2022-09-30 **1** / 13

Date

18.10.2022

Submission of comments on Computer Software Assurance for Production and Quality System Software / 2022-09-13

Docket ID FDA-2022-D-0795

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/computer-software-assurance-production-and-quality-system-software-assurance-production-assurance-production-assurance-production-assurance-production-assurance-production-assurance-production-assurance-production-assurance-production-assurance-production-assurance-production-assurance-production-assurance-production-assurance-production-assurance-production-assurance-production-assurance-production-

Submited by ECA Foundation / European QP Association

Line	Line	Section	Comment and rationale	Proposed changes / recommendation
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general	general			
comment)	comment)		Comment background	
0	0	General	The provided comments have been prepared by an hybrid group of globally acting compliance professionals working for medical device manufacturers (Class III) as well as in the pharmaceutical GMP, GDP, GCP, and GLP areas as well as in research and development, such as: - Quality Assurance representatives, incl. IT QA - Engineers, in particular automation and process control - Laboratory scientists, in particular in charge of the qualification of laboratory equipment - IT department members - Software suppliers - GxP compliance consultants and auditors	
0	0	General	"Computer Software Assurance" vs "Computerised System Validation" If the guidance shall have an impact outside of the medical device sector, the guidance title shall be reconsidered since it contradicts the definition of a "computerised system" based on PIC/S PI 011-3, section 6.2. CSV does not cover software quality only but takes a holistic approach including, beside the computer, the controlled process, the related procedures, and the personnel. These elements are not or only very limited addressed in the guidance possibly causing confusion for the readers. Additionally, in the case of "production and quality system computer systems" the compliance scope cannot be reduced to "computer software" but must cover the computerised system in its entirety. Furthermore, in 2022, since most manufacturing and laboratory equipment are usually computer-controlled, CSV should be emphasised instead of artificially segregating equipment (21CFR820.70(g)) and automated processes (21CFR820.70(i)). The current guidance content could be misundertood by the industry causing a compliance decreasing and a control loss for production and quality system computer systems. See comments to lines 20-22	Please clarify the compliance scope - i.e. CSV - for "production and quality system computer systems"
0	0	General	CSA guidance vs current industry thinking While the GAMP Community proactively endorsed CSA (see GAMP Good Practice Guides "Data Integrity by Design" and "Enabling Innovation", as well as GAMP 5 Second Edition) based on discussions and presentations made by the Agency during the last 5 years, the current guidance draft does not accurately reflect major recommendations provided by GAMP - e.g. "Critical Thinking", "Leveraging Supplier Involvement", although these recommendations and key-concepts represent a significant way to improve the overall compliance maturity and to limit at the same time the necessary compliance effort.	Please emphasise, where appropriate, guidance alignment with current industry thinking as formalised by GAMP.
0	0	General	CSA vs General Principles of Software Validation The choosen approach to amend the GPSV by superseding Section 6 and replacing it with the CSA guidance is highly unfortunate since it causes confusion for the readers. It would be clearer and better to issue a new version of the GPSV with a revised content, including a possible formal scope extension (GCP, GDP, GMP, GLP). See comments to lines 28-31	Please consider to update GPSV instead of creating a new guidance.

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		Footnote 5		The footbole defines readures, function and operation in an arbitrary way (see comment related to line 104). Suggest reword for darity.	
	184		V - A		

