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

Unique Trial Identifying number **(e.g. EudraCT or IRAS)**	**Name of the IMP(s)**

Manufacturing and/or Importation Authorisation for Investigational Medicinal Products (MIA(IMP)) number[1] 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)**

[1] 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[2].

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

This declaration is submitted by:

Signatory _____ Date _____

Print name _____

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