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| **Application for new Manufacturer’s Authorisation for Investigational**  **Medicinal Products MIA(IMP) (Human Use)** | | | | |
| **Section 1 Company information** | | | |
| *Registered Company Name:* | | | |
|  | | | |
| *Address:* | | | |
|  | | | |
| *Company contact person :* |  | | |
| Telephone/Mobile: |  | E-mail: |  |
| Trading Style: |  | | |

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| --- |
| **Communications and/or invoicing address (if different)** |
|  |

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| --- | --- | --- | --- |
| **In case of person applying on behalf of the proposed registration holder** | | | |
| *Name of the contact:* | | | |
| ***Contact details:*** | | | |
| Telephone/Mobile: |  | E-mail: |  |

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| **Application Date** |  | **Purchase Order Number** |  |

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| **Checklist** | |
|  | Section 1 - completed once per application. |
|  | Section 2, 3 & 4 - one copy for each named manufacturing/importation site. |
|  | Section 5 - one copy for each person to be named on the site signed and dated. |
|  | Section 6 - one copy covers three named Storage and Handling sites. |
|  | Section 7 - one copy for each named Contract Laboratory site. |
|  | Section 8 - completed once per application, signed and dated. |

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| **Supporting Documentation** | |
|  | Certificate of incorporation issued by Companies House (or similar). |
|  | Curriculum Vitae information either completed or provided for any nominated person, Qualified Person, Quality Controller or Production Manager. |
|  | Nominated Qualified Person has provided a certificate from a professional Institute. |
|  | Signed Technical Agreements (where applicable) are available. |
|  | Site Master Files are attached or available. |

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| **Do you have a pending/approved Wholesale Distribution Authorisation or other Manufacturing Authorisation** | | |
| Pending | Approved | N/A |

|  |
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| **For advice or assistance please email:** [**pcl@mhra.gov.uk**](mailto:pcl@mhra.gov.uk) **and please read the following useful information before you apply:**  [**https://mhrainspectorate.blog.gov.uk/2017/01/05/helping-us-to-help-you/**](https://mhrainspectorate.blog.gov.uk/2017/01/05/helping-us-to-help-you/) |

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| **Application for new Manufacturer’s Authorisation for Investigational**  **Medicinal Products MIA(IMP) (Human Use)** |

|  |  |
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| **Section 2 Site Information** | |
| *Site Name:* | |
| *Address:* | |
|  | |
| *DUNS Number:* | **-                   -** |

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|  | **Site Contact Person** | | | |
| Name of the contact: | | | | |
| Telephone/Mobile: | |  | E-mail: |  |

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| **Site Activities** |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Are the products for administration to human beings? | **Yes** |  | | | **No** | |  |
|  | | | | | | | |
| Animal Human Origin products are present at this site? | **Yes** | |  | **No** | |  | |

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| **Site Types** |

|  |  |
| --- | --- |
| Manufacture |  |
| Decentralised Manufacture (Point of Care / Modular) |  |
| Import |  |
| Batch Certification (**Not MS Licences)** |  |
| Assembly and Packaging |  |
| Export |  |
| QC Testing |  |
| Biological |  |
| Storage and Handling (picking of goods) |  |
| Other (Please specify) |  |
|  | |

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| 1. **Manufacturing Operations – Medicinal Products** |

|  |  |  |  |
| --- | --- | --- | --- |
| **1.1** | **Sterile products** | | |
| **1.1.1** | **Aseptically prepared**  **(Processing operations for the following dosage forms):** | | **Special**  **Requirement** |
| 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: (Please specify) |  |  |
|  | | | |
| **1.1.2** | **Terminally sterilised**  **(Processing operations for the following dosage forms):** | | **Special**  **Requirement** |
| 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: (Please specify) |  |  |
|  | | | |
| **1.1.3** | Batch certification of sterile products |  |

