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**Veterinary Medicines Directorate** Inspections Administration Team

Woodham Lane, New Haw, Addlestone, Surrey, KT15 3LS

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**Application for a**

**Manufacturer’s/Importer’s Authorisation (ManA)**

**(For Veterinary Medicines only)**

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| Use this form to apply for an authorisation to manufacture/import veterinary medicines only (ManA).  Please read the Guidance on [Manufacturing Authorisations for veterinary medicines](https://www.gov.uk/guidance/manufacturing-authorisations-for-veterinary-medicines) before completing this application form.  If you wish to apply for a Manufacturer’s/Importer’s Authorisation (MIA) for human products, or you already hold such an authorisation and wish to additionally manufacture veterinary medicines, please contact the Medicines and Healthcare products Regulatory Agency (the [MHRA](https://www.gov.uk/guidance/apply-for-manufacturer-or-wholesaler-of-medicines-licences)).  If you wish to apply for an authorisation to manufacture:   * extemporaneous products for administration under the cascade (formerly known as ‘Specials’); * autogenous vaccines; * equine stem cell products; or * blood/blood constituents for treating non-food-producing animals   Please read the Guidance on ‘[Specific Manufacturing Authorisations](https://www.gov.uk/guidance/apply-for-autogenous-vaccine-non-food-animal-blood-bank-equine-stem-cell-centre-authorisation)’ and complete and submit the relevant application form(s). | |
| **Please note that this application form is structured into sections and should be completed as follows:** | |
|  | Section 1 – complete once per application. |
|  | Section 2 (all parts) – one copy for each of the applicant’s manufacturing/importation sites to be listed on the ManA. |
|  | Sections 3, 4 & 5 – one copy for each contract site. |
|  | Section 6 – complete once per application, signed and dated. |

**Please make additional copies of Sections 2-5 as necessary**

**Completed forms, including supporting documentation, should be emailed to the Inspections Administration Team, at** [**inspections@vmd.gov.uk**](mailto:inspections@vmd.gov.uk) **or posted to the VMD at the address above.**

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| **Application for Manufacturer’s/Importer’s Authorisation (ManA)**  **(Veterinary Medicines only)** |

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| **Section 1 Applicant’s Details** |
| Registered Company Name of Proposed Authorisation Holder: |
| Address: |
| Company contact person: |
| Telephone/Mobile:       Email: |
| Companies House number (if applicable) |

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| **Communications and/or invoicing address (if different)** |
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| **Person applying on behalf of the proposed authorisation holder:** |
| Name of person:  Position/relationship to applicant: |
| **Contact details:** |
| Telephone/Mobile:       Email: |

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

**Please list below the sites included on this application and their intended operations**

(Please note: Only the proposed authorisation holder’s sites listed in table (a) will be shown on the ManA published on the Gov.uk)

|  |  |  |
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| 1. **Proposed Authorisation Holder’s Manufacture/Importation Sites** | | |
| Name and address of site | Man | Imp |
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| 1. **Contract Manufacture/QC testing/Storage & Handling Sites** | | | | |
| Name and address of site | | Man | QC | S&H |
|  | |  |  |  |
|  | |  |  |  |
|  | |  |  |  |
|  | |  |  |  |
|  | | | |
| **Section 2 Site Information**  **Complete Section 2 for each site listed in Table 1(a) above – these sites will be named on the published ManA Gov.uk** | | | |
| Site Name: | | | |
| Address: | | | |
| DUNS Number (if available):             -                   - | | | |

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| **Site Contact Person** |
| Name of the contact: |
| Telephone/Mobile:       Email: |

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| **Type of Site:**  **Super site**  **Major site**  **Standard site  Minor site**  ***Site types are defined in Appendix 1. This information will be verified during inspection.*** |

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| **Part 1: Manufacturing Operations – Veterinary Medicinal Products** |

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| Complete Part 1 for authorised manufacturing operations, which include:   * total and partial manufacturing (including various processes of dividing up, packaging or presentation); * quality control testing; * batch certification/release of products manufactured on the named site.   A site authorised for manufacturing operations is understood to be authorised for storage and distribution of the finished products manufactured at the site, unless otherwise specified in section 1.4.3 <Others>.  Complete Parts 2 & 3 for importation activities carried out at this site (whether or not manufacturing activities are also carried out). |

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| **If you intend manufacturing any products listed immediately below, please specify them in the Special Requirement section.** | |
| **1.** | B Lactam Antibiotics |
| **2.** | Other highly sensitising antibiotics |
| **3.** | Live Cells |
| **4.** | Pathogenic Organisms (Biosafety Level 3 or 4) |
| **5.** | Radiopharmaceuticals |
| **6.** | Ectoparasiticides |

