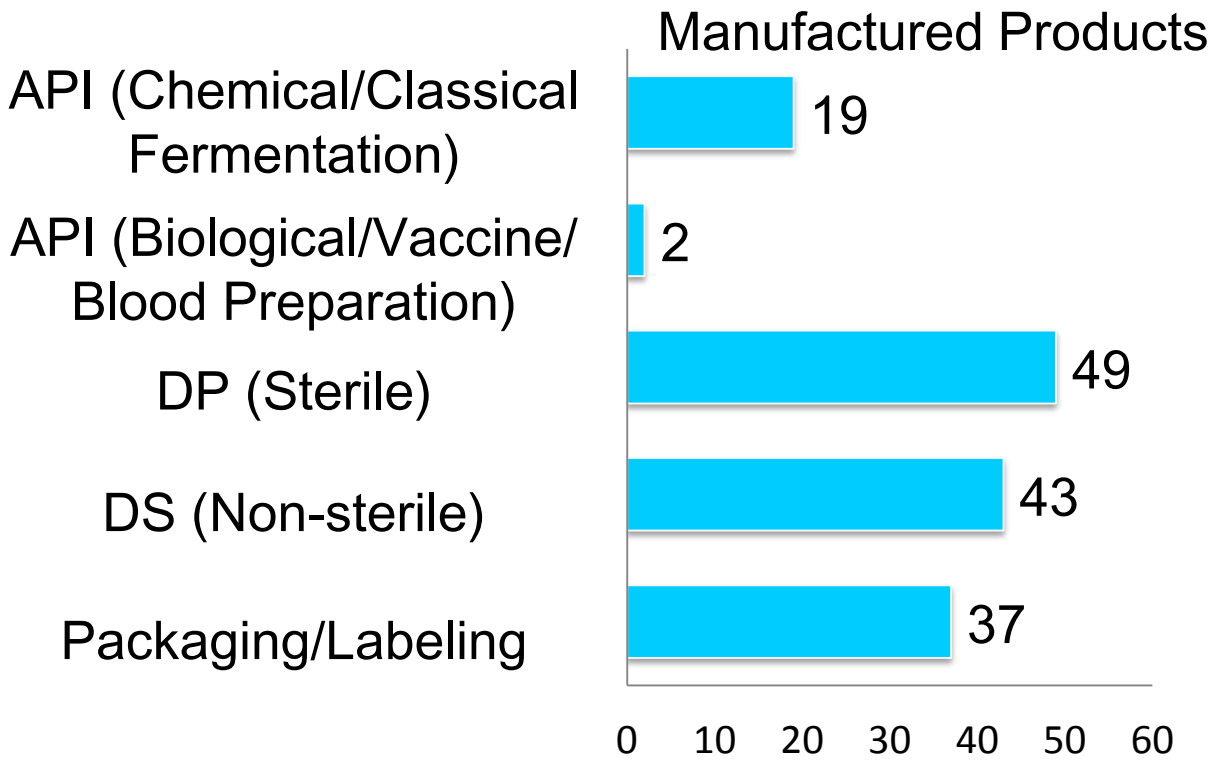
Data Reliability of QC-Lab.



GMP Discussion Forum
- Background of Data Integrity Survey -*1

- Questionnaire was sent to 72 members of JPMA Quality & Technology Committee.
- Analysis was conducted on responses from 56 respondents.



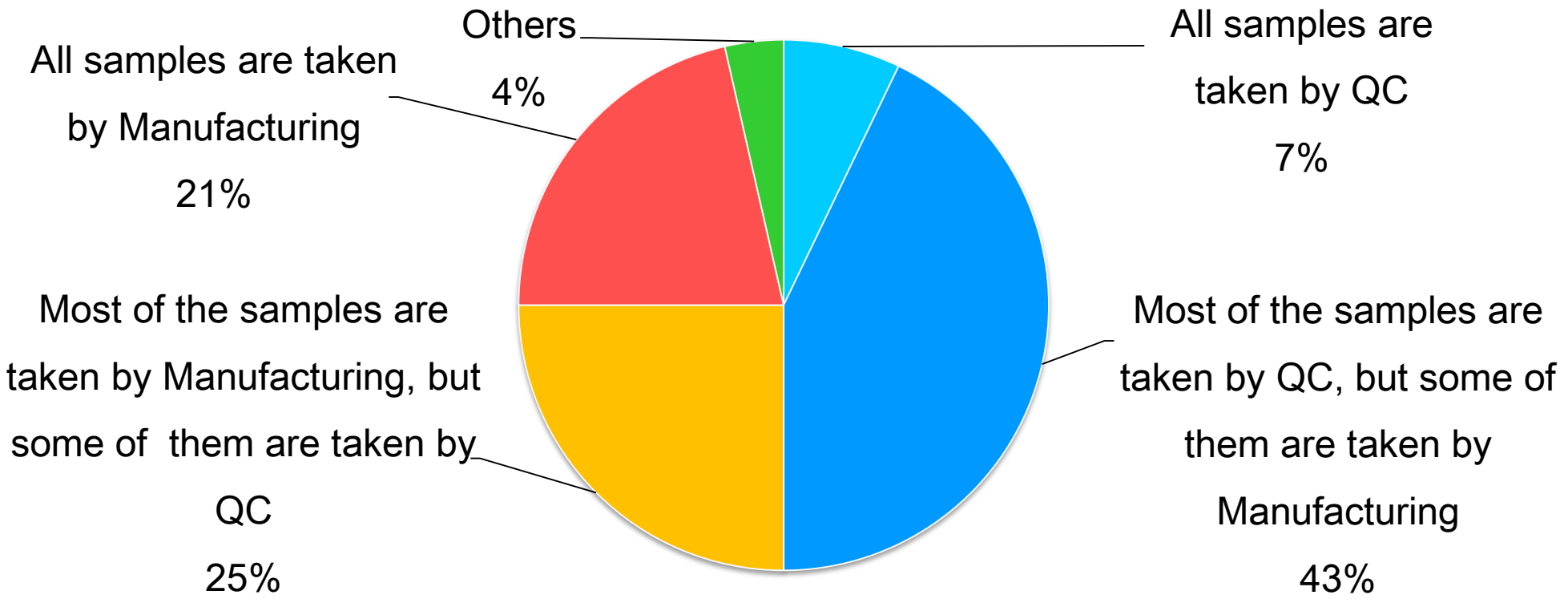


*1: 45th GMP Discussion Forum, JPMA, 3-Oct., 2017

Sample Traceability: Who carries out sampling at manufacturing area ?