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| **1.2** | | **Non-sterile products** | | |
| **1.2.1** | | **Non-sterile products**  **(Processing operations for the following dosage forms):** | | **Special**  **Requirement** |
| 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 (veterinary only) |  |  |
| 1.2.1.16 | | Veterinary premixes (veterinary only) |  |  |
| 1.2.1.17 | | Other non-sterile medicinal product (Please specify) |  |  |
|  | | | | |
| **1.2.2** | Batch certification of non-sterile products | |  |

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| 1. **Manufacturing Operations – Medicinal Products** |

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| **1.3** | **Biological medicinal products** | | |
| **1.3.1** | **Biological medicinal products - Manufacture** | | **Special**  **Requirement** |
| 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 products |  |  |
| 1.3.1.6 | Human or animal extracted products |  |  |
| 1.3.1.7 | Tissue Engineered products (not applicable) |  |  |
| 1.3.1.8 | Other biological medicinal products (Please specify) |  |  |
|  | | | |

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| **1.3.2** | **Biological medicinal products – Batch certification** | | **Special**  **Requirement** |
| 1.3.2.1 | Blood products |  |  |
| 1.3.2.2 | Immunological products |  |  |
| 1.3.2.3 | Cell therapy products |  |  |
| 1.3.2.4 | Gene therapy products |  |  |
| 1.3.2.5 | Biotechnology products |  |  |
| 1.3.2.6 | Human or animal extracted products |  |  |
| 1.3.2.7 | Tissue Engineered products (not applicable) |  |  |
| 1.3.2.8 | Other biological medicinal products (Please specify) |  |  |
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| **1.4** | **Other products or processing activity** | | |
| **1.4.1** | **Manufacture of:** | | **Special**  **Requirement** |
| 1.4.1.1 | Herbal products |  |  |
| 1.4.1.2 | Homeopathic products |  |  |
| 1.4.1.3 | Other (Please specify) |  |  |
|  | | | |
| 1.4.1.4 | Products authorised under regulation 174 (supply in  response to spread of pathogenic agents etc) |  |  |

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| **1.4.2** | **Sterilisation of active substances/excipients/finished products** | |
| 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 |  |
| 1.4.2.7 | Other (Please specify) |  |
|  | | |

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| 1. **Manufacturing Operations – Medicinal Products** |

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| **1.5** | | **Packaging** | |
| **1.5.1** | | **Primary Packing** | |
| 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 (veterinary only) |  |
| 1.5.1.16 | | Veterinary premixes (veterinary only) |  |
| 1.5.1.17 | | Other non-sterile medicinal products (please specify) |  |
|  | | | |
| **1.5.2** | **Secondary Packing** | |  |

|  |  |  |
| --- | --- | --- |
| **1.6** | **Quality Control Testing - Manufacture** | |
| 1.6.1 | Finished product testing. Microbiological: sterility |  |
| 1.6.2 | Finished product testing. Microbiological: non-sterility |  |
| 1.6.3 | Finished product testing. Chemical/Physical |  |
| 1.6.4 | Finished product testing. Biological |  |
| 1.6.5 | Stability Testing on finished marketed medicinal products |  |
| 1.6.6 | Environmental monitoring or process simulation (media fill) to support  sterile manufacture |  |

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| **N**  ***NOTE: All other testing, including raw materials testing, does not require a laboratory to be***  ***named on a licence or hold a GMP certificate.* ting, including raw materials testing, does not require a laboratory to be named on a licence or hold a GMP certificate** |

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| 1. **Importation of medicinal products** |

|  |  |  |
| --- | --- | --- |
| **2.1** | **Quality Control Testing of imported medicinal products** | |
| 2.1.1 | Finished product testing. Microbiological: sterility |  |
| 2.1.2 | Finished product testing. Microbiological: non-sterility |  |
| 2.1.3 | Finished product testing. Chemical/Physical |  |
| 2.1.4 | Finished product testing. Biological |  |
| 2.1.5 | Stability Testing on finished marketed medicinal products |  |
| 2.1.6 | Environmental monitoring or process simulation (media fill) to support  sterile manufacture |  |

