OECD Working Party 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 Party.

Full Name of Document:	**Draft OECD Advisory Document No.17. Supplement No. 1: GLP and Cloud Computing**

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Date:	**06 July 2022**

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. Also include the name and affiliation of the person sending the comments. This information is critical for the Working Party to collate and review comments and to assist in identifying the source of the comment.
   (iii) Column 2: Please enter the section number of the location of the text you wish to comment on.
   (iv) Column 3: Please enter the line number(s) of the text you wish to comment on.
   (v) Column 4: Please include your comment (including the affected text if appropriate).
   (vi) Column 5: Please indicate what change you would like to make to the text as a result of your comment, along with any justification. Where relevant, please provide any proposed new wording.
   (vii) Column 6: This is for OECD WP 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 Party on Good Laboratory Practice.

OECD Working Party on Good Laboratory Practice: Template for submission of comments on draft documents	
Full Name of Draft Document:	Draft OECD Advisory Document No.17. Supplement No. 1: GLP and Cloud Computing

Name of person sending comments, affiliation & Country	Section	Paragraph number	Reviewer Comment	Proposed amendment and Justification	Opinion of the responsible GLP CMA about the comment (WP GLP Use only)
International Society for Pharmaceutical Engineering (ISPE) **Global with headquarters in US**	General	General	The document should discuss additional requirements with respect to geographic location/storage of data and local laws.	Some introductory or background text would be helpful to highlight that there could be different regional requirements for, e.g., general data protection regulation (GDPR), export controls and deemed exports, sanctions etc.	
International Society for Pharmaceutical Engineering (ISPE) **Global with headquarters in US**	General	General	Release cadence and consumption of changes are complex areas in SaaS but this guidance does not discuss it.	Please consider whether to add guidance around how the test facility should manage and consume changes, particularly in a SaaS offering, when those changes are likely driven by the cloud service provider but can significantly impact the validated state of the SaaS offering for the test facility's intended use. A "Management of Change" section may be helpful.	
International Society for Pharmaceutical Engineering (ISPE) **Global with headquarters in US**	4.2	12 3rd bullet	Resource Pooling definition	Many regulated applications are offered in single tenant models. Consider revising the definition of resource pooling. As written, it suggests that only multi-tenant models benefit from resource pooling.	
International Society for Pharmaceutical Engineering (ISPE) **Global with headquarters in US**	4.4	14 3rd main bullet 1st sub-bullet	SaaS GLP section – "The level of computing intervention of the GLP test facility is limited to internal defining permissions used to connect to the system."	Suggest rephrasing to: "The level of computing intervention should also include the configuration of the application to the test facility's intended use, inclusive of security."	
International Society for Pharmaceutical Engineering (ISPE) **Global with headquarters in US**	5.2	18 (Table 1)	Computerized System Validation (CSV) is shown as grey – shared responsibilities for all of IaaS, PaaS and SaaS	CSV to demonstrate that the system is fit for intended use is the responsibility of TFM. For IaaS and PaaS, the application is entirely controlled by the test facility; therefore, it is not possible for the cloud service provider to be responsible for the CSV of something they neither provided nor control. We recommend the CSV row is light grey for IaaS and PaaS columns. For SaaS, it can be reasonably assumed that for the cloud service provider to be successful they must have performed some level of system validation to demonstrate their offering is functional, however the extent of that validation will vary and TFM still retain the final responsibility for validation for test facility's intended use – para 47 emphasizes this.	

