EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22nd March 2013

Submission of comments on
European Commission 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
European Qualified Person Association, IMP Working Group

Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

1. General comments

Stakeholder no. *<to be completed by the Agency>*	General comment (if any)	Outcome (if applicable) *<to be completed by the Agency>*
	The IMP Working Group of th European QP Association welcomes the current activities to harmonise the template for the provision of QP declarations of IMPs manufactured in third countries across the EU. A wide spectrum of individual Qualified Persons from various Member States, working for companies of different size, different product portfolio, different types of technologies and different organizational structures, including companies using advanced technologies are organized in and represented by the European Qualified Person Association. The European QP Association is an organization representing individual QPs rather than the employing pharmaceutical companies.	

2. Specific comments on text

<table>
<tr><th>Line No of the first line(s) affected
<e.g. Line 20-23></th><th>Stakeholder no.
<to be completed by the Agency></th><th>Comment and rationale; proposed changes
<if changes to the wording are suggested, they should be highlighted using “track changes”></th><th>Outcome
<to be completed by the Agency></th></tr>
<tr><td>Part A
header of table</td><td></td><td>Comments: It should be clarified that “third countries” are those outside the EEA (not just outside the EU).

Proposed change (if any): from “Manufacturing site(s)” to “Manufacturing site(s) outside the EEA”</td><td></td></tr>
<tr><td>Part A
table format</td><td></td><td>Comments: It should be possible to cover all products used in a clinical trial with a single declaration to reduce paperwork. This could be achieved e.g. by amending the Part A table with another line or column

Proposed change (if any):
<table>
<tr><td colspan="2">Product: (A)</td></tr>
<tr><td>Manufacturing site(s) outside the EEA</td><td>Activities performed ….</td></tr>
<tr><td></td><td></td></tr>
<tr><td colspan="2">Product: (B)</td></tr>
<tr><td>Manufacturing site(s) outside the EEA</td><td>Activities performed ….</td></tr>
<tr><td></td><td></td></tr>
</table></td><td></td></tr>
</table>

<table>
<tr><th>Line No of the first line(s) affected
<e.g. Line 20-23></th><th>Stakeholder no.
<to be completed by the Agency></th><th>Comment and rationale; proposed changes
<if changes to the wording are suggested, they should be highlighted using “track changes”></th><th>Outcome
<to be completed by the Agency></th></tr>
<tr><td></td><td></td><td>Or
<table>
<tr><td></td><td>Manufacturing site(s) outside the EEA</td><td>Activities performed ….</td></tr>
<tr><td rowspan="2">Product: (A)</td><td></td><td></td></tr>
<tr><td></td><td></td></tr>
<tr><td rowspan="2">Product: (B)</td><td></td><td></td></tr>
<tr><td></td><td></td></tr>
</table></td><td></td></tr>
<tr><td>Part B
table (i)</td><td></td><td>Comments: Chapter 7 of the GMP Guide as well as other chapters have been/are being revised to integrate basic concepts of ICH Q 9, ICH Q10 and anticipating the new regulations of Directive 2011/62. Within the Quality Management System of the Pharmaceutical Manufacturer audits are conducted by a suitably trained and experienced personel within the organisation of the MIA holder. It is not explicitely required that the QP in person conducts each and any audit. Thus, we propose to adapt this section respectively.

Proposed change (if any): from “Personal audit” to “Direct audit by or on behalf of the QP of the MIA holder within the Quality Management System”</td><td></td></tr>
<tr><td>Part B
table (ii)</td><td></td><td>Comments: The term “third party” needs clarification. This term is commonly used for “outsourced audits” conducted by personel outside the organisation of the MIA holder.</td><td></td></tr>
</table>

Line No of the first line(s) affected *<e.g. Line 20-23>*	Stakeholder no. *<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>*
		Proposed change (if any): from "Audit conducted by third party (including another QP employed by the importer)" to "Audit conducted by third party".	
Part B table (i) and (ii)		Comments: Is there really a need to separately list table (i) and (ii) ? The form could be simplified to a single table capturing audits, e.g. Proposed change (if any): table (ii): "Manufacturing site(s) / Third Party/Date of audit" to "Manufacturing site(s) / Auditing Party/Date of audit".	
---		Comments: Not yet captured: "If the IMP being imported is used as a comparator and the site of manufacture is unknown please provide evidence that the product has a Marketing Authorisation in the source country", e.g. NDC-number for US commercial products. This information is currently captured by the MHRA form. Proposed change (if any): Format in the event that comparators are sourced from third countries to be added.	

Please feel free to add more rows if needed.