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| **N**  ***NOTE: All other testing, including raw materials testing, does not require a laboratory to be***  ***named on a licence or hold a GMP certificate.*** |

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| **2.2** | **Batch Certification of imported medicinal products** | |
| **2.2.1** | **Sterile Products** | |
| 2.2.1.1 | Terminally Sterilised |  |
| 2.2.1.2 | Aseptically Prepared |  |
| **2.2.2** | **Non-Sterile Products** |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **2.2.3** | **Biological medicinal products – Importation** | | **Special**  **Requirement** |
| 2.2.3.1 | Blood products |  |  |
| 2.2.3.2 | Immunological products |  |  |
| 2.2.3.3 | Cell therapy products |  |  |
| 2.2.3.4 | Gene therapy products |  |  |
| 2.2.3.5 | Biotechnology products |  |  |
| 2.2.3.6 | Human or animal extracted products |  |  |
| 2.2.3.7 | Tissue Engineered products |  |  |
| 2.2.3.8 | Other biological medicinal products (Please specify) |  |  |
|  | | | |

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| **2.3** | **Other importation activities** | |
| 2.3.1 | Site of physical importation |  |
| 2.3.2 | Importation of intermediate which undergoes further processing |  |
| 2.3.3 | Other (Please specify) |  |
|  | | |

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| **Section 3 Site Information – Operations with Special Requirements** |

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| --- |
| **If you have selected any special requirements in Section 2, please check the appropriate category on the table below. If the Other category applies, provide the required text.** |

|  |  |
| --- | --- |
| **Products with Special requirements** | |
| **1.** | B Lactam Antibiotics |
| **2.** | Other highly sensitising antibiotics |
| **3.** | Live Cells |
| **4.** | Pathogenic Organisms (Biosafety Level 3 or 4) |
| **5.** | Radiopharmaceuticals |
| **6.** | Ectoparasiticides |
| **7.** | Point of Care Manufacturing |
| **8.** | Modular Manufacturing |
| **9.** | Other <Please specify> |

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| **No.** | **1.** | **2.** | **3.** | **4.** | **5.** | **6.** | **7.** | **8.** | **9. (For Other please include text)** | | |
| 1.1.1.1 |  |  |  |  |  |  |  |  |  | |  |
| 1.1.1.2 |  |  |  |  |  |  |  |  |  | |  |
| 1.1.1.3 |  |  |  |  |  |  |  |  |  | |  |
| 1.1.1.4 |  |  |  |  |  |  |  |  |  | |  |
| 1.1.1.5 |  |  |  |  |  |  |  |  |  | |  |
| 1.1.1.6 |  |  |  |  |  |  |  |  |  | |  |
| **No.** | **1.** | **2.** | **3.** | **4.** | **5.** | **6.** | **7.** | **8.** | **9. (For Other please include text)** | | |
| 1.1.2.1 |  |  |  |  |  |  |  |  |  | |  |
| 1.1.2.2 |  |  |  |  |  |  |  |  |  | |  |
| 1.1.2.3 |  |  |  |  |  |  |  |  |  | |  |
| 1.1.2.4 |  |  |  |  |  |  |  |  |  | |  |
| 1.1.2.5 |  |  |  |  |  |  |  |  |  | |  |
| **No.** | **1.** | **2.** | **3.** | **4.** | **5.** | **6.** | **7.** | **8.** | **9. (For Other please include text)** | | |
| 1.2.1.1 |  |  |  |  |  |  |  |  | |  |  |
| 1.2.1.2 |  |  |  |  |  |  |  |  | |  |  |
| 1.2.1.3 |  |  |  |  |  |  |  |  | |  |  |
| 1.2.1.4 |  |  |  |  |  |  |  |  | |  |  |
| 1.2.1.5 |  |  |  |  |  |  |  |  | |  |  |
| 1.2.1.6 |  |  |  |  |  |  |  |  | |  |  |
| 1.2.1.7 |  |  |  |  |  |  |  |  | |  |  |
| 1.2.1.8 |  |  |  |  |  |  |  |  | |  |  |
| 1.2.1.9 |  |  |  |  |  |  |  |  | |  |  |
| 1.2.1.10 |  |  |  |  |  |  |  |  | |  |  |
| 1.2.1.11 |  |  |  |  |  |  |  |  | |  |  |
| 1.2.1.12 |  |  |  |  |  |  |  |  | |  |  |
| 1.2.1.13 |  |  |  |  |  |  |  |  | |  |  |
| 1.2.1.14 |  |  |  |  |  |  |  |  | |  |  |
| 1.2.1.15 |  |  |  |  |  |  |  |  | |  |  |
| 1.2.1.16 |  |  |  |  |  |  |  |  | |  |  |
| 1.2.1.17 |  |  |  |  |  |  |  |  | |  |  |

