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Health systems and products
Medicinal products – quality, safety and efficacy

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TEMPLATE FOR THE QUALIFIED PERSON'S DECLARATION CONCERNING GMP COMPLIANCE OF INVESTIGATIONAL MEDICINAL PRODUCTS MANUFACTURED IN NON-EU COUNTRIES

DRAFT SUBMITTED FOR PUBLIC CONSULTATION

This document provides the template for the *Qualified Person's Declaration Concerning GMP Compliance of the Investigational Medicinal Products* as per Commission Communication CT-1[1] Section 2.7.1 paragraph 62.

The aim is to harmonise this template and hence the dossier submitted with a request for authorisation of a clinical trial.

According to the Commission's proposal for a new 'Clinical Trials Regulation'[2], such template is also going to be necessary for the application process under the new regulatory framework.

Stakeholders are invited to comment on this draft by 2 April 2013 at the latest. Responses should be sent preferably by e-mail to sanco-pharmaceuticals-d6@ec.europa.eu, or by post to Unit SANCO/D/6, DM24 02/050, BE-1049 Brussels.

When sending your comments and responses, you should state whether you are a stakeholder association or a private individual. If you represent an association, please indicate clearly what type of association this is (IMP manufacturer, IMP importer, CRO, sponsor, etc.). If you represent a company, please state whether it falls within the EU definition of a small and medium-sized enterprise (i.e. less than €50 million annual turnover and fewer than 250 employees).

All comments and responses will be made publicly available on the 'Europa website' on clinical trials once the consultation period is over. If you do not wish your contribution to be made public please indicate this clearly and specifically in the documentation you send us (i.e. not just in the covering letter or e-mail). In this case, only an indication of the contributor will be disclosed.

Professional organisations are invited to register in the Union's Register for Interest Representatives (http://europa.eu/transparency-register/) set up as part of the European Transparency Initiative to provide the Commission and the public at large with information about the objectives, funding and structures of interest representatives.

[1] Detailed guidance for the request for authorisation of a clinical trial on a medicinal product for human use to the competent authorities, notification of substantial amendments and declaration of the end of the trial (OJ C82, 30.3.2010, p. 1)

[2] Proposal for a Regulation of the European Parliament and of the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (COM(2012)369 final); see margin number 25 in Annex I.

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QP DECLARATION ON GMP EQUIVALENCE TO EU GMP FOR INVESTIGATIONAL MEDICINAL PRODUCTS MANUFACTURED IN THIRD COUNTRIES

EudraCT number	**Product name**

Manufacturing and Importation Authorisation (MIA) number under which this declaration is made:_____

Part A

Manufacturing site(s) **(Name and address of site where the activity is performed)**	**Activity performed at this site** **(including packaging, labelling and testing)**

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

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) 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 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**

This declaration is submitted by:

Signatory _____ Date _____

Print name _____