PM GROUP

Review/Comments Form

Document Title:	EudraLex - Volume 4 Good manufacturing practice (GMP) Guidelines -Final Version of Annex 15 to the EU Guide to Good Manufacturing Practice - Qualification and validation		
Document Number:	Annex 15	**Revision Number:**	N/A
Reviewer Name:			

Date: 30-Apr-14

Page #	Section	Description of comment	
6	3,2	User Requirements Specification (URS) This section is new to Annex 15 and states that "the specification for new facilities, systems or equipment should be defined in a URS and/or a functional specification" . There is no reference to use of other types of specifications generally used within the industry. Suggest broading this out to a 'specification phase'. With ASTM-E2500 becoming more familiar across industry, terminology has broadened depending on a manufacturers own specific validation strategy.	
6	3,3	Design Qualification (DQ) The draft version indicates that the “next element is DQ” which serves to ensure the compliance of the design with GMP. The use of the term DQ along with statement that, 'user requirments specification should also be verified during the design qualifiation'. is very restricted and specific. It gives the impression that a DQ protocol should be generated and executed (without saying it). Suggest broading this out to design review phase, exeuction of this phase and method of documenting would be at companies descretion. Boradening the definitions (not the intent) will allow felxibility.	
6	Section 3.4 -3.7	FAT/ SAT don’t need to be specifically stated. It is suggested that such specific detail be removed replaced with vendor testing / leveraging section to encourage flexibility. This section would sit under the 'testing phase of the lifecycle'. As stated focus is on leveraging of vendor testing to satisify the defined reqirements (URS) and also negating the need to repeat testing once the integrity of testing can be justified. Terminology across industry is different. Being too specific in these guidlines could potentially stifile innovation.	
6&7	3.8-3.14	Similarly for definition of IQ, OQ and PQ this section is the same as the previous version of annex 15. The very specific definition of terminology can potentially lead into following tradition methods. Suggest broading this to a 'testing phase'. The requirement should focus on highlighing the need for the company to execute against a predefined criteria, the need to document the execution and finally the reporting of results. The detail and exact process can differ between different companies and it should be at their descretion out outline/ define (in the VMP) how this will be managed. It is important that regardless of testing approach that the sequence of test execution is justified. With ASTM-E2500 becoming more familiar across industry, terminology has broadened depending on a manufacturers own specific validation strategy.	
7	4,2	Process Validation A hybrid approach between continuous verification and the traditional Process Validation approach is unclear. Suggest either xpanding and giving a more detailed overview of Hybrid approach or removing detail and altogether and stating they Hybrid model can be used based on documented scientific justification. The latter would leave the company to define andjustify their own specific hybrid process	
14	Glossary	There is no definition of hybrid in the glossary	
N/A	4 (General comment)	Process Validation Within the draft, the terms “Ongoing Process Verification” and “Continuous Process Verification” are used and are further described below. It is recognised that these terms are described in the glossary but there is a concern that due to the cimilarity of the terms that this will lead to confusion	
N/A	General	This document does not reflect the verification models adopted by many of our clients. Is it the intention of the document that ASTM is a non-valid approach?	
N/A	General	Annex 15 also seems to confuse verification and PAT as if PAT is required on an ongoing basis (which isn’t correct).	