Vienna, 02 April 2013

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:

Austrian Qualified Person Association (aqpa)

About aqpa: The Austrian Qualified Person Association (aqpa) was founded in 2008. Because of the unique responsibilities and tasks of a Qualified Person in Europe they need a forum to represent the Qualified Person in Austria. The aqpa provides Austrian Qualified Persons with a platform allowing them to exchange their experience, discuss the latest regulatory requirements, identify and address troubles and challenges and to support a harmonised European approach with a special focus on the specific Austrian national requirements.

Today the Austrian Qualified Person Association is led by the following representatives from the industry: Georg Göstl (Chairman), QP, Baxter AG; Gabriela Schallmeiner (dep. Chairwoman), QP, Affiris AG (part-time) and Inspection-Ready Consulting; Wolfgang Zauner (Secretary), QP and Head QA, AFFiRiS AG Austria and Markus Thiel (Treasurer) , QP and Managing Director, Roche Austria GmbH.

Website: www.Austria-QP.at

AQPA, the Austrian Qualified Person Association, appreciates the opportunity from the European Commission to comment the Draft Template for the "Qualified Person's Declaration Concerning GMP Compliance of Investigational Medicinal Products Manufactured in Non-EU Countries".

Our comments to the document are listed below:

General Comments on the current draft version of the document:

1. The template should be in accordance to the new version of the Annex 16 of the EU GMP Guide part II, which is still under revision by the European Commission.
2. Consequences of different types of mutual recognition agreements (MRA) and agreements on conformity assessments and acceptance (ACAA) for batch certification and import should be taken into consideration.

Specific Comments:

Part B in the current Draft version of the template is written such that the audit, which has to verify the GMP compliance, must be conducted either by the certifying QP or by a third party in the presence of a QP employed by the importer.
Audits do not necessarily have to be performed by a QP. It is common and agreed practice, however, that audits are conducted by a suitably trained and experienced person (who might or might not be a QP).

We therefore suggest changing Part B in the following way:
Part B
I confirm that I am a QP and am authorised to make this declaration.
I declare that compliance with GMP at least equivalent to EU GMP has been verified on the basis of:

(i) ~~Personal audit~~ *Audit conducted by the Manufacturing Authorisation Holder (MAH)*

Manufacturing site(s) *(Name and address of site where the activity is performed)*	*Date of last audit* *(completion) **

** expected to be within the last 3 years*

(ii) or Audit conducted by third party ~~(including another QP employed by the importer)~~

Manufacturing site(s) (Name and address of site where the activity is performed)	Third party	Date of audit (completion) *

* expected to be within the last 3 years

(iii) If an audit of the site has not been performed by the Manufacturing Authorisation Holder or a third party ~~or on behalf of the QP~~, please provide a brief justification and explanation on how the QP knows that standards at least equivalent to EU GMP are being followed at the site.

Manufacturing site	Justification