From: Gabriel Bohl [mailto:Gabriel.Bohl@Quintiles.com]
Sent: Thursday, March 28, 2013 6:20 PM
To: SANCO PHARMACEUTICALS D6
Subject: QP declaration to be included in CTA - draft for consultation

Quintiles - CRO - large size company

Dear All,

Please find below few comments coming from our Regulatory Advisory team on the draft QP declaration issued for consultation: "**QP declaration on GMP equivalence to EU GMP for IMP manufactured in 3rd countries**" provides the template for the qualified person's declaration regarding Good Manufacturing Practice (GMP) compliance as required by "Commission Communication (2010/C 82/01).

We propose 3 comments:

1. Under print name, the QP should add his job qualification (to make sure the QP is signing)
2. For the 3rd category, example of justifications could be proposed in a guidance document to help completing the form (e.g. inspection, review of documents, phone interviews…).
3. The outcome of any audit/inspection is not requested in the form. The applicant and sponsor should be able to rely on the QP when she/he completes the table that no major/critical findings following an audit or inspection are pending having a potential impact on the safety or efficacy of the IMP. The QP should inform the authorities if such a situation is encountered in the course of the study. This comment/warning could be added in the form.

Thank you for issuing this very helpful QP declaration.

Wish you All Happy Easter !

With our kindest regards,

Gabriel Bohl, PharmD, MTOPRA

AD, Regulatory & Start-Up

RSU, Regulatory Affairs

Integrated Site Services

Quintiles

Navigating the new health

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From: Gabriel Bohl
Sent: Thursday, February 28, 2013 12:59 PM
To: Katarina Frank-Holmberg; Jacqueline O'Brien; Kay Mason; Catherine Paulen; Katy Thompson; Christopher Bamford; Gurdeep Bhangra; Maria Jose Frances
Subject: QP declaration to be included in CTA - draft for consultation

Dear All,

This document called "**QP declaration on GMP equivalence to EU GMP for IMP manufactured in 3rd countries**" provides the template for the qualified person's declaration regarding Good Manufacturing Practice (GMP) compliance as required by "Commission Communication (2010/C 82/01).

This template is for **public consultation** with a deadline for comments: **02-Apr-2013**.

This document will be **part of the CTA** under the new regulatory framework and the goal is to harmonise this template and hence the dossier submitted with a request for authorisation of a clinical trial.

EU GMP compliance for the manufacturing sites will be assessed based on 3 categories:

1. Personal audit
2. Audit conducted by 3rd party
3. Brief justification in case no audit performed

I propose 4 comments:

4. Under print name, the QP should add his job qualification (to make sure the QP is signing)
5. For the 3rd category, example of justifications could be proposed in a guidance document to help completing the form (e.g. inspection, review of documents, phone interviews…).
6. As this form may refer to other audit or inspection reports, the QP can decide to annex those to the form. An option of adding appendices should stay open in the form.
7. Also the outcome of audit is not requested in the form – a specific column could be added asking for a summary of the "outcome of audit" e.g. major or critical findings resolved when?

We can consolidate our feedback before sending them to European Commission.

Please feel free to circulate this document. The IMPD team is copied in.

Kind regards,

Gabriel Bohl, PharmD, MTOPRA

Manager

RSU - Regulatory Affairs

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