

GOOD LABORATORY PRACTICE (GLP)

POSITION PAPER regarding:

Is it acceptable to destroy the paper originals of raw data and related study documentation, if an image of the paper is captured in an electronic form (e.g. scanned)?

Working Group on Information Technology (AGIT)

Position Paper 1

Release Date: October 2, 2014

Topic:

Is it acceptable to destroy paper originals of raw data and related study documentation (excluding the final report), if the image of the paper is captured in an electronic form (e.g. scanned)?

Position: Yes, if all requirements below are fulfilled

Rationale:

Verified paper copies are equivalent to raw data on paper. When a thermal print-out is photocopied, the photocopy must be verified for accuracy and completeness and confirmed with dated signature. Once this is completed, the thermal print-out is discarded. The same principles apply to verified electronic copies of paper raw data. This is consistent with the OECD principles [1], section 2.3. paragraph 7.

Background:

OECD Doc. 1 [1]: Acceptance of verified copies as raw data

OECD Doc. 10 [2]: Handling of electronic raw data

OECD Doc. 15 [3]: Requirements for electronic archiving

Requirements:

1. The electronic copy should preserve the accuracy, completeness and content of the original paper data

Accuracy

The electronic copy should be an accurate reproduction of the original paper data. Therefore, the resolution of the electronic form should match the quality of the paper data. For pictures, plots and graphs, a higher scanning resolution may be necessary than for text. The color balance of the electronic copy should also match the color range of the data on paper.

Completeness

The electronic copy should be a 100% match of the data on paper. Therefore special attention should be paid to possible annotations on the margins of the paper data, hand written entries, ink color, shaded areas, one sided or two-sided paper originals etc. The completeness may also be jeopardized by stapled slips of paper, original paper size exceeding the scanning area, etc.

Content

The content of the electronic copy should be identical to that of the original paper data. Pictures in electronic form should display the same content and allow the same interpretation as the original.

2. The scanning process should be established developed and validated; it should result in a non-editable image or reproduction of the original paper data

The scan process should be validated regarding readability, resolution, contrast and color balance, page size, counting of pages, error handling etc. The scan process should produce a read-only image file, in a non-editable form.

In case a search function is desirable, an additional file obtained by Optical Character Recognition (OCR) can be generated. This file is not considered as raw data.

The validated work-flow should be defined in an SOP which describes the responsibilities, the scanning process and its parameters, the verification process including electronic signature, the security and inventory of the electronic copies, destruction of paper originals, and the documentation of all activities.

3. Each individual scanned page should be verified

Each individual scanned page should be compared with the original paper and be checked for accuracy, completeness, and content. This 100% check should be documented by signing electronically the electronic file containing the scanned paper data.

4. The electronic copies should be stored to fulfill the requirements of electronic GLP archiving

Archiving and storage should be operated and maintained in compliance with GLP. Therefore, data archiving/storage should fulfill requirements for electronic GLP archiving ([2], [3], [4]).

5. Disposal of original paper data should be documented

Discarding the original data should be documented.

The sponsor should be informed previously about the scanning process and subsequent discarding of the paper data for his studies.

Critical issues:

Legal requirements may vary from country to country. Before implementing such a process, make sure that the applicable local legal regulations are met.

Recommendations:

It may be appropriate to keep the paper originals until the final report has been signed.

It is recommended that raw data and study related documents generated in an electronic form, e.g. digital photos, study plan, are handled and archived as electronic data, according to the respective guidelines (see point 4).

References:

- [1] OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring No. 1: OECD Principles of Good Laboratory Practice (as revised in 1997). Environment Directorate, OECD, Paris, 1998.
- [2] OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring No. 10: GLP Consensus Document. The Application of the Principles of GLP to Computerised Systems. Environment Monograph No. 116; Environment Directorate, OECD, Paris, 1995.
- [3] OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring No. 15: Advisory Document. Establishment and Control of Archives that Operate in Compliance with the Principles of GLP. Environment Directorate, OECD, Paris, 2007.
- [4] Working Group on Information Technology (AGIT), "Good Laboratory Practice (GLP); Guidelines for the Archiving of Electronic Raw Data in a GLP Environment", *Qual Assur J.* 2003; **7**, 262–269.

WORKING GROUP ON INFORMATION TECHNOLOGY (AGIT)

The Working Group on Information Technology (AGIT) was founded on 27 March 1998 with the objective of discussing relevant problems of Good Laboratory Practice (GLP) in the field of information technology between industry and the monitoring authorities.

The AGIT intends to set up guidelines and position papers based on legislative requirements and practical experience to support test facilities introducing information technology tools to computerised systems in practice. OECD Consensus Document number 10 on the application of the principles of GLP to computerised systems is used as a basis for the discussions.

This position paper reflects the view of AGIT and should not be considered as legally binding.

For the convenience of users, AGIT publications are available on the Swiss GLP Home Page www.bag.admin.ch/agit

Furthermore, links and references to guidelines, laws and regulations, definitions, relevant literature, training courses, workshops etc. are given on the Swiss GLP Home Page.