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Line from*	Line to*	Section number	Comment and rationale (to go to next line within the same cell use Alt + Enter)	Proposed changes / recommendation (if applicable)
	(line Nr or 0 for general comment)			
	,		"For example, a commercial off-the-shelf (COTS) spreadsheet software may be comprised of various functions with different intended uses"	For example, a commercial off-the-shelf (COTS) data management software may be comprised of various functions with different intended uses. When utilizing the basic input functions of the COTS software for an intended use of documenting the
193	206	V - A	Spreadsheet systems are a weak example in regulated environments as they are inherently non-compliant with ERES expections. Suggested revision of this paragraph is provided.	time and temperature readings for a curing process, a manufacturer may not need to perform additional assurance activities beyond those conducted by the COTS software developer and initial installation and configuration. The intended use of the software, "documenting readings," only supports maintaining the quality system record and poses a low process risk. As such, initial activities such as the vendor assessment and software installation and configuration may be sufficient to establish that the software is fit for its intended use and maintains a validated state. However, if a manufacturer utilizes built-in functions of the COTS system to create custom formulas that are directly used in production or the quality system, then additional risks may be present. For example, if a custom formula automatically calculates time and temperature statistics to monitor the performance and suitability of the curing process, then additional validation by the manufacturer might be necessary.
193	206	V - A	Within a regulated context where data integrity represents one of the compliance key-stones, an example based on spreadsheet is fully inappropriate since the use of spreadsheets for performing regulated activities is the source of multiple non-compliances. Even only for visualising a document (worksheet), a spreadsheet tool can deliberately or not deliberately truncate the content, possibly causing inappropriate GxP decisions. GAMP 5 Appendix S3 provides a clearer discussion and a more consistent compliance view on this topic.	Or alternatively (to the comment above) Suppress the reference to spreadsheets Suppress this discussion since it causes more confusion than guidance.
208	214	V - A	Finally this paragraph aims to enforce a "risk-based approach focused on the effective intended use". Everything is only verbiage confusing the reader.	
			Determining the Risk Based Approach	Please consider to update GPSV, if necessary, instead of creating a new guidance.
221	245	V - B	"Risk" respectively "risk-based" is already mentioned 150 time in GPSV! The need for an additional guidance is not obvious. ICH Q9 provides a consistent approach to Quality Risk Management and it could be easily referred to in addition to ISO 14971.	If the guidance scope could be extended to pharmaceutical GxP, Q9 should be referred to as well.
247	290	V - B	The proposed binary approach to risk management based on "high process risk" and "not high process risk" causes a weak granularity hindering the elaboration of an effective scalable and commensurate approach to compliance. It finally contradicts the efforts jointly provided by regulators and industry during the last 20 years for efficiently achieving compliance.	Please reconsider the risk granularity, avoiding a binary approach to risk management.
247	290	V - B	Following the proposed examples of process risks, how would you classify a system used for managing the calibration records? - High process risk? - Not high process risk?	Please consider to provide more nuanced examples
271	277	V - B	The proposed discussion regarding "not high process risk" is doubtful and could lead to inappropriate risk decision making. "Intended use" should be clearly identified; considering that failing to perform according to the intended use is a contradiction to compliance approach. Probably, the idea is to consider some "anciliary" system functionalities not having a direct impact to the supported process and to the generated records being less critical than the core functionalities defining the intended use.	Please revise or suppress this discussion

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Line from*	Line to*	Section	Comment and rationale (to go to next line within the same cell use Alt + Enter)	Proposed changes / recommendation (if applicable)
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general	general			
comment)	comment)			