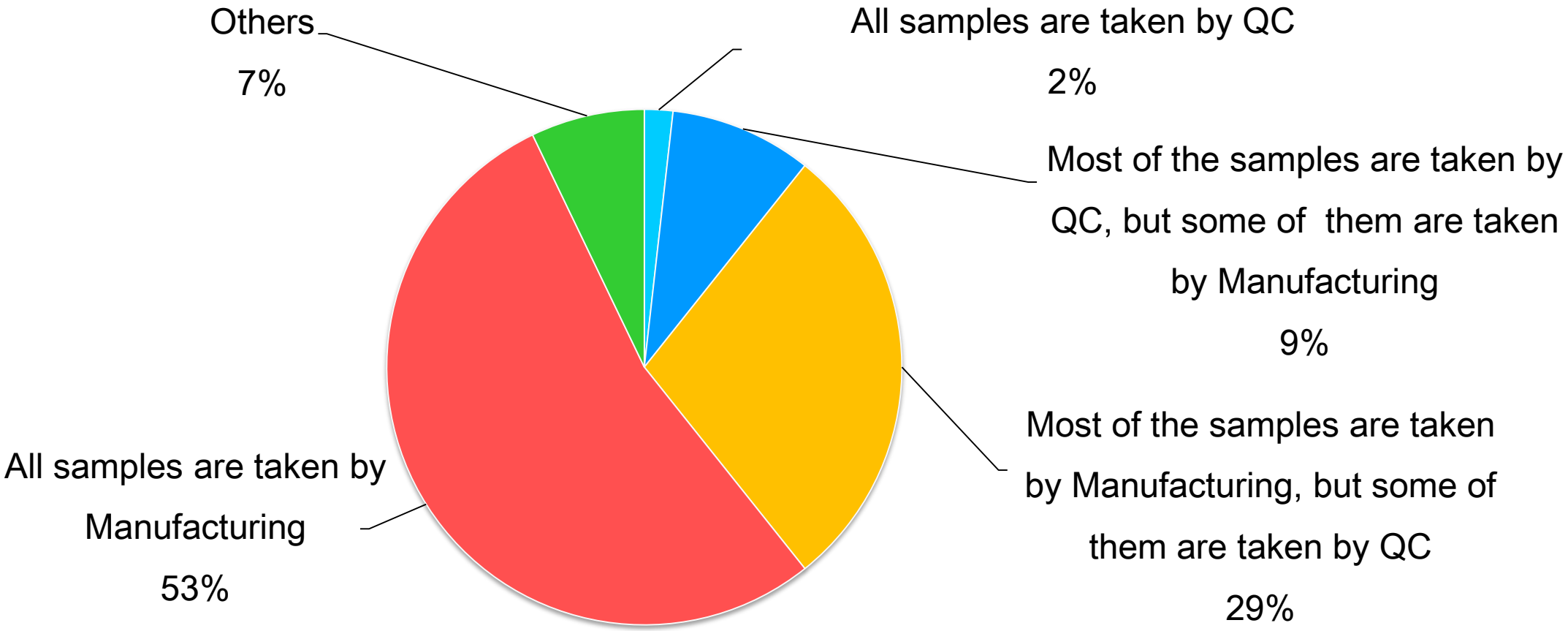
Product Release Test

(Bulk product / Finished product)



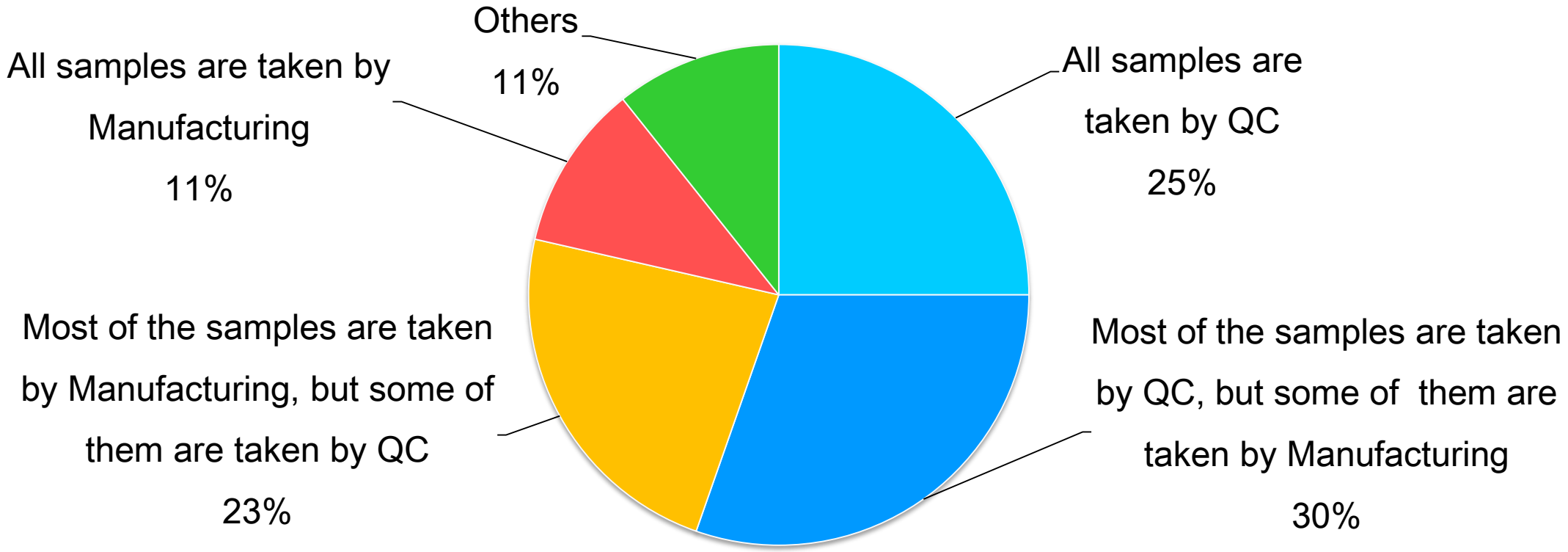
Sample Traceability: Who carries out sampling at manufacturing area ?

