04.01.2023

Submission of comments on 'Concept Paper on the revision of Annex 11 of the guidelines on Good Manufacturing Practice for medicinal products – Computerised Systems' (*EMA/INS/GMP/778340/2022*)

Comments from:

Name of organisation or individual
Good Regulatory Practice Association, ul. Złota 61/100, 00-819 Warszawa, Poland; legislacja@grp.org.pl represented by: MPharm Aleksander Wegner, Head of Audit Committee, Chairman of the Legislative Group

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).

1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	Good Regulatory Practice association fully supports the idea to revise Annex 11 of GMP, as over 11 years since the release of its current version is an epoch in the reality of modern computers and Internet.	

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
GMP Annex 11 wording		Comment: A proposal to make current Annex 11 text more clear – that IT staff involved in pharmaceutical manufacturing is fully undergoing GMP regulations. Proposed change (if any): From: 2. ***Personnel*** There should be close cooperation between all relevant personnel such as Process Owner, System Owner, Qualified Persons and IT. All personnel should have appropriate qualifications, level of access and defined responsibilities to carry out their assigned duties. To: 2. ***Personnel*** There should be close cooperation between all relevant personnel such as Process Owner, System Owner, Qualified Persons and IT. All personnel should have appropriate qualifications, level of access and defined responsibilities to carry out their assigned duties. All relevant IT personnel should follow Chapter 2 requirements.	

GMP Annex 11 wording		Comment: A proposal to clarify that formal agreements between entities within the same companies group are not necessary and that internal documents like SOPs are enough. Proposed change (if any): From: 3. ***Suppliers and Service Providers*** 3.1 When third parties (e.g. suppliers, service providers) are used e.g. to provide, install, configure, integrate, validate, maintain (e.g. via remote access), modify or retain a computerised system or related service or for data processing, formal agreements must exist between the manufacturer and any third parties, and these agreements should include clear statements of the responsibilities of the third party. IT-departments should be considered analogous. To: 3. ***Suppliers and Service Providers*** 3.1 When third parties (e.g. suppliers, service providers) are used e.g. to provide, install, configure, integrate, validate, maintain (e.g. via remote access), modify or retain a computerised system or related service or for data processing, formal agreements must exist between the manufacturer and any third parties, and these agreements should include clear statements of the responsibilities of the third party. IT-departments should be considered analogous. For IT responsibilities shared within the same group of companies Pharmaceutical Quality System internal regulations are satisfactory.	

Lines 64-68		Comment: Full support to the claim that more detail is needed for "restore" as it may mean "data recovery" but also "disaster management" and bringing the particular application back into functioning. Proposed change (if any):	
Line 70		Comment: "The requirement to be able to print data may be reconsidered." – this requirement should be completely removed. In the current world, in majority of situations an "electronic print-out" e. g. PDF file is more than enough. Proposed change (if any): From: 8.1 It should be possible to obtain clear printed copies of electronically stored data. To: 8.1 It should be possible to obtain clear printed copies of electronically stored data. Rendering an electronic document e. g. PDF is satisfactory and no paper printing is required.	

GMP Annex 11 wording		Comment: : A proposal to clarify that electronic signatures within the same companies group are also valid. Proposed change (if any): From: 14. Electronic Signature Electronic records may be signed electronically. Electronic signatures are expected to: a. have the same impact as hand-written signatures within the boundaries of the company, b. be permanently linked to their respective record, c. include the time and date that they were applied. To: 14. Electronic Signature Electronic records may be signed electronically. Electronic signatures are expected to: a. have the same impact as hand-written signatures within the boundaries of the company (or group of companies), b. be permanently linked to their respective record, c. include the time and date that they were applied.	
GMP Annex 11 wording		Comment: Impact of use of mobile equipment (tablets, mobile phones) should also be taken into considerations during the revision of the Annex – there are more and more Android or iOS applications (e. g. used as hand-held scanners or notepads) being used within the pharmaceutical manufacturing, so more detailed guidelines for those IT solutions should be developed. Proposed change (if any):	

Please add more rows if needed.