EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

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

Brussels,
SANCO/D/6/SF/mg/ddg1.d.6(2013)1104750

TEMPLATE FOR THE QUALIFIED PERSON'S DECLARATION EQUIVALENCE TO EU GMP FOR INVESTIGATIONAL MEDICINAL PRODUCTS MANUFACTURED IN THIRD COUNTRIES

This document provides the template for the *Qualified Person's Declaration Concerning GMP Compliance of the Investigational Medicinal Products* as per Commission guideline 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.

Document history:	
Date of discussion of draft by the ad-hoc group for the development of implementing guidelines for the "Clinical Trials Directive" 2001/20/EC:	30 April 2013
Date of publication:	See above
Date of coming into operation:	6 months date of publication
Supersedes:	N/A
Changes compared to superseded version:	N/A

[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)

Commission européenne/Europese Commissie, 1049 Bruxelles/Brussel, BELGIQUE/BELGIË - Tel. +32 22991111
Office: DM24 02/034 - Tel. direct line +32 229-67543 - Fax +32 229-98046; Sanco-pharmaceuticals-d6@ec.europa.eu

QUALIFIED PERSON'S DECLARATION EQUIVALENCE TO EU GMP FOR INVESTIGATIONAL MEDICINAL PRODUCTS MANUFACTURED IN THIRD COUNTRIES[2] (ARTICLE 13(3)(b) OF DIRECTIVE 2001/20/EC)

EudraCT number(s)	**Name of the IMP(s)**

Manufacturing and/or Importation Authorisation (MIA) number[3] under which this declaration is made:_____

Part A

Name of the IMP(s)	**Manufacturing site(s)** **(Name and address 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) Audit

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

[2] Countries other than EU Member States or contracting states of the European Economic Area (EEA).

[3] If no number is issued please state the name of the authorisation holder.

(ii) If an audit of the site has not been performed, 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[4].

Manufacturing site(s) **(Name and address where the activity is performed)**	**Justification**

This declaration is submitted by:

Signatory _____ Date _____

Print name _____

[4] E.g. assessment of documentation provided by the manufacturer, valid GMP certificate (EudraGMP), etc.