SECOND TARGETED STAKEHOLDER CONSULTATION

GMP
Revision on Annex 1
Manufacture of Sterile Products

1. Introduction

The current annex 1 is being reviewed to better ensure the sterility of medicinal products placed on the market for the benefits of patients. The revision was notably necessary to facilitate implementation of the principles of relevant ICH guidelines, to extend the underlying concepts to include new areas of technology and processing not previously covered and also to clarify areas that have been highlighted as ambiguous due to the age of the document.
In order to maintain the global alignment of standards, achieving at the same time assurance for the highest quality, the Annex 1 Working Group (WG) is made of experts from the European Commission, the World Health Organisation (WHO) and the Pharmaceutical Inspection Co-operation Scheme (PIC/S).
A first draft of the revised Annex 1 was published for public consultation from 20 December 2017 to 20 March 2018.
Following the contribution of about 140 stakeholders and after processing more than 6200 comments the WG issued a revised document, version 12, in December 2019.
Due to widespread interest from industry following the first public publication of the Annex 1, it was found necessary to engage with stakeholders in a second targeted consultation on the updated draft guidance, version 12.
The second consultation aims at collecting experience from the sectors on certain changes proposed and concerns raised. The associations representing the sectors were therefore contacted and are expected to provide a contribution.

The draft guideline of version 12 provided has been formatted with prescribed line and page numbers.

To submit feedback, please provide it exclusively using this dedicated template below.

2. Scope of the consultation

This second consultation is intended to be focused and limited to paragraphs that raised concerns or were changed more significantly, as identified below.

2.1. Feedback on the concerns raised by stakeholders		
	Qualification & requalification of cleanroom	from § 4.25 to 4.35
	Handling of water systems	from § 6.7 to 6.15
	Integrity testing of large volume parenteral container	§ 8.21
	Handling of sterilizing filter including pre-use post sterilization integrity testing (Pup	§ 8.88 and 8.95 & 8.96
	Handling of lyophiliser	from § 8.110 to 8.113
	Sterility testing	§ 10.6 & 10.7
2.2. Sections and/or paragraphs which were substantively modified		
	Definition and handling of barriers systems including disinfection/decontamination	from § 4.18 to 4.24
	Handling of gas filters	from § 6.18 to 6.20 and 8.89 & 8.90
	Personnel qualification & gowning	§ 7.5 & 7.6 and from 7.14 to 7.16
	Aseptic production	from § 8.11 to 8.19
	Moist heat sterilisation	from § 8.54 to 8.65
	Personnel monitoring	§ 9.32 & 9.33
	Aseptic process stimulation (APS)	§ 9.34 & 9.40 & 9.47
	Quality control	§ 10.1
2.3. Other significant comments		
	Please avoid re-submitting comments which you already submitted at the first consu	All document

3. Name and contact details of the reviewing organisation

Please don't add any personal information as the comments might be published

4. Comments

Please write your comments using the spreadsheet below

Line number (s)	Comments	Suggested text	Justification