271	291	V - B	The examples mentioned in this discussion are very questionning since in several cases they could not be considered as being "not high process risk". (see in particular comments to lines 286-290). It is highly dangerous to try to deemphasise the process relevance of CAPA, change management or monitoring processes. What would an FDA inspector say during an inspection if a regulated company would miss to correctly apply changes to a manufacturing recipe of an analytical method just because the system supporting change management was considered having "not high process risk"?	Please revise or suppress this discussion, incl. the mentioned examples not forgetting that the intended use of systems supporting quality relevant activities is finally the key-criteron for "high" or "not high process risk".
286	290	V - B	The example related to "alerts when an exception occurs in an established process" is highly unfortunate, since it represents a "high process risk".	See comments to line 271-291
374	496	V-C	Determining the Appropriate Assurance Activities This section is mainly based on the terminology and philosophy defined in IEC/ISO 29119-1. Within the software engineering and software testing communities, IEC/ISO 29119-1 does not represent a consensus. IEC/ISO 29119-1 is definitively not well fitting with GxP expectations. - The testing terms proposed by IEC/ISO 29119-1 are already highly confusing (see the discussions within the industry since the early CSA phase regarding "scripted" and "unscripted" testing. - The related formalism is heavier than the industry does based on an efficient approach to testing and verification. - Implicit expectation that every types of test must be formally documented. However within the scope of engineering activities during the project phase, exploratory testing is common and not subject to formalism. - Only "robust scripted testing" considers traceability to the requirements (see below)	Please suppress the reference to IEC/ISO 29119-1 and propose a less confusing terminology. IEC/ISO 29119-1 has been revised in 2022 (the document refers to the version released in 2013).
413	419	V - C	It is not meaningful to explicitely mention "exploratory" tests as being part of the overall test and compliance strategy, since exploratory tests are part of the engineerig activities (sandbox) prior finalising the specifications and starting with the formal verification and compliance activities. This point represents one of the biggest issue raised by this guidance. Formally integrating exploratory tests in the compliance activities will cause an unnecessary increasing of effort instead of simplifying (as claimed) the compliance activities.	Please remove exploratory tests from this guidance.
421	432	V - C	Confusion between scripted and unscripted when talking about the limited scripted testing => difficulties to decide on the appropriate assurance activities.	Please suppress the reference to IEC/ISO 29119-1 and propose a less confusing terminology.
425	427	V - C	While most testing activities based on so-called documented "unscripted testing", the reference to IEC/ISO 29119-1 causes that only "robust scripted testing" shall provide traceability to the requirements and support auditability. PIC/S PE 009, Annex 11 requires "User requirements should be traceable throughout the life-cycle". It would be a significant regression to require in the future the industry to only make "robust scripted testing" in order to secure requirement traceability. The guidance purpose is to streamline compliance activities, the reference to IEC/ISO 29119-1 destroy this objective in a very efficient way.	Please suppress the reference to IEC/ISO 29119-1 and propose a less confusing and more flexible terminology.
434	442	V - C	"risk-based testing" is not meaningfully and efficiently achievable as long as the definitions provided by IEC/ISO 29119-1 are kept in this guidance.	Please suppress the reference to IEC/ISO 29119-1 and propose a less confusing and more flexible terminology.
444	446	V - C	"When deciding on the appropriate assurance activities, manufacturers should consider whether there are any additional controls or mechanisms in place throughout the quality system that may decrease the impact of compromised safety and/or quality if failure of the software feature, function or operation were to occur." This sentence could be better expressed - see suggested revision - for clarity.	"When deciding on the appropriate assurance activities, manufacturers should consider what existing upstream or downstream quality system controls or mechanisms which mitigate the impact on safety and/or quality should failure of the software function occur."