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| **No.** | **1.** | **2.** | **3.** | **4.** | **5.** | **6.** | **7.** | **8.** | **9. (For Other please include text)** | |
| 1.3.1.1 |  |  |  |  |  |  |  |  |  |  |
| 1.3.1.2 |  |  |  |  |  |  |  |  |  |  |
| 1.3.1.3 |  |  |  |  |  |  |  |  |  |  |
| 1.3.1.4 |  |  |  |  |  |  |  |  |  |  |
| 1.3.1.5 |  |  |  |  |  |  |  |  |  |  |
| 1.3.1.6 |  |  |  |  |  |  |  |  |  |  |
| 1.3.1.8 |  |  |  |  |  |  |  |  |  |  |
| **No.** | **1.** | **2.** | **3.** | **4.** | **5.** | **6.** | **7.** | **8.** | **9. (For Other please include text)** | |
| 1.3.2.1 |  |  |  |  |  |  |  |  |  |  |
| 1.3.2.2 |  |  |  |  |  |  |  |  |  |  |
| 1.3.2.3 |  |  |  |  |  |  |  |  |  |  |
| 1.3.2.4 |  |  |  |  |  |  |  |  |  |  |
| 1.3.2.5 |  |  |  |  |  |  |  |  |  |  |
| 1.3.2.6 |  |  |  |  |  |  |  |  |  |  |
| 1.3.2.8 |  |  |  |  |  |  |  |  |  |  |
| **No.** | **1.** | **2.** | **3.** | **4.** | **5.** | **6.** | **7.** | **8.** | **9. (For Other please include text)** | |
| 1.4.1.1 |  |  |  |  |  |  |  |  |  |  |
| 1.4.1.2 |  |  |  |  |  |  |  |  |  |  |
| 1.4.1.3 |  |  |  |  |  |  |  |  |  |  |
| **No.** | **1.** | **2.** | **3.** | **4.** | **5.** | **6.** | **7.** | **8.** | **9. (For Other please include text)** | |
| 2.2.3.1 |  |  |  |  |  |  |  |  |  |  |
| 2.2.3.2 |  |  |  |  |  |  |  |  |  |  |
| 2.2.3.3 |  |  |  |  |  |  |  |  |  |  |
| 2.2.3.4 |  |  |  |  |  |  |  |  |  |  |
| 2.2.3.5 |  |  |  |  |  |  |  |  |  |  |
| 2.2.3.6 |  |  |  |  |  |  |  |  |  |  |
| 2.2.3.8 |  |  |  |  |  |  |  |  |  |  |

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| **Section 4 Site Activities – Other Information** |

