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 detailsContact 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 [ ]  NoName and address of each contract manufacturing site:  |
|  | Contract laboratories [ ]  Yes [ ]  NoName and address of each contract laboratory:  |

|  |
| --- |
| **Please send the completed form and accompanying documentation by email to** **compliance@hpra.ie****.** |