In-Process Test

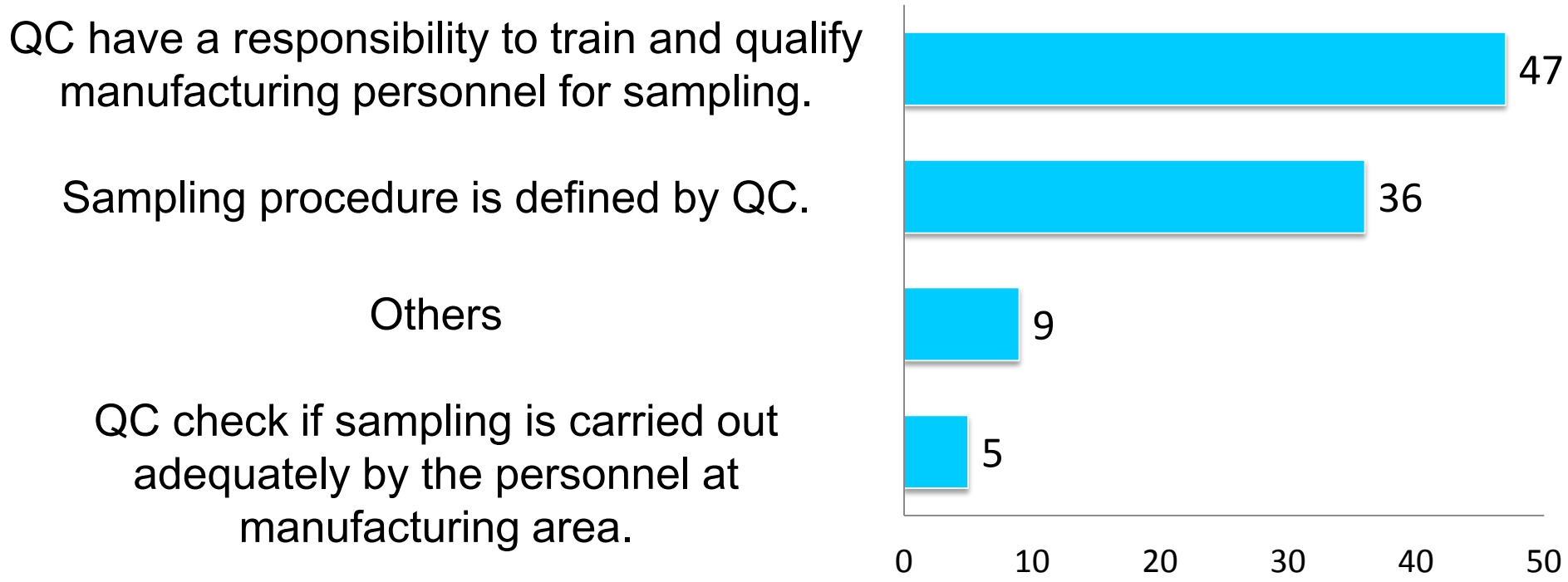


Sample Traceability: Who carries out sampling at manufacturing area ?

Water and Environmental monitoring Test

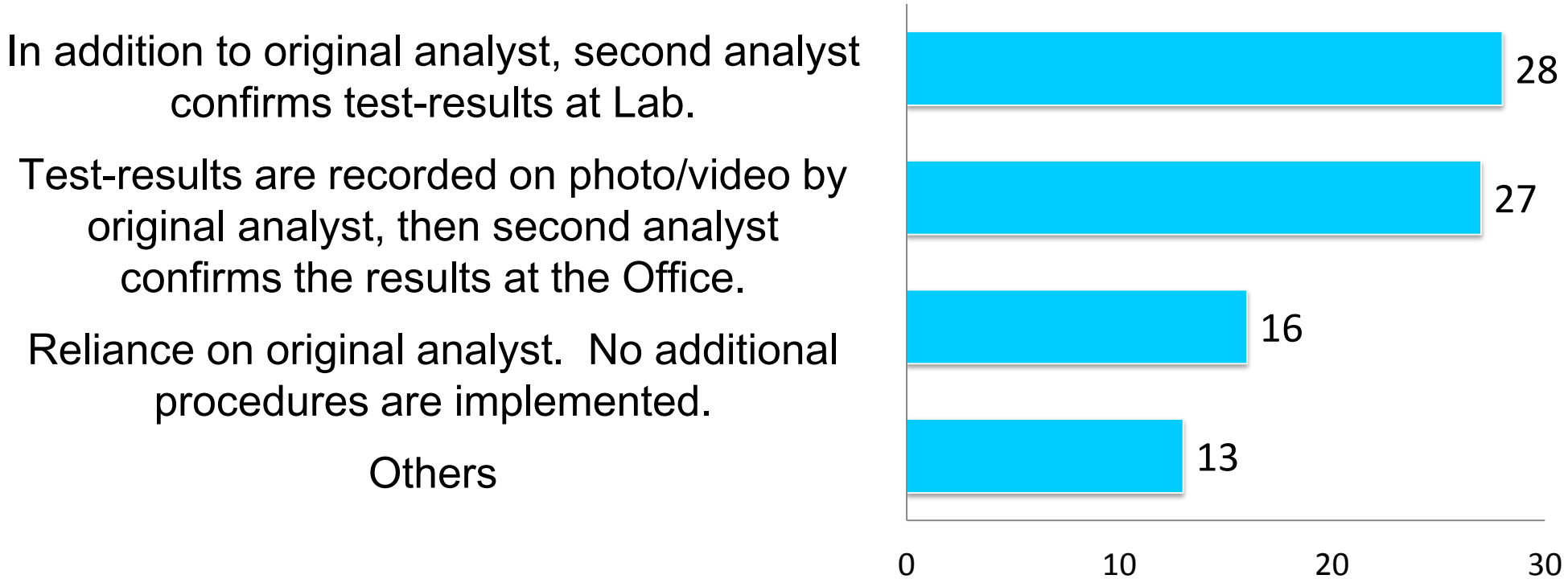


Sample Traceability: If QC doesn't carry out sampling, how to assure sample traceability.