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| **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 below) |  |  |
|  | | | |
| ***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 below) |  |  |
|  | | | |
| ***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  below) |  |  |
|  | | | |
| 1.2.2 | ***Batch certification of non-sterile 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 below) |  |  |
|  | | | |
| ***1.3.2*** | **Batch certification of biological medicinal products –** | | **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 below) |  |  |
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| **1.4** | **Other products or processing activity**  (any other relevant manufacturing activity/product type that is not covered above e.g. sterilisation of active substances, manufacture of biological starting materials (when required by national legislation), herbal or homeopathic products, bulk or total manufacturing, etc.) | | | |
| ***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 below) |  |  | |
|  | | | | |
| ***1.4.2*** | ***Sterilisation of active substances/excipients/finished product*** | | | |
| 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*** *(Please specify below: includes ‘storage’ where a site only stores product but no manufacturing operations are carried out e.g. for batch certification)* | | |  |
|  | | | | |
| **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 | | |  |
| 1.5.1.16 | Veterinary premixes | | |  |
| 1.5.1.17 | Other non-sterile medicinal products (please specify below) | | |  |
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| ***1.5.2*** | ***Secondary Packing*** | | |  |

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| 1.6 | **Quality Control Testing – Manufacture** | |
| 1.6.1 | Microbiological: sterility |  |
| 1.6.2 | Microbiological: non-sterility |  |
| 1.6.3 | Chemical/Physical |  |
| 1.6.4 | Biological |  |

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| **Part 2. Importation of Veterinary Medicinal Products** |

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| Complete Part 2 for authorisation to import and carry out Quality Control testing of authorised veterinary medicine(s) from a 3rd country.  Authorised importation includes administrative activities and/or quality control testing and/or physical storage and distribution. |

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| **2.1** | **Quality Control Testing of imported medicinal products** | |
| 2.1.1 | Microbiological: sterility |  |
| 2.1.2 | Microbiological: non-sterility |  |
| 2.1.3 | Chemical/Physical |  |
| 2.1.4 | Biological |  |

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

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| ***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 (not applicable) |  |  |
| 2.2.3.8 | Other biological medicinal products  (Please specify below) |  |  |
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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 | Biological active substance |  |
| 2.3.4 | Other (Please specify below) |  |
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| **Part 3. For importation activities list all authorised products imported from 3rd countries** |

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| **No.** | **Authorisation No.** | **Product Name** | **Country of origin** |
| **1.** |  |  |  |
| **2.** |  |  |  |
| **3.** |  |  |  |
| **4.** |  |  |  |
| **5.** |  |  |  |
| **6.** |  |  |  |
| **7.** |  |  |  |
| **8.** |  |  |  |
| **9.** |  |  |  |
| **10.** |  |  |  |
| **11.** |  |  |  |
| **12.** |  |  |  |
| **13.** |  |  |  |
| **14.** |  |  |  |
| **15.** |  |  |  |

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| **Part 4. Nominated Site Personnel** |

**You are required to nominate a Qualified Person (QP), a Production Manager/Supervisor (PM) and a Person Responsible for Quality Control (QC) for each site.**

Please note that:

* only one QP is required per site and a QP can be responsible for more than one site;
* the QC can be the same person as the QP but not the same person as the PM
* you must notify the VMD of any change to the listed personnel via a Variation application, which incurs a fee.

Each QP, PM or QC nomination must be signed by both the nominee and the applicant.

All applications must include:

1. A relevant CV that describes the nominated person’s qualifications and experience in the manufacture/importation of veterinary/human medicines.
2. For QPs, a copy of the nominee’s certificate of ‘Eligibility for nomination as a Qualified Person’ from the Joint Professional Body or authorisation from competent authority.

Please ensure you have included all required documentation as the application cannot be processed if it is not provided.

