EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PIC/S

2 April 2026

Submission of comments on: Revision of Good Manufacturing Practice (GMP) Guidelines Annex 15 (Qualification and validation)

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 via the EU survey, in Excel format **(not PDF)**.*
Columns A to E should mandatorily be filled in prior to completing the columns "Comment" and "Rationale" and/or "Proposed wording".
For more details on how to use this template please refer to the tab "Manual for commenter" below.

Country	Organisation raising comment (if no organisation, name of individual)	Line from	Line to	Comment (only one topic per comment) (max 600 characters)	Rationale (must be included when proposing a change) (max 600 characters)	Proposed wording (must be included when proposing a change) (max 600 characters)
Germany	ECA Foundation / European QP Association	0	0	1.7 current version Annex 15: In light of increased knowledge and understanding from any changes during the project phase or during commercial production, the risk assessments should be repeated, as required.	to repeat the full RA is a waste of time & money	In light of increased knowledge and understanding from any changes during the project phase or during commercial production, the risk assessments should be adapted, as required.
Germany	ECA Foundation / European QP Association	0	0	AS production needs the allowance to have a retrospective low level Qualification	some AS-productions units were not qualified so far - but we need these AS - so, we have to allow a low level retrospective Qualification	n/a
Germany	ECA Foundation / European QP Association	0	0	A harmonization with ISPE BG 2nd Rev. and ASTM E2500 is required. E.g. in individual cases—based on risk—qualification is also possible without DQ-, IQ-, and/or OQ-documents.	Different requirements regarding qualifications in the EU and the US result in duplication of work, i.e., additional expenditure in terms of time and money. The newer requirements in the US are technically sound and good; the EU should adopt them or at least accept them.	n/A
Germany	ECA Foundation / European QP Association	0	0	2.3. current version Annex 15 add qualification	qualification projects can become also complex	The inter-relationship between documents in complex **qualification** and validation projects should be clearly defined
Germany	ECA Foundation / European QP Association	0	0	General current version Annex 15 add ICH Q 12 and 13	to become state of the art ICH Q12and 13 should be implemented	The relevant concepts and guidances presented in ICH Q8, Q9, Q10, Q11, **Q12 and Q13** should also be taken into account.
Germany	ECA Foundation / European QP Association	0	0	2.6. current version Annex 15 add qualification	chapter should als reflect qualification aspects too as qualification service by third parties is state of the art	Where **qualification** and validation protocols or other documents are supplied by a third party providing **qualification and** validation services...
Germany	ECA Foundation / European QP Association	0	0	2.8. current version Annex 15 add qualification	chapter should als reflect qualification aspects too	Any implications for the **qualification** and validation should be discussed in the report.
Germany	ECA Foundation / European QP Association	0	0	2.9. current version Annex 15 add qualification	chapter should als reflect qualification aspects too	The review and conclusion of the **qualification** and validation should be reported and... Any subsequent changes to acceptance criteria should be scientifically justified and a final recommendation made as to the outcome of the **qualification** and of the validation.
Germany	ECA Foundation / European QP Association	0	0	3.6. current version Annex 15 add qualification	PQ tests can also be tested in FAT	Where appropiate and justified, documentation review and some tests could be performed at the FAT or other stages without the need to repeat on site at IQ/OQ/**PQ**...
Germany	ECA Foundation / European QP Association	0	0	3.1 current version of Annex 15 only one reference to chapter 6 of the EudraLex, Volume 4, Part I and ICH Q2 (R2) and ICH Q14	Validation of Test Methods are described in details also in ICH Q2 (R2) and ICH Q14	All analytical test methods used in qualificaton, validation or cleaning excercises should be validated accoring to chapter 6 of the EudraLex, Volume 4, Part I **and ICH Q2 (r2) and ICH Q14**
Germany	ECA Foundation / European QP Association	0	0	11 current version of Annex 15 differ between project change control and change control after the finalisation of qualification and validation	During the qualification and validation projects the change control could be different from that one in routine	During the qualification and validation projects the change control could be different from that one in routine
Germany	ECA Foundation / European QP Association	0	0	12 Glossary current version Annex 15	ad utilities to the definitions of DQ, IQ (and OQ) as mentioned in the chapter 3 of current version	The documented verification that facilities, systems, equipment **and utillities**...
Germany	ECA Foundation / European QP Association	0	0	12 Glossary, current version Annex 15	ad a definition for functional specification as mentioned in 3.2 current version	n/a
Germany	ECA Foundation / European QP Association	0	0	12 Glossary, current version Annex 15	a new definition for Performance Qualification like in the first version from 2001, which includes the check	The documented verification that systems and equipment, as connected together, can perform effectively and reproducibly, based on the approved process method and product specification.