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| --- | --- |
| **Letting and/or Accepting Contracts** | |
| Applicant intends to be contract acceptor (i.e. carries out testing partially/wholly for others) |  |
| Applicant intends to be contract acceptor (i.e. manufactures partially/wholly for others) |  |
| Applicant intends to be contract giver (i.e. uses external manufacturers for some products) |  |
| Applicant intends to be contract giver (i.e. uses external Test houses for some/all testing) |  |

|  |  |
| --- | --- |
| **Other specific processes/activities** | |
| Assembly of parallel imported products |  |
| Manufacture and assembly for export |  |
| Assembly for export |  |
| Airline Kits |  |
| Bulk or partial manufacturing |  |
| Narcotic or psychotropic products (Controlled Substances) |  |

|  |  |
| --- | --- |
| **Other Information** | |
| Storage and Handling |  |
| Distribution |  |
| Is this site involved in microbiological testing of finished products and/or raw materials? |  |
| If none of the above. **(Must be Specified)** |  |
|  | |
| Stability Testing |  |
| Is this site involved in doing finished product testing? |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Further Information for the Inspectorate** | | | | |
| Is this site ready for inspection? | **Yes** |  | **No** |  |
| Are you conversant with the Rules and Guidance for Pharmaceutical  Manufacturers and Distributors? | **Yes** |  | **No** |  |
| Do you have available the relevant records and procedures? | **Yes** |  | **No** |  |
| Are signed technical agreements available for inspection? | **Yes** |  | **No** |  |

|  |  |  |  |  |
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| **Site Master File** | | | | |
| Have you submitted a SMF on CD or hard copy with your application? | **Yes** |  | **No** |  |
| If no, will a Site Master File be available on site during inspection? | **Yes** |  | **No** |  |
| **Details of facilities and equipment on site must be included in your Site Master file.** | | | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Decentralised Manufacture (DM) Requirements** | | | | | | |
| DM1 | Confirm the site listed in this application (via Site information in Section 2, on Page 2) is the DM control site. | **Yes** |  | **N/A** |  |
| DM2 | Is this site ready for inspection, with all applicable DM specific aspects of the quality systems in place? | **Yes** |  | **No** |  |
| DM3 | If yes to DM1.: Have you submitted a Decentralised Manufacturing Master File (for an initial product) with your application?  **(CD ROM / electronic or Hard copy)**  **NOTE:** If not provided, it is not possible to progress a DM application | **Yes** |  | | | |
| DM4 | If yes to DM1.: Please state the MHRA confirmed Designation Number of your initial DM product |  | | | | |

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| **Section 5 Site Personnel** |

|  |  |  |  |
| --- | --- | --- | --- |
| **Site Name** |  | **Postcode** |  |

|  |
| --- |
| **Summary of changes to personnel nominated to work at this site:** |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Name** | | **MHRA**  **Number\*** | **Add** | **Delete** | **QP** | **TQP** | **QC** | **PM** | **SC** |
|  | |  |  |  |  |  |  |  |  |
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**\*If available**

***NOTE: One set of the following three pages should be provided per nominated person***

|  |  |  |  |
| --- | --- | --- | --- |
| **Site Name** |  | **Postcode** |  |

|  |
| --- |
| **Site Personnel** |

|  |  |  |  |
| --- | --- | --- | --- |
| **Nominated Person** | | | |
| Name: | | | |
| Telephone/Mobile: |  | E-mail: |  |
| *Business Address:* | | | |
|  | | | |

|  |  |
| --- | --- |
| **Person number, if already named on a MHRA licence/authorisation** |  |

|  |
| --- |
| **Person nominated to be named as:** |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Qualified Person** |  | **Transitional Qualified Person** |  | | |
| **Production Manager** |  | **Quality Controller** |  | **Site Contact** |  |

|  |
| --- |
| **Qualified Persons/Transitional Qualified Persons Only** |

|  |
| --- |
| **Professional Information** |

|  |  |  |
| --- | --- | --- |
| **Documentation** | A copy of the nominated Qualified Persons certificate or  Transitional Qualified Persons letter of eligibility is attached. |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Have you ever been disciplined and/or struck off a professional register?  For applicants already named on licences, have there been any changes  to your professional status since your last submission to the MHRA? | **Yes** |  | **No** |  |

