Draft Guidance or Consultation Document title: Docket No. FDA-2017-D-1105 for "Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations Questions and Answers Guidance for Industry"

Comments submitted by the International Society for Pharmaceutical Engineering (ISPE), regulatorycomments@ispe.org

GENERAL COMMENTS ON THE DOCUMENT
Terms such as: "intended use", "intended purpose" and "intended function" should be more clearly defined as related to the context of the record, system, and clinical process. These phrases could be defined as part of the Glossary.
System Design documentation (such as Plans, Specifications, etc.) is not mentioned throughout the document, leaving the impression these are not important / required. Consideration should be given to including a question relating to System Design Documentation.
ISPE suggests adding a comment related to the information being maintained electronically. References to documentation and records should not be interpreted as always requiring traditional hard-copy documents. The maintenance of records and information in appropriate and effective software tools may be used.

Specific Comments on the Text

ISPE indicates text proposed for deletion with ~~strikethrough~~ and text proposed for addition with **bold and underlining**.

	Current Text	**Proposed Change**	**Rationale or Comment**
Q7 (290-292)	Alternatively, sponsors should review the vendor's UAT and document that the UAT was reviewed and was found to be adequate	Alternatively, sponsors should review the vendor's UAT and document that the UAT was reviewed, verified, and found to be adequate	UAT is user acceptance testing and Vendor would not normally do a UAT on behalf of sponsors. If this does occur, this should be called out as functional verification.
Q7 (297-300)	Changes that affect operational limits or design specifications should be validated. Finally, all changes to the system should be documented. It may be appropriate for FDA to request documentation of system validation during an FDA inspection.	Changes that affect use, operational limits or design ~~specifications~~ documentation (such as Plans, Specifications, etc.) should be validated. Finally, all changes to the system should be documented. It may be appropriate for FDA to request documentation of system validation during an FDA inspection.	Changes in the intended use of the system should be added. The influence on other critical aspects of the system should also be noted. Therefore, instead of only mentioning the influence on Design specifications it should be broadened to Design Documentation (such as Plans, Specifications, etc.)

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Q7 (299/300)	It may be appropriate for FDA to request documentation of system validation during an FDA inspection.	It may be appropriate for FDA to request documentation of system validation**, including documentation created and maintained by the vendor,** during an FDA inspection. **It is the responsibility of the Sponsors to ensure the documentation is available.**	It is unclear who must provide the validation documentation, especially in a software as a service (SaaS) setting.
Q8 (309 /310)	Sponsors should create a diagram that depicts the flow of data from creation to final storage.	Sponsors should create a diagram that depicts the flow of data from creation to final storage **for each clinical investigation or group of clinical investigations**.	
Q8 315ff		The bullet list should mention that setup and validation documentation that is specific to the clinical investigation (e.g. eCRFs, IRT configuration, etc.) should be included.	It has been observed that some companies/service providers only focus on trial-specific UATs and disregard validation aspects related to the core/base system. The base system (e.g. the EDC) should be validated and then the clinical investigation-specific customization/setup should be completed and validated.
Q17 (589 – 590)	Yes, FDA recommends that sponsors and other regulated entities have written service level agreements (SLAs) with IT service providers that describe how the IT services will meet the sponsor's requirements.	Yes, FDA recommends that sponsors and other regulated entities have written agreements that define the sponsor's expectations of the IT service provider e.g. service level agreements (SLAs) and/or Quality Agreements.	Although the question relates to service level agreements, ISPE recommends that there could be other written agreements such as quality agreements and these should be mentioned.
Q18 (614ff)		Suggest adding a bullet: **Relevant Validation Documentation as generated by the vendor following the vendor's processes**.	It is unclear who should provide the validation documentation, especially in a SaaS setting. FDA expectations regarding validation documentation (similar to the EMA Notice to Sponsors) are unclear.
Q18 (621)	Documentation of ongoing oversight of IT services	Suggest changing to: Documentation of ongoing oversight of IT services **and related quality aspects.**	ISPE suggests that reference is made to related quality management aspects

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