Vienna, 31 October 2013

Submission of comments on '< **Certification by a Qualified Person and Batch Release (Annex 16 to EU GMP Guidelines)** >'

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 “Annex 16-Certification by a Qualified Person and Batch Release”.

Our comments to the document are listed below:

1) General: The Scope (1.1) states […] *The principles of this guidance also apply to investigational medicinal products, subject to any difference in the legal provisions and more specific guidance in Annex 13 to the Guide.*
Although we agree, that the same principles should be followed for batch release of IMPs, in our view, this statement is too general. A clearer definition,

which requirements of Annex 16 in addition to the requirements of Annex 13 have to be fulfilled for IMP release, should be included.

2) Section 2.2 indicates that the QP is responsible for knowing the laws in all destination countries world-wide where the drug is registered. As national legal requirements (and knowledge about their interpretation in the respective countries) may not be available to QPs located within the EU and due to possible language issues, we suggest revising this requirement to focus the QP responsibility during the release process on details specified in the Marketing Authorization for the destination country only. Complying with the marketing authorization in a given country suggests that compliance to the respective national laws is also given. Our suggested text is also consistent with point 2.3.2 “The certification of the finished product batch performed by a Qualified Person signifying that the batch is in compliance with EU GMP and the requirements of its marketing authorisation.”

   Please find our suggested wording below:

   2.2. However, the responsibility for ensuring that a particular batch has been manufactured in accordance with its marketing authorisation for the destination country of the medicinal product, with EU Good Manufacturing Practice (GMP), or equivalent, and that it is in compliance with the laws in force in the Member State where certification takes place ~~and of the destination country of the medicinal product~~, lies with the QP certifying that batch as being suitable for release.

3) A similar argument applies for section 2.4.3: for the reasons given above, we suggest to limit the QP responsibility to destination country-specifc requirements that are mentioned in the marketing authorisation.

   Please find our suggested wording below:
   „Any other relevant legal requirements of the destination country **mentioned in the marketing authorisation**, are taken into account“.

4) The current Annex 16 reads (section 4.1): “Each site […] should have at its disposal the services of at least one QP.” whereas the draft reads (section 3.3): “Each manufacturing site in the EEA must have at least one QP.”

   Although the basis for this statement (Article 48 of 2001/83/EC) remains unchanged, the difference could lead to the interpretation that now at each site, at least one QP must be permanently physically present. This expectation

might grow with the next sentence in the draft: “Where the site only undertakes partial manufacturing […] then a QP **at** that site must at least confirm […]”, which also implies that there is a QP physically at that site. Depending on the type and extent of business, some pharmaceutical manufacturing sites in the EU accommodate the offices of several QPs, whereas others do not permanently have a QP physically present. This is accepted in the majority of EU countries, provided the other requirements of Annex 16 are met.
In view of these facts and to avoid expectations that exceed the framework of the directive, we suggest staying with the current wording (see below):

“Each manufacturing site in the EEA must have at its disposal the services of at least one QP”
and to slightly adapt the next sentence to
“Where the site only undertakes partial manufacturing […] then a QP **responsible for** that site must at least confirm […]”.