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To whom it may concern

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Request for Advice and Interpretation on the OECD No. 22 Advisory Document on GLP Data Integrity

In section 6 of the respective document, the ALCOA+ requirements are introduced as a general basis to ensure data integrity e.g., for manual hardcopy recordings. It´s subsequently be highlighted that „The number of used templates compared to the number of available copies should be controlled to avoid duplication and to support the identification of data integrity issues".

For study-based data documentation, the study director may be responsible to control the availability of applicable templates or forms e.g., by documenting the number of copies and the printing date.
Besides the GLP study personnel, also the GLP Quality Assurance (QA) personnel produces e.g., study-based and facility-based inspection data, which – at least in small test facilities – are still documented on controlled hardcopy templates or forms.
In the light of OECD No. 23 Quality Assurance and GLP, one could come to the conclusion that the Test Facility Management (TFM) may be responsible to control the availability of such hardcopy templates or forms.
Furthermore, the Quality Assurance program is subject to TFM verification, e.g. by performing regular inspections of the QA activities, which may be documented on templates or forms made available to the TFM.

In large GLP test facilities there may be electronic systems in place performing control and reconciliation through automated procedures.
However, small test facilities often can not afford such cost-extensive electronic systems.

Questions:

1. Who should control and reconcile hardcopy templates and forms made available to the QA personnel e.g., for performing inspections? If the TFM should control and reconcile: Given the workload and responsibilities the TFM should cope with, could it alternatively be acceptable that this task can be delegated within the QA unit?
2. Who should control and reconcile hardcopy templates and forms made available to the TFM e.g., for QA program verification?

Thank you for your advice and interpretation 😊

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