PDA Europe gGmbH
Adalbertstraße 9
16548 Glienicke/Berlin
Germany
Tel: +49 (33056) 2377 -10
Fax: +49 (33056) 2377 -77
Georg Roessling, PhD
General Manager
Senior Vice President PDA Europe
http://europe.pda.org

April 2, 2013

European Commission
Health and Consumers Directorate –General, Brussels
sanco-pharmaceuticals-d6@ec.europa.eu

Ref: Template For The Qualified Person's Declaration Concerning GMP Compliance of Investigational Medicinal Products Manufactured In Non-EU Countries

To the Health and Consumers Directorate-General:

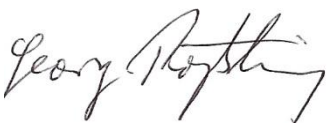
PDA is pleased to provide comments on the template submitted for public consultation. PDA is a non-profit international professional association of more than 10,000 individual member scientists having an interest in the fields of pharmaceutical, biological, and device manufacturing and quality. Our review was completed by an international group of expert volunteers with experience in investigational medicinal products, regulatory affairs and GMP on behalf of our Regulatory Affairs and Quality Advisory Board.

Overall PDA feels the template is well prepared and adequate for the purpose.

PDA believes that the Qualified Person has to be able to rely on the quality system implemented in the company for which he or she is working. The QP must also have the ability to rely on audits performed by an independent auditing organisation within the company and/or by qualified external auditors. In addition PDA supports a risk based approach to determining the appropriate time limit between audits. We agree with the basic expectation of a 3 year interval but recommend that longer intervals be acceptable when justified.

If you have any questions, please contact me.

With very best regards,



Georg Roessling, Ph.D.
Senior VP, PDA Europe
Roessling@pda.org