OECD Working Group on Good Laboratory Practice

Template for submission of comments on draft GLP Guidance Documents

Instructions for Use

1. First, please complete the table below giving the full name of the draft document and your name and contact details. Comments received without the identity of the submitter may not be considered by the Working Group.

Full Name of Document:	**Draft Advisory Document of the Working Group on Good Laboratory Practice on GLP Data Integrity**

Submitter's Name:	**Carol Winfield on behalf of ISPE**
Position in Organisation:	**Sr. Director Regulatory Operations**
Organisation / Affiliation:	**International Society for Pharmaceutical Engineering (ISPE)**
Address	**6110 Executive Blvd., Suite 600, N. Bethesda, MD 20852**
Country / Economy	**United States**
Email:	**regulatorycomments@ispe.org**

Date:	**14 September 2020**

2. Second, insert your comments into the template attached using the following instructions:
   (i) Go into the header of the template and enter the full name of the document. This will ensure this critical information appears on each page.
   (ii) Column 1: Please enter a commonly accepted two or three letter abbreviation code for your country or economy. Do this for each comment. This information is critical for the Working Group to collate and review comments and to assist in identifying the source of the comment.
   (iii) Column 2: Please enter the line number (or paragraph number and line number within the paragraph, depending on how the document is presented) of the text you wish to comment on.
   (iv) Column 3: Please include your comment (including the affected text if appropriate), along with any justification.
   (v) Column 4: Please indicate what change you would like to make to the text as a result of your comment. Where relevant, please provide any proposed new wording.
   (vi) Column 5: This is for OECD WG use only.

3. Finally, once completed, please forward your comments to the appropriate authority (see Instructions)

Thank you for your contribution to the work of the OECD Working Group on Good Laboratory Practice.

OECD Working Group on Good Laboratory Practice: Template for submission of comments on draft documents	
Full Name of Draft Document:	Draft Advisory Document of the Working Group on Good Laboratory Practice on GLP Data Integrity

1	2	3	4	5
Country[1]	**Line No(s). / Para No. & Line No(s)**	**Comment (justification for change)**	**Proposed change**	**OECD GLP WG Use Only: WG reviewer(s) comments**
AU	Line 30 / 2.3	Pleased to see discussion and clarification around data quality vs. integrity	none	
AU	Line 30 / 2.3	We suggest defining data integrity based on the terms already defined in ALCOA. “Trustworthy” and “reliable” are not defined.	Remove “trustworthy and reliable.”	
AU	Line 125 / 4.6	Risk (for example in according to GAMP5 and when using other risk management tools such as FMECA)) is normally defined as severity x occurrence x detection. Impact (severity) is therefore inherent in the risk and does not need to be separately called out.	commensurate with the risk ~~and impact~~ of a data integrity failure.	
AU	Line 182 / 5.3	The meaning of “faithful transcription” is not clear.	Please replace “faithful transcription” with either “**generating true copies**” or “**generating static copies**” depending upon the intended meaning.	
USA	Line 185 / 5.4	We suggest specifically mentioning interaction with other systems as it aligns well with the human intervention statement.	It is expected to consider not only the computerised system in isolation but also **interfaces to other systems up-stream and down-stream and** all supporting activities and functions such as: guidance, process, human intervention, training and quality systems.	
USA	Line 202 / 6.1	We suggest adding approved or pre-approved and rephrasing the sentence for better flow and clarity.	Access to **controlled, approved, or pre-approved blank paper proformas for raw/source data recording should be used where this is appropriate**. Reconciliation, or the use of controlled books with numbered pages, may be necessary to prevent recreation of a record.	
NL	262 / 7.1	What is meant by ‘full’ audit trail is unclear. When that is ‘all the captured audit trails’, then it is fine.	Computerised system design should always provide for the retention of ~~**full**~~ audit trails to show all changes to the data without obscuring the original data.	
UK	263 / 7.1	Current text: “It should be possible to associate all changes to data with the persons having made those changes, for example, by use of timed and dated (electronic) signatures.” In practice, only a minority of such changes will have regulated electronic signatures associated with them. Most will be changes performed according to technical and procedural controls and recorded in a data audit trail or equivalent without an associated electronic signature.	“It should be possible to associate all changes to data with the persons having made those changes, for example, by use of **data audit trail or equivalent mechanisms, or where appropriate and necessary** by use of timed and dated (electronic) signatures.”	