Germany	ECA Foundation / European QP Association	0	0	2.3 current version Annex 15 add Tracebility Matrix	tests identified in the risk assessments should be traceable in qualification protocols and reports	The inter-relationship between documents in complex qualification and validation projects should be clearly defined and the tests traceable to risk assessments (Tracebility matrix)
Germany	ECA Foundation / European QP Association	0	0	7 Validation of Packaging	concrete regarding process parameters in the packaging process	CPPs and CQAs should be based on risk assesements coming from the development of the packaging process
Germany	ECA Foundation / European QP Association	0	0	2.10 of current version Annex 15	more details in what cases a conditional approval can be possible, i.e examples	Conditional approval (e.g. regarding missing documentation or...) to proceed to the next qualification stage can be given to the next qualification stage can be given...
Germany	ECA Foundation / European QP Association	33	33	To extend the concept of the "Validation Master File",..... It is not clear for what does "Validation Master File" mean (XAZN)	The new term may bring potential confusion that what does "Validation Master File" mean, whether a new type of document is required.	Suggest to change "Validation Master File"to "validation master plan" to align with current version 1.4.
Germany	ECA Foundation / European QP Association	82	82	Please consider to allow for more than 3 months of consultation	It is a major scope change, and in order for ensuring proper and correct review and feed back more time will make a huge difference. It is known, that the commenting of these important guidelines are coordinated via relevant organisations like Efpia and ISPE, which also should be given a fair chance to provide well worked thru comments and alignment. Explicitly the use of CMOs within DS can pose a risk	Suggest to provide minimum 4 months but ideally 6 months
Germany	ECA Foundation / European QP Association	1	116	With the broader scope, this could open up for some confusion throughout the document. E.g. like primary packaging - this will be two completely different things for respectively DP/FP or DS	To give clarity	n/a
Germany	ECA Foundation / European QP Association	0	0	Manufacturing of ATMPs should also be included in the Scope of Annex 15	in part IV of EU GMP Guideline are too less details regarding qualification and validation	n/a
Germany	ECA Foundation / European QP Association	0	0	It is essential to secure consistency between the future revisions of Annex 15 and Annex 11. The current versions - Annex 11:2011 and Annex 15:2015 - are relatively well aligned.	Possible evolutions of Annex 15 should be coordinated with the working groups in charge of revising Annex 11, Chapter 4 and Chapter 1. Furthermore, in particular in terms of process validation, an appropriate alignment between Annex 15 and the future Annex 22 must be achieved.	n/a
Germany	ECA Foundation / European QP Association	0	0	In addition to the comment before: Annex 15 provides a qualification and validation scheme - DQ, IQ, OQ, PQ - which is used as a kind of "foundation" by Annex 11 for computerised system validation, see Annex 11 draft (2025), section 9.1.	Without Annex 11 repeating some of Annex 15 content (see A11 draft, section 9), in order to provide sufficient flexibility during project execution, it is important to emphasize that Annex 15 provides an overall qualification framework which can be adapted as long as the qualification objectives are properly achieved.	n/a
Germany	ECA Foundation / European QP Association	0	0	For clarity and consistency reasons, it is important to provide clear definitions of "critical items/aspects".	ASTM E2500-25, figure 1 - *Alignment of CDEs, CAs, CPPs, and CQAs to Product Quality and Patient Safety* - provides a clear taxonomy. For consistency, it would be greatly appreciate if the future Annex 15 could use the same taxonomy in order to secure an unambiguous understanding of the different types of " *critical item* ".	n/a
Germany	ECA Foundation / European QP Association	0	0	It is important that Annex 15 encourages the industry to undertake its digital transformation, leveraging digital resources and digital records for supporting qualification and validation activities.	Qualification and validation should not conduct to an over documentation of the performed activities. More over it should emphasize the electronic tools to be used.	n/a
Germany	ECA Foundation / European QP Association	46	48	While the objective is clear, this topic - failing to meet pre-defined acceptance criteria - should be carefully addressed; otherwise the risk is to cause a compliance overkill.	It should be clearly differentiated between qualification test incidents - i.e. test cases not fulfilling the test pre-defined acceptance criteria - and the handling of out-of-specification (OOS) test results during operation. In the both cases, the test incident must be investigated until its resolution. However, the expected documentation effort and formality are not equivalent. It would be helpful to consistently use a clear taxonomy for avoiding confusion; e.g.: 1/ commissioning / qualification / validation test incidents 2/ OOS during operation (i.e. process is already validated).	n/a
Germany	ECA Foundation / European QP Association	53	58	The mentioned requirement regarding " *robust process development* " is consistent with FDA CPG 7346.832 (version 2022), 4[1k] objective: " *commitment to quality in pharmaceutical development* ".	Everything improving consistency between the regulations is highly appreciate.	n/a