IMP Expedited Assessment of Variations to Annex 3 and/or 4 Application Form

See the guidance document ‘Guide to New Applications and Variations to Manufacturer's Authorisations’ for instructions on completing this form and details of the supporting documents required. This document is available on [www.hpra.ie](http://www.hpra.ie).

A QP declaration template is provided in Appendix 1 of this form.

|  |
| --- |
| Applicant Details (*\*This section is mandatory.*)Authorisation/licence number:      Legally registered name of authorisation/licence holder:      Legally registered address of the authorisation/licence holder:      Eircode:      Organisation Management Service ID (ORG ID):      Organisation Management Service Location ID (LOC ID):      Company Registration Office number:      Address of manufacturing or premises (if different from that of the holder):      Eircode:      Organisation Management Service Location ID (LOC ID):      Name, telephone number and email address of a designated QP named on the authorisation:      Name and address of applicant to whom correspondence should be addressed:      Contact telephone:      Email address of contact:       |

ANNEX 3 CONTRACT MANUFACTURER(S)

List each removal and change to name/address of existing contract manufacturers in the table below.

[ ]  Deletion of a contract manufacturer (administrative variation)

[ ]  Change in the name of a contract manufacturing site (administrative variation)

[ ]  Change in the address of a contract manufacturing site (technical variation)

|  |  |
| --- | --- |
| **Present Wording** | **Proposed Wording** |
|       |       |

Please complete a separate Annex 3 for each additional contract manufacturer.

[ ]  Addition of contract manufacturing site (technical variation)

[ ]  Addition of production activities at an approved contract manufacturing site (technical variation)

[ ]  Deletion of operations carried out at a contract manufacturing site (administrative variation)

|  |  |
| --- | --- |
| Name and address of the contract manufacturing site |       |
| Organisation Management Service ID (ORG ID) |       |
| Organisation Management Service Location ID (LOC ID) |       |
| Located within the USA? | [ ] Yes [ ]  No |
| Date of last FDA inspection |       |
| FDA establishment identification (FEI) number |       |

Please check the relevant items and delete any checkbox items below which are not applicable.

