|  |
| --- |
| For VMD use.  **AN: SAM** |

****

**Manufacturers Application Form For Products covered under Schedule 6 of the current Veterinary Medicines Regulations (Exemption Scheme for Pet Animal Medicines)**

**PLEASE COMPLETE ALL RELEVANT SECTIONS IN THIS FORM**

**TYPED OR IN BLOCK CAPITALS LEGIBLY, USING BLACK INK**

**1. APPLICATION FORM: ADMINISTRATIVE DATA**

**1.1 Applicant’s Details If you are applying for a variation to your licence**

**please tick this box and only complete section 1**

**and those sections that require a change.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Company Name: | |  | | |
|  | | | | |
| Licence No. (if known) | |  | | |
|  | | | | |
| Trading Style(s): | |  | | |
|  | | | | |
| Applicant’s Name: | |  | | |
|  | | | | |
| Address: | |  | | |
|  | | | | |
| Postcode: |  | | Telephone: |  |
|  |  | |  |  |
| Mobile: |  | |  |  |
|  |  | |  |  |
| E-mail: |  | | | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Are you applying on behalf of the Proposed Authorisation Holder? |  |  |  |  |  |
| (e.g. if you are a consultant/representative) |  | **Yes** |  |  | **No** |
| If **YES**, please fill out section **1.2** | | | | | |

**1.2 Contact Details for Communication** (*if different from above*)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Contact Name: | |  | | |
|  | |  | | |
| Company Name: | |  | | |
|  | |  | | |
| Address: | |  | | |
|  | |  | | |
| Postcode: |  | | Telephone: |  |
|  |  | |  |  |
| Mobile: |  | |  |  |
|  |  | |  |  |
| E-mail: |  | | | |

**1.3 Invoicing Address Details** (*if different from Authorisation Holder Address*)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Contact Name: | |  | | |
|  | |  | | |
| Company Name: | |  | | |
|  | |  | | |
| Address: | |  | | |
|  | | | | |
| Postcode: |  | | Telephone: |  |
|  |  | |  |  |
| Mobile: |  | |  |  |
|  |  | |  |  |
| E-mail: |  | | | |

**2. SITE INFORMATION**

**2.1 Site Details**

***You will need to complete a copy of this section for each site that you wish to include on the Authorisation:***

|  |  |  |  |
| --- | --- | --- | --- |
| Site ID: |  | | |
|  |  | | |
| Site Name: |  | | |
|  |  | | |
| Address: |  | | |
|  |  |  |  | |
| Postcode: |  |  |  | |
|  |  |  |  | |
| Contact Name: |  | | | |
|  |  |  |  | |
| Telephone: |  |  |  | |
|  |  |  |  | |
| Mobile: |  |  |  | |
|  |  | | |
| E-mail: |  | | |

**2.2 Site Activities**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Manufacture |  |  | Assembly and Packaging |  |  | Storage and Handling |  |
|  |  |  |  |  |  | *(picking of goods)* |  |
|  |  |  |  |  |  |  |  |
| Distribution |  |  | Analytical Testing |  |  | Batch Release |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| \*Import |  |  |  |  |  |  |  |

**\*Please Supply details of manufacturing site(s) from which importation occurs and GMP certification for site(s) if available:**

|  |
| --- |
|  |

**Manufacturing Operations – Site Functions**

Please cross **MA** (*Manufacture and Assembly*) or **MO** (*Manufacture Only*) for each of the site functions proposed to be conducted:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **NON-STERILE PRODUCTS** | |  | **MA** |  | **MO** |
|  | |  |  |  |  |
| Unit and multi-dose liquids for internal use | |  |  |  |  |
|  | |  |  |  |  |
| Unit and multi-dose liquids for external use | |  |  |  |  |
|  | |  |  |  |  |
| Unit and multi-dose liquid aerosols (pressurised) | |  |  |  |  |
|  | |  |  |  |  |
| Semi-solid and other liquid non-sterile dosage forms | |  |  |  |  |
|  | |  |  |  |  |
| If **MA/MO** crossed please specify: |  | | | | |
|  | |  |  |  |  |
| Solid unit-dose forms – tablets | |  |  |  |  |
|  | |  |  |  |  |
| Solid unit-dose forms – capsules, hard shell | |  |  |  |  |
|  | |  |  |  |  |
| Solid unit-dose forms – capsules, soft shell | |  |  |  |  |
|  | |  |  |  |  |
| Solid unit-dose forms – suppositories/pessaries | |  |  |  |  |
|  | |  |  |  |  |
| Solid multi-dose forms (including powders and granules) | |  |  |  |  |
|  | |  |  |  |  |
| Traditional Herbal Medicinal products | |  |  |  |  |
|  | |  |  |  |  |
| Other solid non-sterile dosage forms | |  |  |  |  |

