Request for Pre-submission Meeting for Manufacturer’s/Importer’s Authorisation (MIA)

It is recognised that interaction may be sought with the HPRA at different stages of an MIA application and that some of the information requested on this form may not be available to all organisations seeking advice, but please provide as much detail as possible. If there is not enough space in the boxes provided, please attach any relevant documentation to this form.

1. Administrative information

|  |  |
| --- | --- |
|  | Date of request: |
|  | Proposed applicant’s contact details  Contact person:  Telephone:  Email address: |
|  | Have you had any previous interactions with the HPRA Compliance department relating to an application or authorisation, e.g. MIA, wholesaler, active substance registration?  Yes HPRA reference number(s) (*if applicable):*  No |

1. About the MANUFACTURER

|  |  |
| --- | --- |
|  | Legally registered name of proposed authorisation holder:  Companies Registration Office Number: |
|  | Legally registered address of proposed authorisation holder: |
|  | Address(es) of manufacturing site(s): |
|  | Type of MIA required  Manufacturer’s authorisation for medicinal products for human use  Manufacturer’s authorisation for investigational medicinal products for human use  Manufacturer’s authorisation for medicinal products for veterinary use |
|  | Manufacturing operations (according to part 1)  Importation of medicinal products (according to part 2) |
|  | Manufacturing operations  Sterile products manufacture  Aseptically prepared  Terminally sterilised  Batch certification of sterile products  Non-sterile product manufacture  Batch certification of non-sterile products  Biological medicinal products manufacture  Batch certification of biological products  Other products or manufacturing activity, e.g. herbal products, homoeopathic products, other:  Sterilisation of active substances/excipients/finished product  Packaging  Quality control testing |
|  | Importation of medicinal products  Quality control testing of imported medicinal product  Batch certification of imported medicinal products  Other importation activities |
|  | Name (if known) of the QP proposed for the authorisation: |

1. Contract Sites

|  |  |
| --- | --- |
|  | Contract manufacturers  Yes  No  Name and address of each contract manufacturing site: |
|  | Contract laboratories  Yes  No  Name and address of each contract laboratory: |

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| **Please send the completed form and accompanying documentation by email to** [**compliance@hpra.ie**](mailto:compliance@hpra.ie)**.** |