|  |
| --- |
| If you answered **‘Yes’,** pleaseprovide details below. |
|  |

|  |
| --- |
| **Employment Status** |

|  |  |  |  |
| --- | --- | --- | --- |
| **Permanent Employee** |  | **Consultant** |  |

|  |
| --- |
| **If you are a consultant, how frequently will you visit the site?** |
|  |
|  |

|  |  |  |
| --- | --- | --- |
| **Documentation** | A copy of the nominee’s Curriculum Vitae is attached, or the  relevant sections of this form have been completed. |  |

|  |
| --- |
| **Quality Controller** |

|  |  |  |
| --- | --- | --- |
| **Documentation** | A copy of the nominee’s Curriculum Vitae is attached, or the  relevant sections of this form have been completed.  Note: the Named QC should be a permanent employee |  |

|  |
| --- |
| **Production Manager** |

|  |  |  |
| --- | --- | --- |
| **Documentation** | A copy of the nominee’s Curriculum Vitae is attached, or the  relevant sections of this form have been completed. |  |

|  |
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| **Curriculum Vitae – Only required if a CV is not attached to the application** |

|  |
| --- |
| **Qualifications (relevant to this licence) – All applicants** |
|  |

|  |
| --- |
| **Professional Associations – QP only** |
|  |

|  |
| --- |
| **Experience (brief details of employment and responsibilities relevant to**  **this licence) All applicants** |
|  |

|  |
| --- |
| **PM and QC only - Name and function of the person(s) to whom he/she reports** |
|  |

|  |
| --- |
| **PM and QC only - Area of responsibility** |
|  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Site Name** |  | **Postcode** |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Declaration by nominated person** | | | |
| I confirm that the above particulars are accurate and true to the best of my knowledge and belief.  I agree to be nominated as indicated. | | | |
| **Signed**  **(Nominated Person)** |  | **Date** |  |
| **Print Name** |  | | |
| **Signed (Applicant)** |  | **Date** |  |
| **Print Name** |  | | |

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| --- |
| **Section 6 Storage and Handling site(s)** |

|  |  |  |  |
| --- | --- | --- | --- |
| *Site Name:* | | | |
| *Address:* | | | |
|  | | | |
| *Site contact person:* |  | | |
| Telephone/Mobile: |  | E-mail: |  |
| *DUNS Number:* | **-                   -** | | |

|  |  |
| --- | --- |
| This site is named on a current Wholesale Distribution Authorisation. |  |

|  |  |
| --- | --- |
| Site Number |  |

|  |  |  |  |
| --- | --- | --- | --- |
| *Site Name:* | | | |
| *Address:* | | | |
|  | | | |
| *Site contact person:* |  | | |
| Telephone/Mobile: |  | E-mail: |  |
| *DUNS Number:* | **-                   -** | | |

|  |  |
| --- | --- |
| This site is named on a current Wholesale Distribution Authorisation. |  |

|  |  |
| --- | --- |
| Site Number |  |

|  |  |  |  |
| --- | --- | --- | --- |
| *Site Name:* | | | |
| *Address:* | | | |
|  | | | |
| *Site contact person:* |  | | |
| Telephone/Mobile: |  | E-mail: |  |
| *DUNS Number:* | **-                   -** | | |

|  |  |
| --- | --- |
| This site is named on a current Wholesale Distribution Authorisation. |  |

|  |  |
| --- | --- |
| Site Number |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Section 7 Contract laboratory Site Information** | | | |
| *Site Name:* | | | |
| *Address:* | | | |
|  | | | |
| *Company contact:* |  | | |
| Telephone/Mobile: |  | E-mail: |  |
| *DUNS Number:* | **-                   -** | | |

|  |  |
| --- | --- |
| The licence/authorisation holder has assessed the laboratory as fit for purpose. |  |

|  |  |
| --- | --- |
| **Quality Control Testing carried out by the site.** | |
| Finished product testing. Microbiological: Sterility |  |
| Finished product testing. Microbiological: Non-Sterility |  |
| Finished product testing. Chemical/Physical analysis of finished products |  |
| Finished product testing. Biological testing of finished products |  |
| Stability Testing on finished marketed medicinal products |  |
| Environmental monitoring or process simulation (media fill) to support sterile manufacture |  |

