EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

<Date of submission>

Submission of comments on 'GMP Annex 16 Certification by a Qualified Person and Batch Release' (Revision 1)

Comments from:

Name of organisation or individual
Polish Industrial Gases Association (Polska Fundacja Gazow Technicznych)

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)*
	Thank you for considering our comments from the Polish Industrial Gases Association.	
	PIGA's members agreed that some of the proposals can negatively affect the current manufacturing process of Medicinal Gases and therefore clarifying guidance regarding the QP activities is strongly desired. Taking in to consideration speed of the manufacturing process of medicinal gases and a requirement of prompt release by a QP, to avoid different interpretation of some requirements across European countries there was agreed to submit following proposals:	

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)*
3.3, 1st paragraph		Comment: EU legislation Directive 2001/83/EC requires at least one QP to be at the disposal of a manufacturing authorisation holder but makes no reference to requirements per site. In order to stay in line with the Directive 2001/83/EC and avoid interpretations that exceed this directive, we propose to change the wording of Annex 16 with additional clarification. Proposed change: Delete sentence: "~~Each manufacturing site in the EEA must have at least one QP~~." And replace with : *Each manufacturing site should have at its disposal the services of at least one QP.* *It is allowed that one QP is acting for more than one manufacturing site in the EEA*	
7. Glossary		Comment: In the glossary, there is given a definition of certification of finished products but there is no definition of batch release	

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)*
		A definition of 'batch release' would be helpful, using the words of par 2.3.3 Proposed change: Add: **Batch release of the finished product:** Assigning of release status to the finished batch of product which takes into account the certification performed by the QP	