Sample Traceability: How to assure the reliability of QC-test results that are judged visually by analyst.

- Some kinds of tests (Color reaction/Sterility/Bioburden/TLC/etc.), the results are not recorded automatically. Both judgment and recording of test results are done by single analyst.

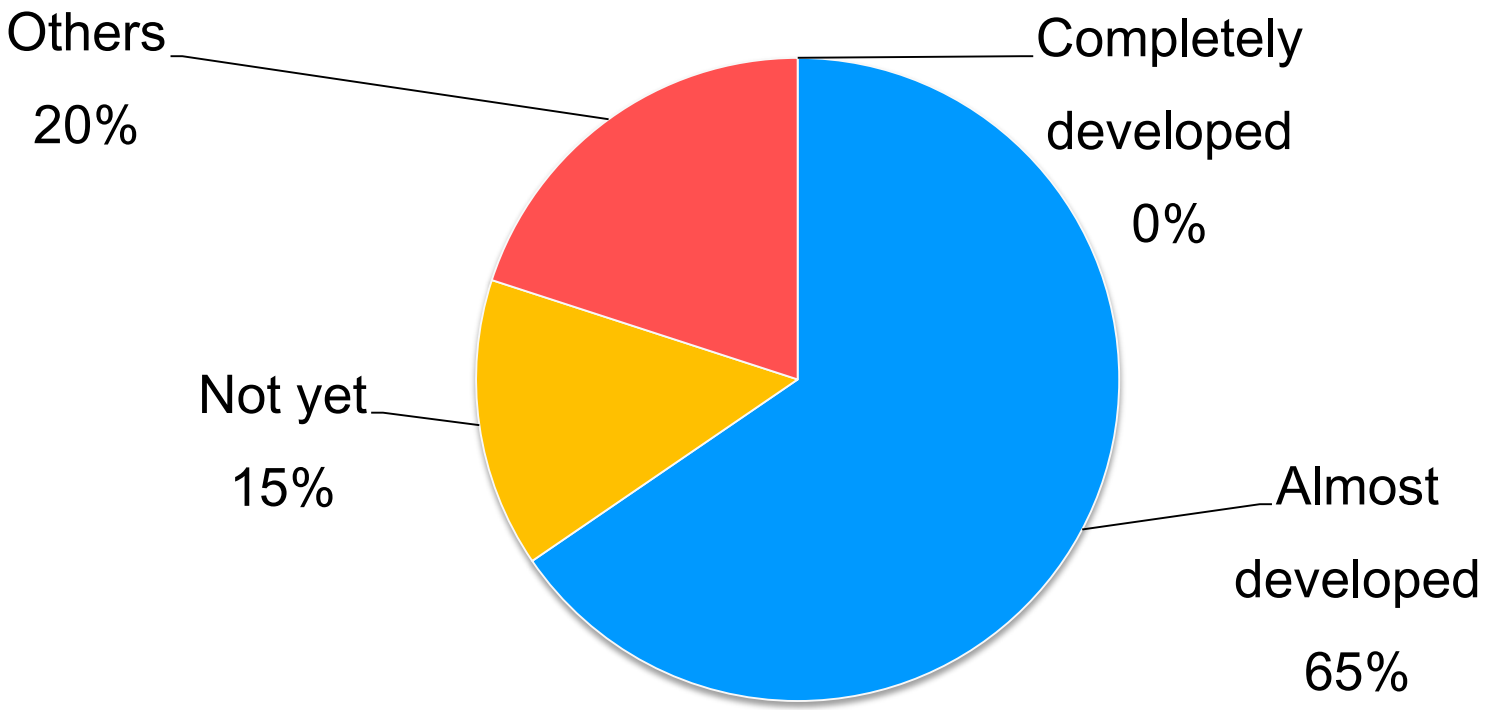


Sample Traceability: Summary

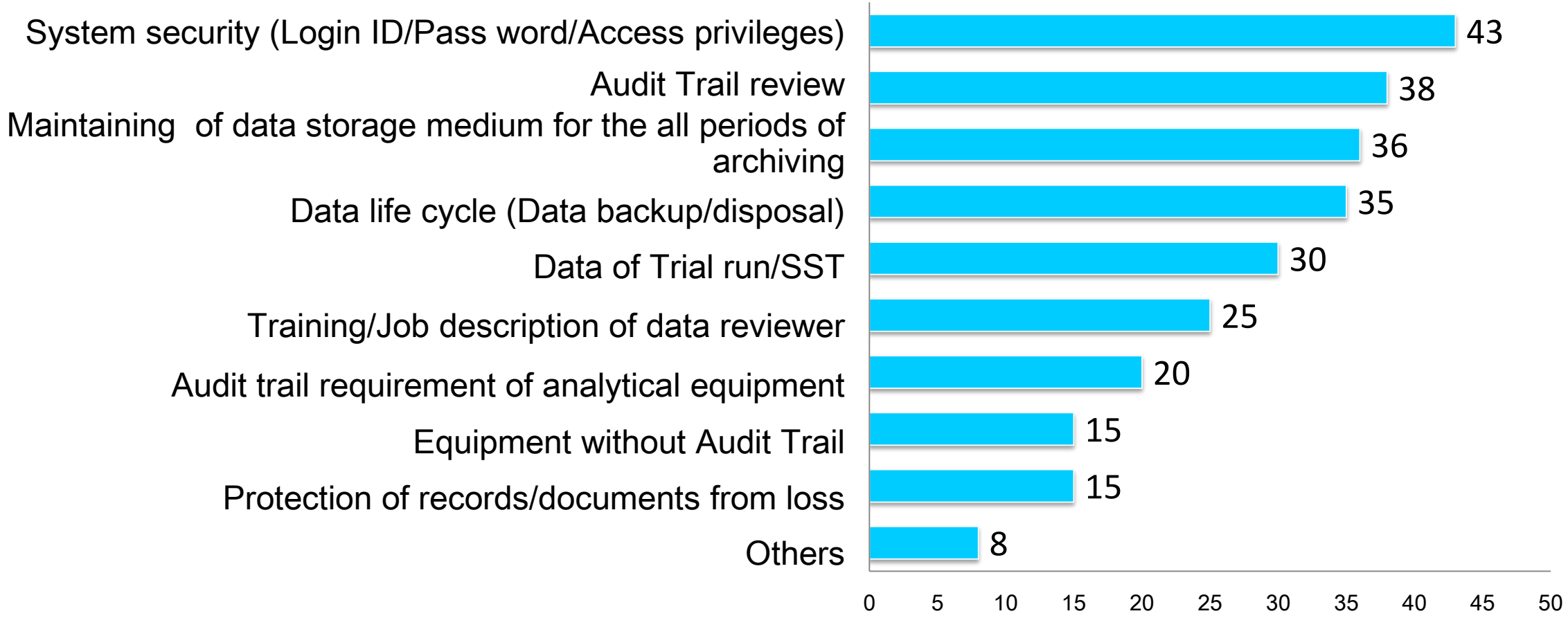
- JPMA member companies have strict sample traceability to assure the reliability of QC-testing data.
- Even if manufacturing personnel carry out sampling , sampling operation is fully under QC control.
  - Personnel who carry out sampling are trained and qualified by QC.
  - Sampling procedure is defined by QC.
  - QC check if sampling is carried out adequately by the personnel at manufacturing area.
- The reliability of QC-test results that are judged visually by analyst is adequately assured.
  - The risk of data falsification is low.