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Line from*	Line	Section	Comment and rationale (to go to payt line within the same cell use Alt + Enter)	Proposed changes / recommendation (if applicable)
from*	to* (line Nr or 0 for	number	(to go to next line within the same cell use Alt + Enter)	(п аррисале)
general	general			
comment)	comment)			
Í			These paragraph is finally advocating for "computerised system validation" based on the definition of a "computerised system" provided by	
			PIC/S PI 011, section 6.2.	
444	453	V - C		
			Finally - and fortunately - CSV remains the main compliance objective.	
			The main question is "does the industry need this CSA guidance?" since this section widely provides a reasonable statement.	Please consider to update GPSV instead of creating a new guidance.
			The main question is does the mussiy need this COA guidance: since this section widely provides a reasonable statement.	i lease consider to update of 5v instead of cleating a new guidance.
444	482	V - C	Nevertheless please consider the proposed improvements (rewording or suppression) related to lines 444-482, see below.	
450	400	V . C	"For some lower-risk software features, functions, and operations, this may be all the assurance that is needed by the manufacturer."	This statement is not needed - and lacks clarity - suggest delete.
458	460	V - C		
			" these controls can serve as additional mechanisms to detect and correct the occurrence of quality problems that may occur if a	This statement is a repetition of for example lines 444-449 - suggest delete.
			software feature, function, or operation were to fail to perform as intended in this example, the presence of these controls can be leveraged	This statement is a repetition of for example into 444 440 suggest dolote.
466	468	V - C	to reduce the effort of assurance activities appropriate for the software."	
			This part could cause confusion since it mixes assurance activities related to the project phase and assurance activities reletaed to	A better structure would be meaningful.
470	474	V - C	operation.	
			"The use of Computer System Validation tools"	"The use of tools supporting software development and system life cycle activities
			The use of computer System variation tools	"
477	477	V - C	Use of the term "Computer System Validation" here could be confusing - see suggest revision	
			, ,	
			" by leveraging vendor validation records."	" by leveraging vendor records e.g. quality management system records and
488	488	V - C	L	software development life cycle records (software installation, configuration, testing
			Validation remains the responsibility of the regulated company. See suggested revision	etc)"
			"Manufacturers may leverage any of the activities or a combination of activities that are most appropriate for risk associated with the	"Manufacturers may leverage any of the activities, or a combination of activities,
			intended use."	that are most appropriate for the mitigation of identified risks associated with the
495	496	V - C		intended use.
			Minor revision for clarity suggested.	
504	524	V - D	The rows of Table 1 are not presented in order of rigor - this may be confusing or unhelpful to practitioners.	Suggest to resequence - as per Appendix S2 in ISPE GAMP RDI Good Practice
524	524	V - D		Guide - Data Integrity by Design.
			Table 1 : Examples of Assurance Activities and Records	
			After reading this table, it is not clear how the proposed approach simplifies the validation activities compared to the GAMP guide.	
			It was expected FDA would support that regulated users could rely on the results of the software test and verification activities performed by	
524	525	V - D	the supplier, as long as the outcomes of the supplier audit results provide sufficient confidence in the supplier's QMS.	
			Spreadsheet: The monitoring of environmental parameters can have a direct impact on the product quality and patient safety.	Please clarify the example and remove the mention to spreadsheet.
			Spreadings	. 1323 Sam, the example and femore the mention to opioadeneet.
F22	E24	V - D	Additionally it is very unlucky to provide an example based on spreadsheet in a compliance guidance.	
533	534	V - D		
			See comments to lines 193-206	
			WTh.	Disease sharify the assessment and new area the manufactor to annual debaset
			"The manufacturer conducted rapid exploratory testing of specific functions used in the spreadsheet to ensure that analyses can be created, read, updated, and/or deleted."	rease ciarily the example and remove the mention to spreadsheet.
			, dead, dysalics, dries district.	
			If this data is used for a regulatory purpose (e.g. investigation of a non-conformance) it is in the scope of 21CFR11 (and other data integrity	
535	556	V - D	related guidances) which require a complete record according to ALCOA+ principles - deletion is not permitted.	
			See comments to lines 193-206 See comments to lines 413-419	
			See Collitions to lines 413-418	
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general	general			
comment)	comment)			
535	556	V - D	We are moving to avoid using spreadsheets for GxP activities and we argue in this guidance by taking this kind of tools?	Please remove the mention to spreadsheet.
537	538	V - D	See comments to lines 413-419	Please remove exploratory tests from this guidance.
584	586	V - D	"Manufacturers have expressed confusion and concern regarding the application of Part 11, Electronic Records; Electronic Signatures, to computers or automated data processing systems used as part of production or the quality system."	This is a repetition of the statement at 69 -72. Suggest delete.
597	599	V - D	"In the context of computer or automated data processing systems, for computer software used as part of production or the quality system, a document required under Part 820 and maintained in electronic form would generally be an "electronic record" within the meaning of Part 11 (see 21 CFR 11.3(b)(6))." Vague statement when regulation is clearer - see suggested revision.	
			Example 1: Non conformance Management system	Appendix A shall be fully rewritten ensuring clarity and consistency of the proposed
			Table 2: Computer Software Assurance Example for a Nonconformance Management System	examples.
611	617	Appendix A - Example 1	Electronic signature - 21CFR11 - requirements are more complete than the risks identified in this table! (link to document, access management, training, etc). The corresponding column content "Establishing the appropriate record" seems to be neither complete nor focused on the identified risks.	It would be very appreciate that examples related to manufacturing equipment and quality control equipment would be proposed.
			Example 2: Learning Management System (LMS)	Consider the risk evaluation otherwise we are lost
622	623	Appendix A - Example 2	Table 3: Computer Software Assurance Example for an LMS Failure of these features, functions, or operations to perform as intended would impact the integrity of the quality system record but would not foreseeably compromise safety. As such, the manufacturer determined that the features, functions, and operations do not pose high process risk. If the training concerns an operator working a critical process then we have high risk that the GmP requirements are not fullfilled. A non performed training for an operator could have an impact on Data Integrity requirement ALCOA + (Contemporaneous not respected)	Consider the risk evaluation otherwise we are lost
			Example 3: Business Intelligence Applications	The software is intended to provide information regarding product and process performance over time, in order to facilitate the identification of improvement
627	628	Appendix A - Example 3	Table 4: Computer Software Assurance Example for a Business Intelligence Application "The software is intended to better understand product and process performance over time, in order to provide identification of improvement opportunities." Statement reworded for clarity.	
631	632	Appendix A - Example 3	Example 3: Business Intelligence Applications Table 4: Computer Software Assurance Example for a Business Intelligence Application Clairfy the scope of the system: Data Integrity vs trending or analysis.	Rework example 3