NB Columns 1, 2, 3, 4 are compulsory

1 **Country** = Please use commonly recognised two or three letter code and place against each comment

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NL	278 / 7.2	The meaning of this sentence is unclear: "Where data are generated as a result of direct computer input (e.g. typing a value) by an individual then this should be identified at the time of data input by the person responsible for the entry."? Can this be explained, or is this just the capturing of the audit trail?	Since the intent of the sentence is hard to understand, we find it difficult to offer a better suggestion.	
AU	Line 303 / 7.4	Audit trails are metadata and must be integral to the original record.	We suggest adding a sentence at the end of the paragraph **"Audit trails to data are part of the associated metadata."**	
AU	Line 316 / 7.5	We suggest defining data integrity based on the terms already defined in ALCOA. "Trustworthy" and "reliable" are not defined.	Remove "trustworthy and reliable."	
UK	Line 372 / 7.9	Current text: "The selected method should ensure that data of appropriate accuracy, completeness, content and meaning are collected and retained for its intended use. Systems that generate dynamic data should allow the dynamic nature of the data to be retained. Retention of static (printed/manual) data generated from dynamic data is not appropriate." There could be occasions when retention of static data is an accurate record of dynamic data.	"The selected method should ensure that data of appropriate accuracy, completeness, content and meaning are collected and retained for its intended use. Systems that generate dynamic data should allow the dynamic nature of the data to be retained. Retention of static (printed/manual) data generated from dynamic data is not appropriate **if the accuracy, completeness, content and meaning required for its intended use is not preserved."**	
USA	Line 381 / 7.9	We suggest adding "approved" and "pre-approved" and rephrasing the sentence for better flow.	If used, **controlled, approved, or pre-approved** blank forms (including, but not limited to, worksheets and laboratory notebooks) should be controlled by documented procedures.	
USA	Line 413-416 / 7.11	We suggest this section should include a statement that processing data should be objective and possibly provide instructions and limitations, for example, chromatography integration. We suggest a sentence to be added at the end of the paragraph	There should be adequate traceability of any user-defined parameters used within data processing activities to the raw data, including attribution to who performed the activity examples include the selection and application of chromatography integration parameters or selection of gating parameters for analysis of a flow cytometry assay. **There should be defined procedures for processing data.**	
UK	Line 425 / 7.12	We suggest that this section explicitly mention the exclusion of data.	"Data may only be invalidated **or excluded** where it can be demonstrated…. "	
USA	Line 432 / 7.13	We suggest changing "retained and reported" to "retained and accounted for"	All data (even if invalidated) should be retained and ~~reported~~ **accounted for** with the original data set and be available for review in a format that allows the validity of the decision to exclude the data to be confirmed.	

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AU	Line 449 / 7.13.1	An example of a static electronic record would be helpful.	Add example of static electronic record.	
AU	Line 515 / 7.13.2	Printing is not the only mechanism; static electronic records would achieve the same end	Replace 'printed records' with '**the static records'**	
AU	Line 520 / 7.14	Transcription can also be the manual entry (by typing) of data from a written record into a computerized system.	Suggest revising the first sentence: "Transcription is the **manual recording of data into an original record or the manual entry of data from the original record into a computerised system."**	
UK	Line 554 / 7.16	Suggest this section be renamed to and use the more specific term "data audit trail" to distinguish this usage from the many other uses of the very general term "audit trail". This is consistent with the use of data audit trail by MHRA and ISPE "GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems." (ISPE, 2008)	Replace "Audit Trail" with "Data Audit Trail."	
UK	Line 573 / 7.16	Current text: "Where a system administrator amends or switches off the audit trail functionality, the audit trail should record this automatically recording any changes made." In practice, this may be recorded by other means rather than in the audit trail itself.	"Where a system administrator amends or switches off the audit trail functionality, **this should be recorded or logged using an appropriate mechanism**."	
AU	Line 616 / 7.17	Suggest adding a bullet point related to time	• **How the time and date of the signature will be recorded along with the username and meaning of the signature.**	
AU	Line 739 / 7.21	Backup does not make provision for sourcing alternative computer equipment – that is Disaster Recovery	Consider alternative text and make it a sentence "**Provisions should be made for the recovery of data files or software, or for the restart of processing. In the case of the use of alternative computer equipment following a system failure or disaster, disaster recovery procedures should be followed**.	
UK	Line 746 / 7.21	Current text: "Each back up should be verified to ensure that it has functioned correctly e.g. by confirming that the data size transferred matches that of the original record." This is not always possible or practical	Consider replacing current text with: "**Mechanisms for ensuring that backups have completed successfully should be considered"**	

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