**ASSEMBLY OPERATIONS**

***Primary Packaging***

|  |  |  |  |
| --- | --- | --- | --- |
| Filling of primary containers |  |  | Yes |
|  |  |  |  |
| Liquid dosage forms |  |  | Yes |
|  |  |  |  |
| Semi-solid dosage forms (including creams and ointments) |  |  | Yes |
|  |  |  |  |
| Solid dosage forms (including tablets and powders) |  |  | Yes |
|  |  |  |  |
| Blister and/or strip packaging |  |  | Yes |
|  |  |  |  |
| Others |  |  | Yes |

***Secondary Packaging***

|  |  |  |  |
| --- | --- | --- | --- |
| Labelling of primary containers |  |  | Yes |
|  |  |  |  |
| Secondary packaging of primary containers |  |  | Yes |
|  |  |  |  |
| Packaging for parallel importation |  |  | Yes |

**OTHER OPERATIONS**

|  |
| --- |
|  |

**LETTING AND/OR ACCEPTING CONTRACTS**

|  |  |  |  |
| --- | --- | --- | --- |
| Applicants intends to be contract acceptor |  |  |  |
| (i.e. manufactures partially/wholly for others) |  |  | Yes |
|  |  |  |  |
| Applicants intends to be contract giver |  |  |  |
| (i.e. uses external manufacturers for some products) |  |  | Yes |
|  |  |  |  |
| Applicant intends to be contract acceptor |  |  |  |
| (i.e. carries out testing partially/wholly for others) |  |  | Yes |
|  |  |  |  |
| Applicants intends to be contract giver |  |  |  |
| (i.e. uses external test houses for some/all testing) |  |  | Yes |

**Please give contact details of contract manufacturers and analysis providers and enclose copies of manufacturers authorisation / GMP certificate, if available:**

|  |
| --- |
|  |

**OTHER INFORMATION**

*The following information is required for inspectorate action but will not appear on your authorisation*:

|  |  |  |  |
| --- | --- | --- | --- |
| Are products of Animal/Human Origin (AHO) present at this site? |  |  | Yes |
|  |  |  |  |
| Do you supply stock which requires refrigeration or low temperature storage? |  |  | Yes |
|  |  |  |  |
| Are premises sound and secure and ready for inspection? |  |  | Yes |
|  |  |  |  |
| Are you conversant with Eudralex Volume 4 – Medicinal Products for Human & Veterinary Use: Good Manufacturing Practice? |  |  | Yes |
|  |  |  |  |
| Are signed technical agreements available for inspection where applicable? |  |  | Yes |
|  |  |  |  |
| Do you import intermediate products for further processing? |  |  | Yes |

Please list the ingredients and pharmaceutical form to be manufactured under this authorisation, with trade names where known:

|  |  |  |
| --- | --- | --- |
| Active/Relevant Ingredient Name | Pharmaceutical Form | Trade Name |
|  |  |  |

**ANALYTICAL TESTING ACTIVITIES**

***Analytical Testing Activities at this Site***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Chemical/physical |  | Yes |  |  | No |
|  |  |  |  |  |  |
| Microbiological/Environmental/LAL |  | Yes |  |  | No |
|  |  |  |  |  |  |
| Others |  | Yes |  |  | No |
|  |  |  |  |  |  |
| Is this lab involved in doing finished products testing? |  | Yes |  |  | No |
|  |  |  |  |  |  |
| Is this lab involved in microbiological testing of finished products and/or raw |  | Yes |  |  | No |
| materials? |  |  |  |  |  |

**SUPPLEMENTARY TESTING INFORMATION AT THIS SITE**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Stability testing |  | Yes |  |  | No |

**2.3 Further information which should be attached**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Have you submitted a Site Master File with your initial application? |  | Yes |  |  | No |
|  |  |  |  |  |  |
| If NO, will a Site Master File be available on site during an inspection? |  | Yes |  |  | No |

**3. NAMED PERSONS**

**Please indicate below how many of the following types of personnel you have working at this site:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Personnel** |  |  | **Number** |
| 1. | Person responsible for release of product on to the market | (PR) |  |  |
| 2. | Production Manager/Supervisor | (PM) |  |  |
| 3. | Person responsible for Quality Control | (QC) |  |  |
| 4. | Total no. of personnel involved in the manufacturing process, e.g. Production, QC, QA, Maintenance etc. |  |  |  |

***For each and every personnel type listed in boxes 1-3, please complete one of the appropriate following sections:***

**3.1 Person responsible for release of product on to the market**

**All applications by a PR must include a relevant CV and each PR nomination must be signed by both the nominee and the applicant. The PR should not be the same person as is responsible for production.**

**Please complete a separate entry for each PR:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Title: |  | Personnel ID: |  |  |
|  |  |  |  |  |
| First name(s): |  | | | |
|  |  |  |  |  |
| Last name: |  | | | |
|  |  |  |  |  |
| Business Address: |  | | | |
|  |  |  |  |  |
| Postcode: |  | Telephone: |  | |
|  |  |  |  |  |
|  |  | Mobile: |  | |
|  |  |  |  |  |
| E-mail: |  | | |  |