Data Integrity: Have you developed Standards or SOPs for Data Integrity at your site?

- Under development (7%)
- Some requirements are described in SOP, but higher level documents (e.g. - Standard) have not been developed (5%)

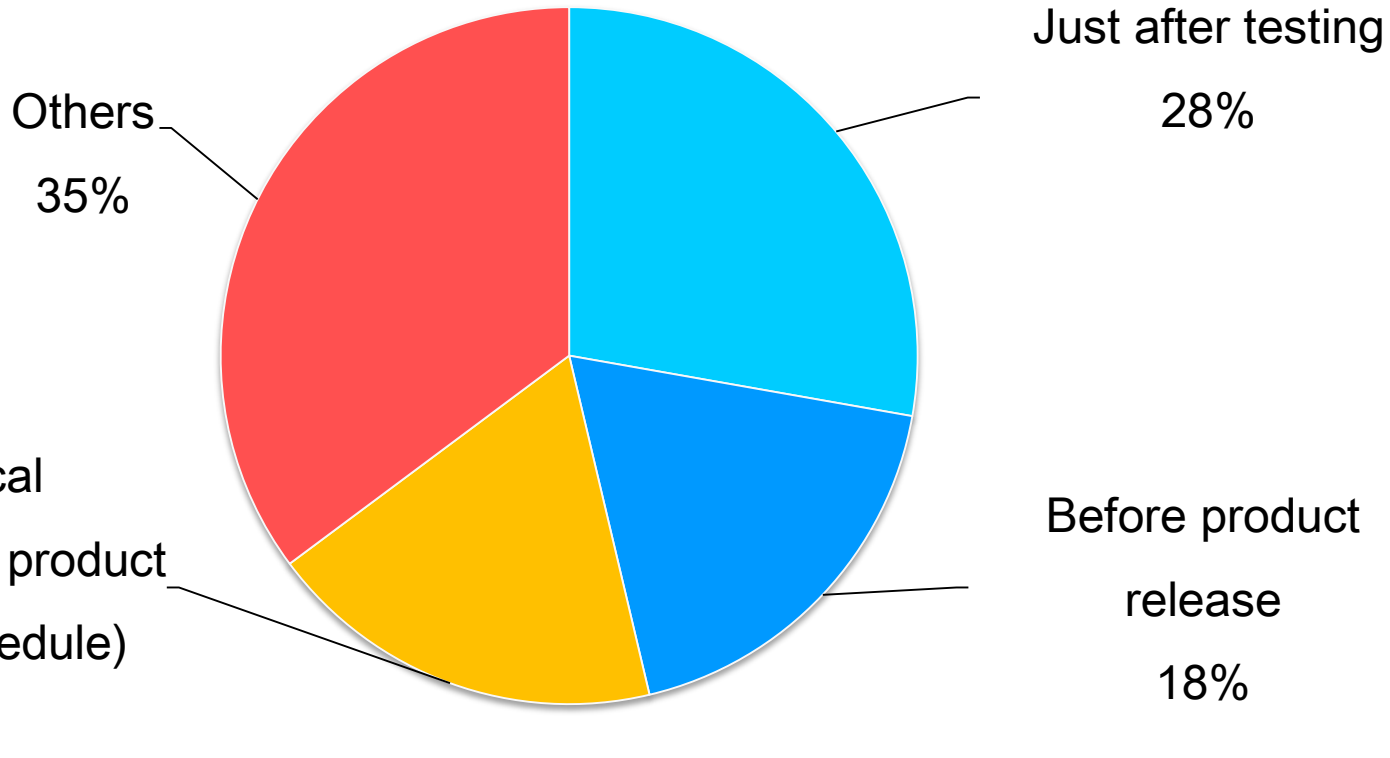


Data Integrity: What requirements are defined in your SOP?