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| --- |
| **N**  ***NOTE: All other testing, including raw materials testing, does not require a laboratory to be***  ***named on a licence or hold a GMP certificate.* sting, including raw materials testing, does not require a laboratory to be named on a licence or hold a GMP certificate** |

|  |  |
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| **Letting and/or accepting contracts.** | |
| Applicant intends to be a contract acceptor (i.e. carries out testing partially/wholly for others). |  |
| Applicant intends to be a contract giver (i.e. uses external test houses for some/all testing). |  |

|  |  |
| --- | --- |
| **Section 8B: To be completed by the nominated Contract Laboratory** | |
| I confirm there is a written contract/technical agreement in place. |  |

|  |  |  |  |
| --- | --- | --- | --- |
| I hereby confirm the contract laboratory are aware they have been named and may be subject to inspection by the MHRA, a written contract/technical agreement is in place and the contract laboratory is in agreement and aware of what is expected of them.  To the best of my knowledge and belief the particulars I have provided in are correct, truthful and complete. | | | |
| **Signed** |  | **Date** |  |
| **Print Name** |  | **Job Title** |  |
| **Company** |  | | |

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| **Section 8 Declaration** |

|  |  |  |  |
| --- | --- | --- | --- |
| I/We apply for the grant of a Manufacturer’s licence for investigational medicinal products MIA(IMP) to the proposed holder named in this application form in respect of the activities to which the application refers.  To the best of my knowledge and belief the particulars I have given in this form are correct, truthful and complete.  The applicant undertakes to ensure fulfilment of the obligations arising by virtue of the terms and conditions of the licence. | | | |
| **Signed** |  | **Date** |  |
| **Print Name** |  | **Job Title** |  |

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| **Section 9 Declaration of Inspection Readiness** |

The application process described in the [Guidance](https://www.gov.uk/guidance/apply-for-manufacturer-or-wholesaler-of-medicines-licences#:~:text=To%20make%2C%20assemble%20or%20import,GMP%20inspections%20of%20your%20site.) and [‘Notes for applicants and holders of a Manufacturer’s Licence’](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/405883/Medicines_-_notes_for_applicants_and_holders_of_a_manufacturer_licence.pdf) commonly referred to as MHRA Guidance Note 5, requires the completion of mandatory [application forms for a manufacturer licence](https://www.gov.uk/government/publications/medicines-application-forms-for-a-manufacturer-licence). Section 4 requires a declaration that the site is inspection ready.

This ‘Declaration of Inspection Readiness’ (DIR) form has been developed as a self-assessment tool to help applicants understand and consider what ‘inspection ready’ means for their site.

The DIR should be signed by the applicant and the QP nominated in the licence application.

All questions are based on existing regulations and GMP requirements as set in The Human Medicines Regulations 2012 (as amended).