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| **Details of Nominated QP, PM or QC** | | | |
| Name: | | | |
| Telephone/Mobile: |  | Email: |  |
| Business Address: | | | |

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

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| **Nominated Person to be named as:** |

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| **Qualified Person (QP)** | **Production Manager/Supervisor (PM)  Quality Controller (QC)** | |
| **Permanent Employee  Consultant** | | **Transitional** |

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| **Additional Information – Qualified Persons Only** |

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| If you are a consultant QP please confirm that there is a contract in place defining your responsibilities and describe how frequently you will visit the site. (Alternatively, you may provide a copy of your contract with this application) |
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| **Documentation** | A copy of the nominated Qualified Person’s certificate or Transitional Qualified Person’s letter of eligibility or competent authority approval is attached. |  |

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

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| If you answered **‘Yes’,** pleaseprovide details below. |
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| **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 3: Contract Manufacturing Site Information** |

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| **Site Name:** |
| **Address:** |
| Company contact: |
| Telephone/Mobile:       Email: |
| DUNS Number (if available):            -                   - |

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| **I confirm that:**   * Either this manufacturing site possesses a current UK (MHRA)/EU/EEA GMP certificate – **certificate number**:   or that I understand that it will be subject to GMP inspection by the VMD   * This manufacturing site is aware that it has been named on this application * A written contract/technical agreement is in place with the applicant.   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 4: Contract laboratory (QC testing) Site Information** |
| Site Name: |
| Address: |
| Company contact: |
| Telephone/Mobile:       Email: |
| DUNS Number (if available)*:*             -                   - |

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

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| **Quality Control Testing carried out by the site.** | |
| Microbiological: Sterility |  |
| Microbiological: Non-Sterility |  |
| Chemical/Physical analysis of finished products |  |
| Biological testing of finished products |  |
| Stability Testing on finished marketed medicinal products |  |
| Is the site involved in finished product testing? |  |
| Is this site involved in microbiological testing of finished products or raw materials? |  |
| Other (Please specify) |  |
|  | |

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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). |  |

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| **I confirm that:**   * Either this contact laboratory (QC testing) site possesses a current UK (MHRA)/EU/EEA GMP certificate – **certificate number**:       or that I understand that it will be subject to GMP inspection by the VMD. * This contact laboratory (QC testing) site is aware that it has been named on this application. * A written contract/technical agreement is in place with the applicant.   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 5: Contract Storage Site Information** |

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| Site Name: |
| Address: |
| Site contact person: |
| Telephone/Mobile:       Email: |
| DUNS Number (if available):            -                   - |

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| **I confirm that:**   * Either this site is named on a current Wholesale Distribution Authorisation (WDA) for veterinary medicines – **authorisation number**:   or that I understand that it will be subject to GMP inspection by the VMD   * This site is aware that it has been named on this application * There is a written contract/technical agreement is in place with the applicant.   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 6: Checklist and Declaration** |

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|  | **Checklist**: Supporting Documentation |
|  | Site information including nominated personnel fully completed for each site to be named on the authorisation |
|  | For each nominated QP, a certificate from the Joint Professional Body or authorisation from EU/EEA competent authority |
|  | Copies of appropriate authorisations for contract storage/handling sites and contract manufacturing sites (where applicable) |
|  | Copies of valid EU/EEA GMP certificates for contract manufacturing sites and QC testing sites (where applicable) |
|  | Copies of the contract/Technical Agreement with each contracted company/site/QP (where applicable) |
|  | Copy of the current Site Master File (see template guidance Eudralex Volume 4 Part 3) |

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| **Declaration** | | | |
| I am authorised to apply for the Manufacturer’s/Importer’s Authorisation (ManA) for 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 activities are to be only in accordance with the information set out in the application or furnished in connection with it.  The applicant undertakes to ensure fulfilment of the obligations arising by virtue of the terms and conditions of the authorisation.  All required supporting documentation is provided.  I am conversant with cGMP requirements and the Veterinary Medicines Regulations 2013.  Relevant procedures and records are in place; and the named site(s) is ready for inspection.  I understand that once the application is validated1 by the VMD the ManA application fee will be charged; and any changes to the information provided in this application will require a Variation application to be submitted, which incurs a fee (fees are set out in Appendix 2).  1 validation will be completed within 10 days of the application being received providing all required information is correctly provided. | | | |
| **Signed** |  | **Date** |  |
| **Print Name** |  | **Job Title** |  |

**Appendix 1: Site Types**

A “**super site**” is a site at which 250 or more relevant persons are employed;

A “**major site**” is a site at which 60 or more, but fewer than 250, relevant persons are employed;

A “**standard site**” is a site at which 10 or more, but fewer than 60 relevant persons are employed;

A “**minor** site” is a site at which fewer than 10 relevant persons are employed;

A “relevant person” means a person employed on the premises and systems inspected.

**Appendix 2: Fees**

The application fee for a manufacturing authorisation is £3040.

An inspection fee is also payable, the fee will depend on the Site Type.

A table of fees is published [here](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/770500/_719774-v4-Fees_sheet.pdf)