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| Logo of the European Commission, 12 yellow stars on a blue background arranged in a circle and framed by two light grey graphic elements representing the Berlaymont building, which is the headquarter of the European Commission. | EUROPEAN COMMISSIONDIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETYHealth systems, medical products and innovation**Medical products: quality, safety, innovation** |

Brussels

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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]](#footnote-1)

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

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| --- |
| **Document history:** |
| Date of discussion by the Clinical Trial Expert Group: | 06/07/2022 |
| Date of publication: | 06/09/2022 |
| Date of coming into operation: | At publication |
| Supersedes: | Version May 2013 |

**QUALIFIED PERSON'S DECLARATION EQUIVALENCE TO EU GMP FOR IMP MANUFACTURED IN THIRD COUNTRIES[[2]](#footnote-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]](#footnote-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)** |
|  |  |  |
|  |  |  |

(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]](#footnote-4).

|  |  |
| --- | --- |
| **Manufacturing site(s)****(Name and address as in part A)** | **Justification**  |
|  |  |
|  |  |

This declaration is submitted by:

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name and role \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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 [↑](#footnote-ref-1)
2. Countries other than EU Member States or contracting states of the European Economic Area (EEA). [↑](#footnote-ref-2)
3. If no number is issued please state the name of the authorisation holder. [↑](#footnote-ref-3)
4. E.g. assessment of documentation provided by the manufacturer, valid GMP certificate (EudraGMP), etc. [↑](#footnote-ref-4)