|  |  |  |
| --- | --- | --- |
| 1.1 Sterile products |  |  |
| *1.1.1 Aseptically prepared (processing operations for the following dosage forms)* | **Addition** | **Removal** |
| 1.1.1.1 [ ]  Large volume liquids | [ ]  | [ ]  |
| 1.1.1.2 [ ]  Lyophilisates | [ ]  | [ ]  |
| 1.1.1.3 [ ]  Semi-solids | [ ]  | [ ]  |
| 1.1.1.4 [ ]  Small volume liquids | [ ]  | [ ]  |
| 1.1.1.5 [ ]  Solids and implants | [ ]  | [ ]  |
| 1.1.1.6 [ ]  Other aseptically prepared products <free text> | [ ]  | [ ]  |
| *1.1.2 Terminally sterilised (processing operations for the following dosage forms)* | **Addition** | **Removal** |
| 1.1.2.1 [ ]  Large volume liquids | [ ]  | [ ]  |
| 1.1.2.2 [ ]  Semi-solids | [ ]  | [ ]  |
| 1.1.2.3 [ ]  Small volume liquids | [ ]  | [ ]  |
| 1.1.2.4 [ ]  Solids and implants | [ ]  | [ ]  |
| 1.1.2.5 [ ]  Other terminally sterilised prepared products <free text> | [ ]  | [ ]  |
| 1.2 Non-sterile products |  |  |
| *1.2.1 Non-sterile products (processing operations for the following dosage forms)* | **Addition** | **Removal** |
| 1.2.1.1 [ ]  Capsules, hard shell | [ ]  | [ ]  |
| 1.2.1.2 [ ]  Capsules, soft shell | [ ]  | [ ]  |
| 1.2.1.3 [ ]  Chewing gums | [ ]  | [ ]  |
| 1.2.1.4 [ ]  Impregnated matrices | [ ]  | [ ]  |
| 1.2.1.5 [ ]  Liquids for external use | [ ]  | [ ]  |
| 1.2.1.6 [ ]  Liquids for internal use | [ ]  | [ ]  |
| 1.2.1.7 [ ]  Medicinal gases | [ ]  | [ ]  |
| 1.2.1.8 [ ]  Other solid dosage forms | [ ]  | [ ]  |
| 1.2.1.9 [ ]  Pressurised preparations | [ ]  | [ ]  |
| 1.2.1.10 [ ]  Radionuclide generators | [ ]  | [ ]  |
| 1.2.1.11 [ ]  Semi-solids  | [ ]  | [ ]  |
| 1.2.1.12 [ ]  Suppositories | [ ]  | [ ]  |
| 1.2.1.13 [ ]  Tablets | [ ]  | [ ]  |
| 1.2.1.14 [ ]  Transdermal patches | [ ]  | [ ]  |
| 1.2.1.15 [ ]  Intraruminal devices | [ ]  | [ ]  |
| 1.2.1.16 [ ]  Veterinary premixes | [ ]  | [ ]  |
| 1.2.1.17 [ ]  Other non-sterile medicinal products <free text> | [ ]  | [ ]  |
| 1.3 Biological medicinal products |  |  |
| *1.3.1 Biological Medicinal Products (list of product types)* | **Addition** | **Removal** |
| 1.3.1.1 [ ]  Blood products | [ ]  | [ ]  |
| 1.3.1.2 [ ]  Immunological products | [ ]  | [ ]  |
| 1.3.1.3 [ ]  Cell therapy products | [ ]  | [ ]  |
| 1.3.1.4 [ ]  Gene therapy products | [ ]  | [ ]  |
| 1.3.1.5 [ ]  Biotechnology productsPlease specify which of the following activities 1.3.1.5 relates to: [ ]  Cell culture mammalian[ ]  Cell culture bacterial[ ]  Fermentation[ ]  Isolation/purification[ ]  Low bioburden bulk intermediate[ ]  Final dosage form | [ ]  | [ ]  |
| 1.3.1.6 [ ]  Human or animal extracted products | [ ]  | [ ]  |
| 1.3.1.7 [ ]  Tissue engineered products | [ ]  | [ ]  |
| 1.3.1.8 [ ]  Other biological medicinal products <free text> | [ ]  | [ ]  |
| 1.4 Other products or manufacturing activity |  |  |
| *1.4.1 Manufacture of:* | **Addition** | **Removal** |
| 1.4.1.1 [ ]  Herbal products | [ ]  | [ ]  |
| 1.4.1.2 [ ]  Homoeopathic products | [ ]  | [ ]  |
| 1.4.1.3 [ ]  Other <free text> | [ ]  | [ ]  |
| *1.4.2 Sterilisation of active substances/excipients/ finished product* | **Addition** | **Removal** |
| 1.4.2.1 [ ]  Filtration | [ ]  | [ ]  |
| 1.4.2.2 [ ]  Dry heat | [ ]  | [ ]  |
| 1.4.2.3 [ ]  Moist heat | [ ]  | [ ]  |
| 1.4.2.4 [ ]  Chemical | [ ]  | [ ]  |
| 1.4.2.5 [ ]  Gamma irradiation | [ ]  | [ ]  |
| 1.4.2.6 [ ]  Electron beam | [ ]  | [ ]  |
| *1.4.3* [ ]  *Other* <free text>[ ]  Storage | [ ] [ ]  | [ ] [ ]  |
| 1.5 Packaging |  |  |
| *1.5.1 Primary packing* | **Addition** | **Removal** |
| 1.5.1.1 [ ]  Capsules, hard shell | [ ]  | [ ]  |
| 1.5.1.2 [ ]  Capsules, soft shell | [ ]  | [ ]  |
| 1.5.1.3 [ ]  Chewing gums | [ ]  | [ ]  |
| 1.5.1.4 [ ]  Impregnated matrices | [ ]  | [ ]  |
| 1.5.1.5 [ ]  Liquids for external use | [ ]  | [ ]  |
| 1.5.1.6 [ ]  Liquids for internal use | [ ]  | [ ]  |
| 1.5.1.7 [ ]  Medicinal gases | [ ]  | [ ]  |
| 1.5.1.8 [ ]  Other solid dosage forms | [ ]  | [ ]  |
| 1.5.1.9 [ ]  Pressurised preparations | [ ]  | [ ]  |
| 1.5.1.10 [ ]  Radionuclide generators | [ ]  | [ ]  |
| 1.5.1.11 [ ]  Semi-solids  | [ ]  | [ ]  |
| 1.5.1.12 [ ]  Suppositories | [ ]  | [ ]  |
| 1.5.1.13 [ ]  Tablets | [ ]  | [ ]  |
| 1.5.1.14 [ ]  Transdermal patches | [ ]  | [ ]  |
| 1.5.1.15 [ ]  Intraruminal devices | [ ]  | [ ]  |
| 1.5.1.16 [ ]  Veterinary premixes | [ ]  | [ ]  |
| 1.5.1.17 [ ]  Other non-sterile medicinal products <free text> | [ ]  | [ ]  |
|  | **Addition** | **Removal** |
| *1.5.2* [ ]  *Secondary packing* | [ ]  | [ ]  |
| 1.6 Quality control testing | **Addition** | **Removal** |
| *1.6.1* [ ]  *Microbiological: sterility* | [ ]  | [ ]  |
| *1.6.2* [ ]  *Microbiological: non-sterility* | [ ]  | [ ]  |
| *1.6.3* [ ]  *Chemical/Physical* | [ ]  | [ ]  |
| *1.6.4* [ ]  *Biological*[ ]  *Stability (additionally identify category of testing above, refer to guidance)* | [ ] [ ]  | [ ] [ ]  |