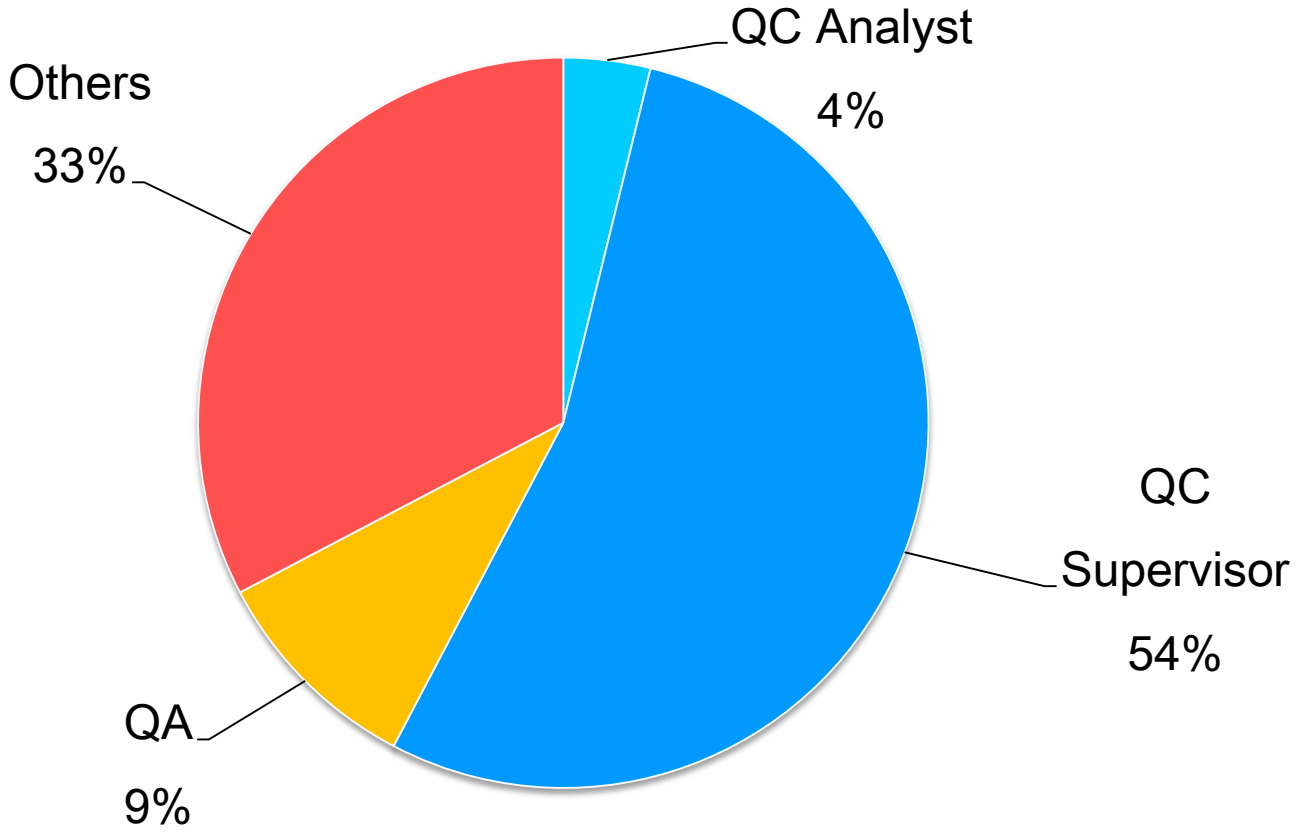
Data Integrity: When are Audit Trail reviewed?

- Depend on the product/equipment (11%)
- Not yet (5%)

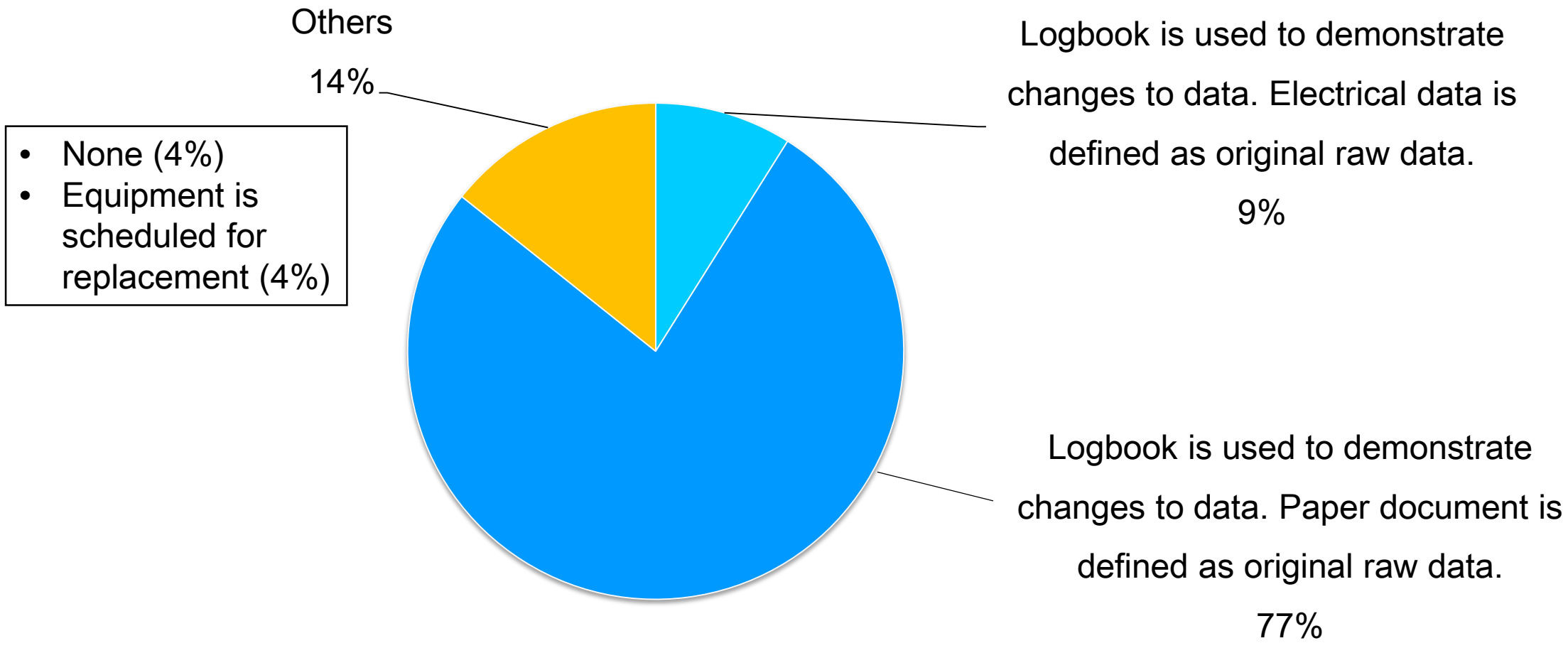


Data Integrity: Who reviews Audit Trail?

