<Date of submission>

Submission of comments on TEMPLATE FOR THE QUALIFIED PERSON'S DECLARATION CONCERNING GMP COMPLIANCE OF INVESTIGATIONAL MEDICINAL PRODUCTS MANUFACTURED IN NON-EU COUNTRIES (SANCO/D/6/SF/mg/ddg1.d.6(2013)179167)

Comments from:

Name of organisation or individual
EFPIA

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

<table>
<tr><th>Stakeholder number

(To be completed by the Agency)</th><th>General comment (if any)</th><th>Outcome (if applicable)

(To be completed by the Agency)</th></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td></td><td>We welcome the intent of having a single EU-wide template for the provision of QP declarations concerning GMP compliance of investigational medicinal products manufactured in non-EU countries. This will address the current situation with various requirements in different member states and pave the way for the new Clinical Trial Regulation with its single submission. Current practice is that the submission requirements for a dossier to authorise a clinical trial are not the same in every EU member state. In order to reduce this undesired complexity, it is therefore important that a QP Declaration documented with the filled template in the proposed format will be acceptable in every member state as providing sufficient information to support the declaration.</td><td></td></tr>
<tr><td></td><td>We would prefer the template not to have the EudraCT number. This would facilitate the creation of Product/Site declarations which can then be used in multiple submissions, In turn, this would reduce redundancy during late stage development when a number of (parallel) studies (which will each have a different EudraCT number but will require redundant certification by the QP) are utilising the same products.
A validity date tied to the date of last audit completion could be added to the template to ensure appropriate limitation on the declaration’s use in this way.
In the event that the decision is that the declaration must be for a given EudraCT number, then it should be possible to cover all the products used in that trial with a single declaration. An amended Part A format such as given below would readily facilitate this:

<table><tr><td>Product name</td><td>Third country site(s) (Name and address of site)</td><td>Activities performed at this site (Manufacturing, packaging, labelling and/or testing)</td></tr></table></td><td></td></tr>
</table>

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	1)	
	The form should be simplified in that Part B (i) and (ii) are combined to a single table capturing audits including information on a possible 'auditing party'.	
	We request that there is greater clarity provided, either on the form or via an associated guidance document, regarding the scope of activities that are intended to be covered by this declaration, with regard to the following points: 1) The current template covers only those activities pertaining to secondary product manufacture, packaging, labelling and/or testing. 2) All testing sites of IMP are in scope. 3) Active pharmaceutical ingredient or bulk biopharmaceutical active are not in scope. 4) 'Third countries' are countries outside the EEA (not just outside EU). 5) Expectations for citation of audits relating to large sites where multiple activities are conducted and audited separately, e.g. manufacturing, packaging and labelling and analytical testing. For instance, the date of the last audit of the site should be provided, rather than the date of last audit of each single activity.	

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)*
Title		Comment: The consultation title states "non-EU countries" ; the declaration template title states « third countries ». Need to clarify if EEA states e.g. Norway require a declaration or not. Proposed change (if any): "QP DECLARATION ON GMP EQUIVALENCE TO EU GMP FOR INVESTIGATIONAL MEDICINAL PRODUCTS MANUFACTURED OUTSIDE THE EEA".	
Below first table		Comment: Manufacturing and Importation Authorization (MIA) number: This implies that the site has both a manufacturing and import authorization under one license. This is the case for the UK, but not for all member states. Proposed change (if any): We suggest "Manufacturing and/or Importation Authorisation number"	
Part A		Comment: It would help to clarify scope and standardise wording if the template contained drop-down menu options for activities performed at the site. Proposed change (if any): Add drop-down selection of Activities to the table.	
Part B		Comment: This section is unnecessarily complicated and there is a lack of clarity, e.g. the statement in parenthesis in part (ii) could be	

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		read as meaning that a third party audit has to include a QP employed by the importer, or that an audit by another QP employed by the importer is included within the definition of a third party audit (because it is not conducted by the signatory). The separation of Part B (i) and (ii) serves no real value – they are both providing evidence of compliance on the basis of an audit by or on behalf of the QP. Proposed change: The form should be simplified with Part B (i) and (ii) combined to a single table capturing audits. This could be in the format of the proposed part (ii) with 'Third party' replaced by 'Auditing party' (which could be the signatory, another QP on the licence, a corporate audit group or a third party contract auditor).	
Part B (i) and (ii)		Comment: Audit frequency is mentioned as "expected to be within the last 3 years". In practice, the frequency may be determined based on risk analysis considerations and the interval between audits could be greater than 3 years. The template should allow for this possibility to be justified. Proposed change (if any): It is suggested to add a field for a justification if last audit is >3years, in line with the template QP declaration for API.	
Table (iii)		Comment: The first column should be consistent with that of other tables on the declaration – 'site' should be 'site(s)' and there should be prompt for name and address.	

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		Proposed change (if any):	
Table (iii)		Manufacturing sites' audits conducted by representatives from the Sponsor's compliance team, without the participation of a QP, will have to be listed under Part B (iii).	
Table (iii)		Comment: It is not clear how one can address utilization of audits performed by Competent Authorities, and the GMP certificates issued herein. As the Commission is aware, for medicinal products proposed for marketing authorization, references can be made to EudraGMP for sites both within and outside the EU. It is not clear then why a greater burden is anticipated for medicines under 2001/20/EC, as the regulation did not envision this. Proposed change (if any): Recommendation is to allow for QPs to utilize Competent Authority Audits/GMP certificates as part of their assessment. Suggest to then add EudraGMP reference as a column header.	

Please add more rows if needed.