ANNEX 4 CONTRACT laboratory

List each removal and change to name/address of existing contract laboratories in the table below.

[ ]  Deletion of a contract laboratory (administrative variation)

[ ]  Change in the name of a contract laboratory (administrative variation)

[ ]  Change in the address of a contract manufacturing site (technical variation)

|  |  |
| --- | --- |
| **Present Wording** | **Proposed Wording** |
|       |       |

Please complete a separate Annex 4 for each additional contract laboratory.

[ ]  Addition of a new contract laboratory (technical variation)

[ ]  Addition of activities at an approved contract laboratory (technical variation)

[ ]  Deletion of testing activities carried out at a contract laboratory (administrative variation)

|  |  |
| --- | --- |
| Name of contract laboratory |       |
| Address of contract laboratory |       |
| Organisation Management Service ID (ORG ID) |       |
| Organisation Management Service Location ID (LOC ID) |       |
| Tick relevant testing operations below: | **Addition** | **Removal** |
| [ ]  Microbiological: sterility | [ ]  | [ ]  |
| [ ]  Microbiological: non sterility  | [ ]  | [ ]  |
| [ ]  Chemical/physical  | [ ]  | [ ]  |
| [ ]  Biological | [ ]  | [ ]  |
| [ ]  Stability (additionally identify category of testing above, refer to guidance) | [ ]  | [ ]  |
| Located within the United States? | [ ]  Yes[ ]  No |
| Date of last FDA inspection |       |
| FDA establishment identification (FEI) number |       |

|  |
| --- |
| **Background**Please give a brief background explanation for the proposed changes to your authorisation/licence and attach additional supporting data as detailed in HPRA ‘Guide to New Applications and Variations to Manufacturer’s Authorisations’, and as indicated throughout application form.      |
| feesAn application fee must be submitted with each request for variation to an authorisation/ licence. Please refer to the ‘Guide to Fees for Human Products’ Section 3 / ‘Guide to Fees (Veterinary)’ Section 2, on [www.hpra.ie](http://www.hpra.ie). Complete and submit only the relevant section of the fee application form. |
| declarationI hereby make application for the above authorisation/licence to be varied in accordance with the proposals given above, and certify that the changes will not adversely affect the quality, efficacy or safety of any medicinal product tested. I declare that amended documents have been supplied and that the supporting information is correct. I declare that all changes have been identified and that there are no other changes in the amended documentation.Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:      Print name:       Title/position:       |

Send to:

Email: compliance@hpra.ie

Compliance Department

Health Products Regulatory Authority

Earlsfort Centre

Earlsfort Terrace

Dublin 2

D02 XP77

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Fax: + 353 1 676 7836

Please do not submit applications more than once.

Appendix 1

Template for QUALIFIED PERSON'S DECLARATION EQUIVALENCE TO EU GMP FOR INVESTIGATIONAL MEDICINAL PRODUCTS MANUFACTURED IN THIRD COUNTRIES[[1]](#footnote-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 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:

1. Audit

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

1. If an audit of the site has not been performed, please provide a brief justification and explanation of how the QP knows that standards at least equivalent to EU GMP are being followed at the site[[2]](#footnote-3).

|  |  |
| --- | --- |
| **Manufacturing site(s)** **(name and address where the activity is performed)** | **Justification** |
|       |       |
|       |       |

This declaration is submitted by:

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

Print name:

1. Countries other than EU Member States or contracting states of the European Economic Area (EEA). [↑](#footnote-ref-2)
2. E.g. assessment of documentation provided by the manufacturer, valid GMP certificate (EudraGMDP), etc. [↑](#footnote-ref-3)