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				Most of the time the shared activity comprises the test facility leveraging whatever testing the cloud service provider may have completed, however it may not always be in a recognized GLP validation format.	
International Society for Pharmaceutical Engineering (ISPE) **Global with headquarters in US**	5.3.1	22	Risk based approach appears to be a little narrow and applicable only to systems that have been prospectively developed to GLP principles.	Certainly, a risk-based approach should be applied to a cloud service provider during the selection process. As written though the paragraph seems to suggest that only applications that are "… developed, released, and managed to comply with the GLP principles" would be considered. We suggest rephrasing to: "While selecting systems that have been developed exclusively for GLP may seem optimal, it does then limit the use of technologies that may be configurable to meet GLP needs, but whose development may not necessarily have been directly aligned with GLP principles. In this situation, the test facility should evaluate if the cloud service provider's internal activities and controls fundamentally meet GLP needs."	
International Society for Pharmaceutical Engineering (ISPE) **Global with headquarters in US**	5.3.1	23	Introduction (e.g., Section 1, Para 1, 2) discuss data integrity, data quality and data availability. Para 23 only mentions risks to data integrity and data quality.	We suggest adding data availability since cloud brings unique challenges for availability – not just risk of data loss but also loss of connection and even loss of access after ending cloud subscription. This comment would also apply to section 5.3.4, para 42.	
International Society for Pharmaceutical Engineering (ISPE) **Global with headquarters in US**	5.3.1	24 3rd bullet	The list of GLP compliance considerations will not change, but rather the method of delivery and storage	We suggest rephrasing to: • "Risks to be assessed include (but not limited to)… o Impact on GLP compliance requirements, especially the methods of delivery and storage, resulting from adopting the system provided by the cloud service (non-exhaustive list):"	
International Society for Pharmaceutical Engineering (ISPE) **Global with headquarters in US**	5.3.1	24 3rd bullet 3rd sub-bullet	Recovery Time Objectives and Recovery Point objectives (RTO/RPO)	Recovery Time Objectives and Recovery Point objectives are critical to be understood by both TFM and the cloud service provider; we suggest adding new bullet (after the bullet dealing with disaster recovery strategy).	
International Society for Pharmaceutical Engineering (ISPE) **Global with headquarters in US**	5.3.1	24 3rd bullet, 5th sub-bullet	There should be no impact on data ownership.	The cloud service provider does not own the data, so data ownership is unaffected by any decision to move to a cloud solution. Suggest removing the data ownership bullet or clarify that this relates to data reclamation after exiting the cloud	

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International Society for Pharmaceutical Engineering (ISPE) **Global with headquarters in US**	5.3.1.	24 3rd bullet, 6th sub-bullet	Not sure why a cloud solution would impact competence	We suggest rephrasing to: "Any skills and experience the study personnel have with the system"	
International Society for Pharmaceutical Engineering (ISPE) **Global with headquarters in US**	5.3.1	25 4th bullet	This information may be proprietary. The vendor should be assessed to determine if the IT operating principles are following NIST and ISO principles as well as good engineering practices.	We suggest summarizing the areas to consider and associated tools when evaluating a third party/vendor for services normally provided on premise or references are given to where such considerations and guidance may be found. Examples of references could be ISPE GAMP Good Practice Guide: IT Infrastructure Control & Compliance 2nd Edition and ISPE GAMP Good Practice Guide: Enabling Innovations.	
International Society for Pharmaceutical Engineering (ISPE) **Global with headquarters in US**	5.3.1	25 5th bullet	Direct access to the database using a database administrator (DBA) account is always a major concern here	Under level of control of access, suggest rephrasing the text in brackets to "(remote access, cloud providers' access to systems and data, cloud providers' access to perform changes directly within the database)"	
International Society for Pharmaceutical Engineering (ISPE) **Global with headquarters in US**	5.3.1	25 8th bullet	SOPs govern the use of the system not explain it.	Suggest rephrasing to: "SOPs that will be required to govern the routine use, administration and maintenance of the system"	
International Society for Pharmaceutical Engineering (ISPE) **Global with headquarters in US**	5.3.1	25 Last bullet, last sub bullet	The suggested activities are insufficient to maintain a validated state	Suggest rephrasing as: "If the cloud solution is a SaaS, periodic evaluation and/or ongoing monitoring of the system to assess if the validated state has been maintained. This would include review of any software updates and their impact on the validation for the test facility's intended use, review of configuration changes and user access, and assessment of the quality and integrity of the data within the system."	
International Society for Pharmaceutical Engineering (ISPE) **Global with headquarters in US**	5.3.2	27	Qualification and validation are separate and different concepts.	Please remove "(qualification)" from the paragraph 27 and remove "validation/qualification" from both para 28 and para 40 and replace simply with validation throughout.	
International Society for Pharmaceutical Engineering (ISPE)	5.3.2	28	The application should be validated, not qualified.	It could be confusing to have the GMPs (21 CFR 11.10(a) and EU & PIC/S Annex 11 Principle) requiring systems / applications to be validated, and this GLP document stating applications should be	

