EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

<Date of submission>

Submission of comments on 'Draft concept paper on the revision of chapter 6 of the EU GMP guide quality control' (EMA/INS/GMP/632654/2010)

Comments from:

European Industrial Pharmacists Group (EIPG)

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).

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1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	1. Chapters of Volume 4: Good manufacturing practice (GMP) Guidelines of the EudraLex are high-level documents with the scope of providing guidance for the interpretation of the principles and guidelines of good manufacturing practices for medicinal products for human and veterinary use. One should therefore avoid introducing technical details for analytical method transfers in such a document. Such details should be issued in a separate guideline, such as ICH Q2(R1) for the Validation of Analytical Procedures. 2. Comment on statement “The need to provide specific guidance for endotoxin and microbiological testing will also be considered.” In the spirit of Comment 1 above, it is not clear why endotoxin and microbiological testing should be given such importance in a document meant to provide guidance on analytical transfer activities.	

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)*
		Comment: Proposed change (if any):	
		Comment: Proposed change (if any):	
		Comment: Proposed change (if any):	

Please add more rows if needed.