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Health systems, medical products and innovation
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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 certification by the qualified person in the Union that the manufacturing of an investigational medicinal product (IMP) outside of the EU/EEA complies with GMP at least equivalent to the GMP in the Union, as described in the Clinical Trials Regulation 536/2014[1]

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

Document history:	
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1 Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on Clinical Trials On Medicinal Products For Human Use, And Repealing Directive 2001/20/EC

QUALIFIED PERSON'S DECLARATION EQUIVALENCE TO EU GMP FOR IMP MANUFACTURED IN THIRD COUNTRIES[2] (ARTICLE 63 AND ANNEX I (F) (33) (b) OF REGULATION (EC) 536/2014)

EUCT 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(-ies) is (are) performed)**	**Activity(-ies) performed at this site** **(including packaging, labelling, storage, testing and release)**

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 as in part A)**	**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. Also, please explain 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 as in part A)**	**Justification**

This declaration is submitted by:

Signature _____ Date _____

Name and role _____

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