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Global with headquarters in US				qualified. Suggest rephrasing as: "…. (URS), understand what needs to be validated (the application as fit for its intended use within the business process) and how the TFM will ensure all requirements for computerized system validation are met."	
International Society for Pharmaceutical Engineering (ISPE) **Global with headquarters in US**	5.3.2	29	IQ/OQ may be a little narrow	Many SaaS providers do not perform a traditional IQ, rather they leverage an ISO27001 certificate to provide assurance that Cloud servers are change-managed and secure. Often the term OQ is not used by a cloud service provider. We suggest alternative text such as: "For example, in the case of a SaaS: • the SaaS provider can provide evidence of the successful installation and management of the application, such as application functional testing, automated testing, unit testing, application programming interface (API) testing etc has been performed; even though this may have happened independently of the test facility involvement or approval. • The additional testing that needs to be completed by the test facility and the controls needed for the ongoing compliant use of the system"	
International Society for Pharmaceutical Engineering (ISPE) **Global with headquarters in US**	5.3.3	35	Leverageable standards.	Consider adding as a helpful example references to ISO27001 and SOC 2 Type 2 as applicable to external cloud service providers. Both are extremely leverageable in support of an I/S/Paas organization's capability relative to security, data integrity and consistent cloud service delivery. If these certification/accreditations are absent from a cloud service provider serious consideration should be given as to the provider's appropriateness in support of regulated activities.	
International Society for Pharmaceutical Engineering (ISPE) **Global with headquarters in US**	5.3.3	36	Not all providers will be amenable to audit.	Suggest adding an additional sentence to the end of the para: "Where the provider is not open to audit, the test facility will need to determine whether the objectives of the audit can be fulfilled through alternative means, for example, scrutinizing available provider documents, certifications, and existing 3rd party audit reports".	
International Society for Pharmaceutical Engineering (ISPE) **Global with headquarters in US**	5.3.3	38 6th bullet	Qualification of Equipment	Apart from a few extremely specialized providers (see validated Cloud as an example) the concept of Equipment Qualification does not translate. However, the controlled use and configuration of equipment (hardware) can be accomplished through adherence to one or more of the standards referenced earlier. This comment also applies to para 39 last bullet Suggest rephrasing to "managed infrastructure"	

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International Society for Pharmaceutical Engineering (ISPE) **Global with headquarters in US**	5.3.3	39	All of these items are vital for SaaS but may not be relevant to IaaS or PaaS	Suggest clarifying "where applicable" as applicable primarily to SaaS, although there could be some risk to IaaS or PaaS depending on the particular situation.	
International Society for Pharmaceutical Engineering (ISPE) **Global with headquarters in US**	5.3.3	39 3rd high level bullet	"data changes (i.e. date, initials or signature with reason for change)" by manual mark-up do not happen any more, and a test facility would not be using a provider who relies on manual mark-up of the documents instead of keeping them updated. Also 'documents' can imply a discrete static record which is not necessarily available or desirable in modern development approaches.	Suggest rephrasing to: "Information and records [requirements, specifications, traceability, change management, etc.] about the life cycle of the provided system.	
International Society for Pharmaceutical Engineering (ISPE) **Global with headquarters in US**	5.3.4	45	SLA requirements	Consider adding an allowance for risk justification here. Suggest adding new sentences at the end of the bullet "While a GLP aligned cloud service provider is optimal, it is possible that not all requirements will be met. In this situation the Test Facility can use risk management approaches to determine the severity of any gaps, and potential for implementing their own mitigations within the test facility if feasible."	
International Society for Pharmaceutical Engineering (ISPE) **Global with headquarters in US**	5.3.4	53 6th bullet	Qualified Infrastructure	Same comment as on para 38. It is not typical for SaaS/PaaS to qualify their infrastructure. AWS, Azure, Google Cloud Platform etc. do not do this. Suggest rephrasing to "managed infrastructure"	
International Society for Pharmaceutical Engineering (ISPE) **Global with headquarters in US**	5.3.4	59	There may be audit trails at the system level that are different to audit trails on the GLP data. There may be system configuration data which is not unique to the test facility.	Suggest rephrasing as: The SLA should clearly describe the test facility's right to obtain all their **GLP** data and metadata (including audit trails)…"	

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International Society for Pharmaceutical Engineering (ISPE) **Global with headquarters in US**	6.2	62	Insurance vs assurance	Suggest removing "insurance on" from 2nd and 3rd bullets for readability	
International Society for Pharmaceutical Engineering (ISPE) **Global with headquarters in US**	6.3	All	The concepts in 6.3 apply equally to archived data and live application data	Suggest rewording the title to cover both.	
International Society for Pharmaceutical Engineering (ISPE) **Global with headquarters in US**	6.3	66	Physical inspection	As ISO27001 certificates are written as specific to locations and require physical inspection by the audit firm this certificate could be leveraged to meet any national requirements requiring physical inspection. We suggests adding this to point 66 as a solution to this requirement.	

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