|  |  |  |  |
| --- | --- | --- | --- |
| No. | Question | Answer  Yes  No  N/A | Comments, clarification, additional detail as required |
|  | **EU GMP Chapter 1** |  |  |
| 1.1 | Is there an operational Pharmaceutical Quality System incorporating Good Manufacturing Practice and Quality Risk Management? | Yes  No  N/A |  |
| 1.2 | Are there approved procedures covering all processes and activities performed and managed by the site(s)? | Yes  No  N/A |  |
| 1.3 | Is there Validation Master Plan or validation strategy in place? | Yes  No  N/A |  |
|  | **EU GMP Chapter 2** |  |  |
| 2.1 | Is there an organisation chart in which the relationships between different units are clearly presented? | Yes  No  N/A |  |
| 2.2 | Do staff in responsible positions have duties recorded in written job descriptions? | Yes  No  N/A |  |
| 2.3 | Is there clear independence of Quality Control/Assurance unit from Production department? | Yes  No  N/A |  |
| 2.4 | Are all staff trained in the principles of GMP, relevant guidance and procedures (SOPs) specific to the company’s operations? | Yes  No  N/A |  |
|  | **EU GMP Chapter 3** |  |  |
| 3.1 | Are premises completed and fit for their intendent use? | Yes  No  N/A |  |
| 3.2 | Has equipment been installed and qualified to appropriate extent? | Yes  No  N/A |  |
|  | **EU GMP Chapter 4** |  |  |
| 4.1 | Is there a documentation control system in place and are the procedures in use and records ready for inspection? | Yes  No  N/A |  |
|  | **EU GMP Chapter 5** |  |  |
| 5.1 | Are there approved procedures which clearly describe production operations? | Yes  No  N/A |  |
| 5.2 | Have any batches been manufactured?  (technical/ pilot/ engineering batch(es), Regulatory Submission batch(es), Validation batch(es) or other)  If Yes, please provide details opposite | Yes  No  N/A |  |
| 5.3 | Are process validation reports available for inspection (for all manufacturing operations relevant to this licence application)? | Yes  No  N/A |  |
| 5.4 | Is there a documented cross contamination control strategy in place? | Yes  No  N/A |  |
|  | **EU GMP Chapter 6** |  |  |
| 6.1 | Are analytical methods validated / verified? | Yes  No  N/A |  |
|  | **EU GMP Chapter 7** |  |  |
| 7.1 | Are there approved quality / technical agreements covering all outsourced activities with contract acceptors? | Yes  No  N/A |  |
| 7.2 | Are the assessments e.g. audits of contractor acceptors (e.g. storage sites, contract manufacturing, contract laboratory etc.) completed? | Yes  No  N/A |  |
| 7.3 | Are there approved quality / technical agreements in place with all contract givers (e.g. Marketing Authorisation Holders) where applicable? | Yes  No  N/A |  |
|  | **EU GMP Chapter 8** |  |  |
| 8.1 | Are there procedures for  handling complaints and recalls? | Yes  No  N/A |  |
|  | **EU GMP Chapter 9** |  |  |
| 9.1 | Is there a self-inspection / an internal audit programme in place?  Has there been a critical review of your new organisation / operations / premises etc. conducted to verify fitness for purpose and inspection readiness? | Yes  No  N/A |  |
|  | **Other** |  |  |
| 10.1 | Please attach a flowchart or a description of your business model. This should include activities performed by the site and details of physical and fiscal flow of the medicinal products; specify countries / territories involved and marketing status of the products. |  |  |
| 10.2 | Is the QP nominated in this application named on any other licences (MIA, MIA(IMP) ManA)?  If Yes, please provide details opposite. | Yes  No  N/A |  |
| 10.3 | Is the QP’s training related to SOPs, documentation and products specific to the application complete? | Yes  No  N/A |  |
| 10.4 | Are the sites to which this application applies named on other Authorisations (e.g. MIA, ManA, MS, ManSA, MIA(IMP), WDA(H), WDA(V))  If Yes, please provide details opposite. | Yes  No  N/A |  |
| 10.5 | Is the Home Office Controlled Drugs (CD) Licence granted, where applicable? | Yes  No  N/A |  |

**DECLARATION**

I confirm to the best of my knowledge that the information provided above is accurate and that I consider the sites nominated as part of this licence application to be ready for an inspection against the requirements of GMP by the MHRA.

|  |  |
| --- | --- |
| Applicant | |
| Job Title |  |
| Name |  |
| Signature |  |
| Date |  |
| Nominated Qualified Person | |
| Name |  |
| Signature |  |
| Date |  |

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