- Other QC (Data reviewer/IT/etc.) (7%)
- Two QC personnel (Supervisor/Manager/reviewer) (4%)

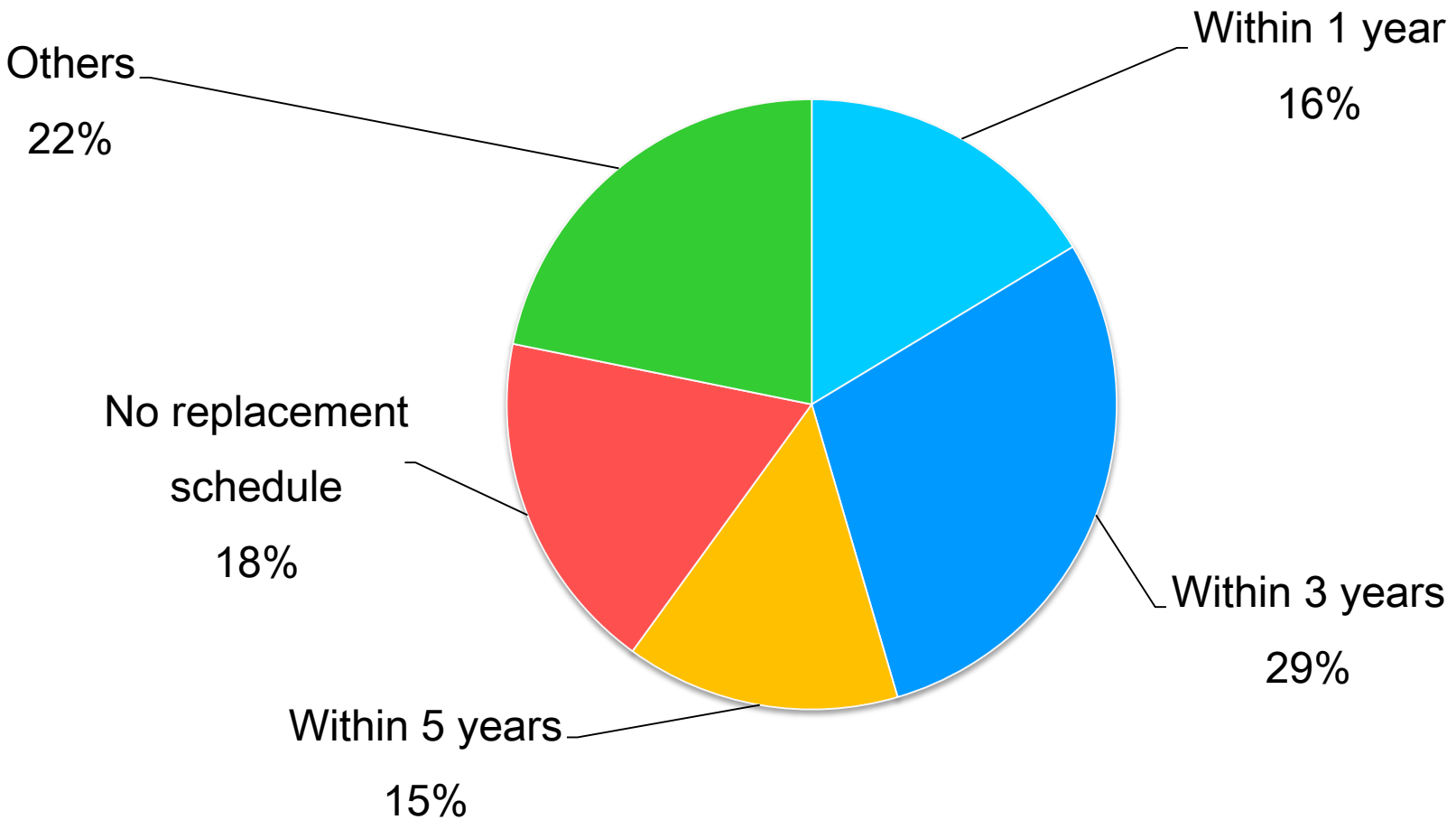


Data Integrity: For equipment without electronic Audit Trail, how to assure Data Integrity.



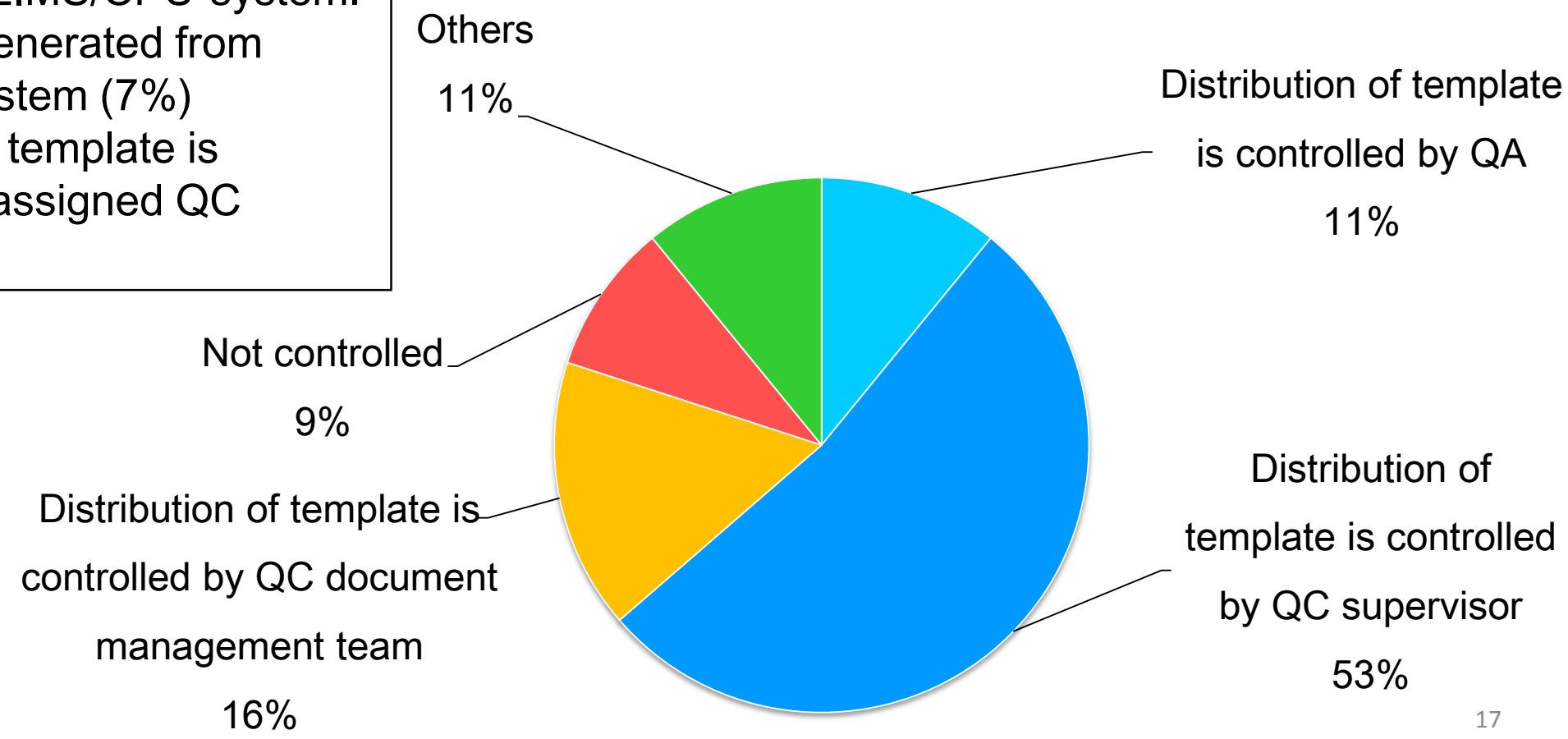
Data Integrity: When will major equipment without electronic Audit Trail be replaced?