**Please indicate your status:**

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

**If you are a consultant, please give details of your availability. How frequently will you visit?**

|  |
| --- |
|  |

**Qualifications relevant to this authorisation:**

|  |
| --- |
|  |

**Experience (brief details of employment and responsibilities) relevant to this authorisation:**

|  |
| --- |
|  |

**Professional Association(s):**

|  |
| --- |
|  |

**Please submit a copy of the nominee’s QP certificate of eligibility from the RPSGB, IOB or RSC, if available.**

**I confirm that the above particulars are accurate and true to the best of my knowledge and belief.**

**I agree to be nominated as a Person responsible for release of product on to the market.**

|  |  |  |  |
| --- | --- | --- | --- |
| ***Signed* (Nominee)**: |  | Date: |  |
|  |  |  |  |
| Print Name: |  |  |  |
|  |  |  |  |
| ***Signed* (Applicant)**: |  | Date: |  |
|  |  |  |  |
| Print Name: |  |  |  |

**3.2 Person Responsible for Production**

*Please complete a separate sheet for each person responsible for production.*

**In what capacity are you signing this? Please indicate in the box below:**

|  |  |  |  |
| --- | --- | --- | --- |
| Manager of Production |  | Supervisor of Production |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Title: |  | Personnel ID: |  |  |
|  |  |  |  |  |
| First name(s): |  | | | |
|  |  |  |  |  |
| Last name: |  | | | |
|  |  |  |  |  |
| Business Address: |  | | | |
|  |  |  |  |  |
| Postcode: |  | Telephone: |  | |
|  |  |  |  |  |
|  |  | Mobile: |  | |
|  |  |  |  |  |
| E-mail: |  | | |  |

**Qualifications relevant to this authorisation:**

|  |
| --- |
|  |

**Experience (brief details of employment and responsibilities) relevant to this authorisation:**

|  |
| --- |
|  |

**Name and function of the person(s) to whom they report to (if applicable):**

|  |
| --- |
|  |

**Area of responsibility**

|  |
| --- |
|  |

**I confirm that the above particulars are accurate and true to the best of my knowledge and belief.**

**I agree to be nominated as the person responsible for production.**

|  |  |  |  |
| --- | --- | --- | --- |
| ***Signed* (Nominee)**: |  | Date: |  |
|  |  |  |  |
| Print Name: |  |  |  |
|  |  |  |  |
| ***Signed* (Applicant)**: |  | Date: |  |
|  |  |  |  |
| Print Name: |  |  |  |

**3.3 Person Responsible for Quality Control**

**Please give the following details of the person(s) with overall responsibility for quality control.**

**The person responsible for quality control should not be the same person as is responsible for production**.

**Where this responsibility is shared between more than one person, please complete a separate page for each person, and give details of each person’s area of responsibility.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Title: |  | Personnel ID: |  |  |
|  |  |  |  |  |
| First name(s): |  | | | |
|  |  |  |  |  |
| Last name: |  | | | |
|  |  |  |  |  |
| Business Address: |  | | | |
|  |  |  |  |  |
| Postcode: |  | Telephone: |  | |
|  |  |  |  |  |
|  |  | Mobile: |  | |
|  |  |  |  |  |
| E-mail: |  | | |  |

**Qualifications relevant to this authorisation:**

|  |
| --- |
|  |

**Experience (brief details of employment and responsibilities) relevant to this authorisation:**

|  |
| --- |
|  |

**Name and function of the person(s) to whom they report to (if applicable):**

|  |
| --- |
|  |

**Area of responsibility:**

|  |
| --- |
|  |

**I confirm that the above particulars are accurate and true to the best of my knowledge and belief.**

**I agree to be nominated as the person responsible for Quality Control.**

|  |  |  |  |
| --- | --- | --- | --- |
| ***Signed* (Nominee)**: |  | Date: |  |
|  |  |  |  |
| Print Name: |  |  |  |
|  |  |  |  |
| ***Signed* (Applicant)**: |  | Date: |  |
|  |  |  |  |
| Print Name: |  |  |  |

**4. COMMENTS**

**Please provide any other information that may support your application. You can also detail any change to addresses, person names etc. Please also provide details of any other authorisations, approvals or registrations held for this site, for example registered veterinary practice premises, registered pharmacy or approved SQP Retailer’s premises.**

**If applying for a variation to your existing SAM, please detail each variation required in the box below.**

|  |
| --- |
|  |

**5. DECLARATION**

**I/We apply for the Grant of a Manufacturer’s Authorisation for products exempted under Schedule 6 of the current Veterinary Medicines Regulations, to the proposed holder named in this application form and in respect of the activities to which the application refers.**

5.1a The activities are to be only in accordance with the information set out in the application or furnished in connection with it.

5.2b To the best of my knowledge and belief the particulars I have given in this form are correct and complete.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ***Signed* (Applicant)**: |  | | Date: |  |
|  |  | |  |  |
| Print Name: |  | |  |  |
|  |  | |  |  |
| State capacity in which signed: | |  | | |

**Please send completed form to: Inspections Administration Team**

**Veterinary Medicines Directorate**

**Woodham Lane, New Haw**

**Addlestone**

**Surrey**

**KT15 3LS**

inspections@vmd.gov.uk

**We will acknowledge receipt of the application, please await the invoice before sending payment.**