- Replacement schedule is being considered (9%)
- Equipment without audit trail will be replaced based on equipment life cycle (5%)
- Replacement is completed (4%)



How to control paper template used for QC-testing.

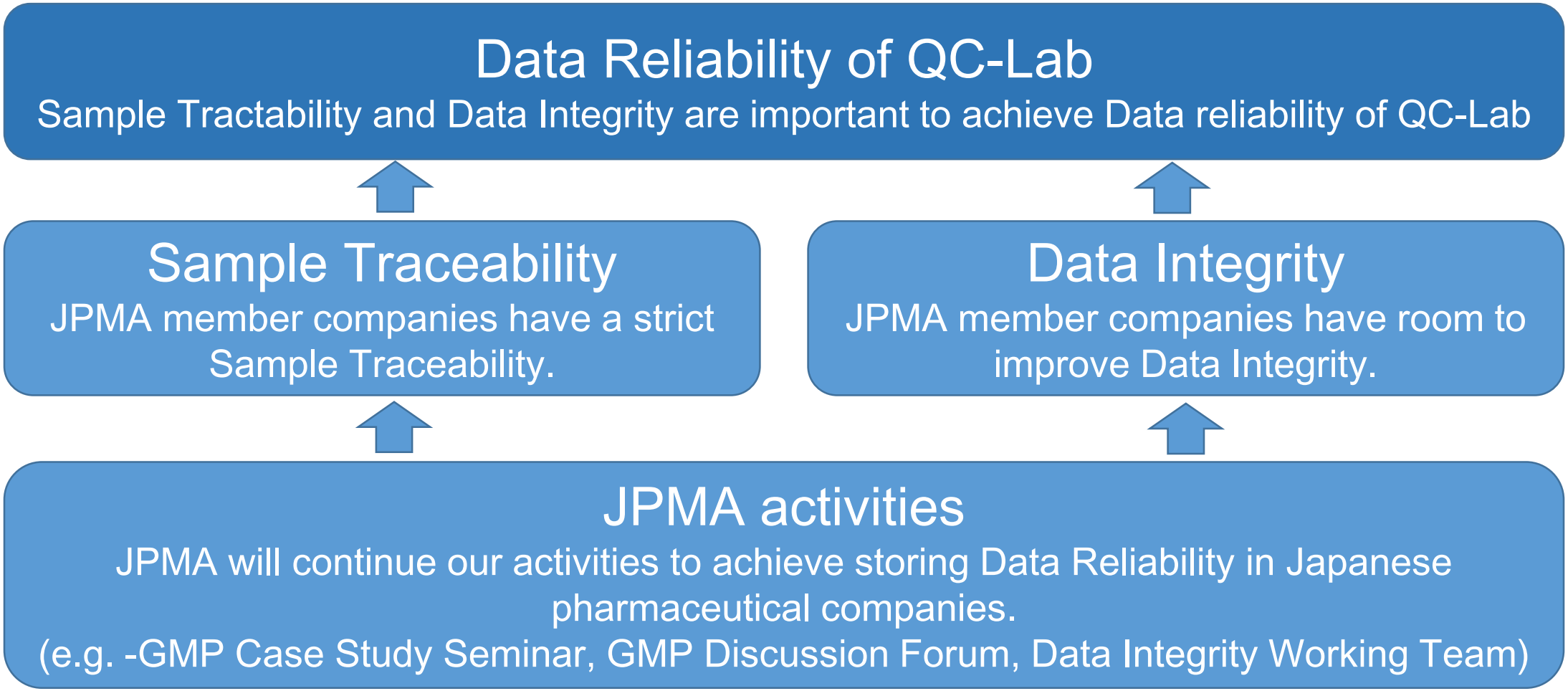
- Distribution of template is controlled by LIMS/CPU-system. Template is generated from LIMS/CPU-system (7%)
- Distribution of template is controlled by assigned QC people (2%)



Data Integrity: Summary

- The JPMA member companies have been working on Data Integrity, but we have room for improvement regarding Data Integrity requirements.
- Most companies have developed Standard/SOP for Data Integrity but the contents vary according the organization.
- Most companies have developed procedures for Audit Trail reviews, but reviewers and review timing vary according the organization.
- For equipment without Audit Trail, most companies use logbook to demonstrate changes to data, but 20% companies have no defined schedule of equipment replacement.

Conclusion


Data Reliability of QC-Lab
Sample Tractability and Data Integrity are important to achieve Data reliability of QC-Lab
Sample Traceability
JPMA member companies have a strict Sample Traceability.
Data Integrity
JPMA member companies have room to improve Data Integrity.
JPMA activities
JPMA will continue our activities to achieve storing Data Reliability in Japanese pharmaceutical companies.
(e.g. -GMP Case Study Seminar, GMP Discussion Forum, Data Integrity Working Team)