****

**VETERINARY MEDICINES DIRECTORATE**

Inspections Administration Team

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

Enquiries +44(0)1932 336911

**Variation Application Form**

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

**(Products for Veterinary Use only)**

|  |
| --- |
| **Notes:****Please read the Guidance on the GOV.UK website before completing this form (search Manufacturing Authorisations for veterinary medicines).** **This form should be used by applicants who wish to vary a Manufacturer’s/Importer’s Authorisation (ManA) for Veterinary Products Only. Variations to authorisations for human products should be directed to the MHRA.** **Completed forms should be emailed to the Inspections Administration Team, at** **inspections@vmd.gov.uk** **or posted to the VMD at the address above.*****Please note that an incomplete form will lead to your application being returned to you*.** |

**Administrative Particulars**

1. **Full name, address and contact details of the Authorisation Holder:**

|  |
| --- |
|  |

|  |  |
| --- | --- |
| **Contact Name:** |  |

|  |  |
| --- | --- |
| **E-mail address:** |  |

|  |  |
| --- | --- |
| **Tel No:** |  |

2. **Name, address and email address for Invoicing (if different to 1 above)**

|  |
| --- |
|  |

|  |  |
| --- | --- |
| 3. **ManA Number:** |  |

4**. Type of variation required. (*Tick all boxes which apply*)**

|  |  |  |  |
| --- | --- | --- | --- |
| *a)* | *Change of Name and/or Address of the Authorisation Holder* |  |  |
|  |  |  |  |
| *b)* | *Removal or Addition of Site* |  |  |
|  |  |  |  |
| *c)* | *Change to Site Type and Manufacturing Operations/Importation Activities for existing Site/included for new Site* |  |  |
|  |  |  |
|  |  |  |  |
| *d)* | *Change of Products to be Imported for existing Site/included for new Site* |  |  |
|  |  |  |  |
| *e)* | *Removal or addition of Qualified Person for existing Site/included for new Site* |  |  |
|  |  |  |  |
| *f)* | *Removal or addition of Person Responsible for Production for existing Site/included for new Site* |  |  |
|  |  |  |
|  |  |  |  |
| *g)* | *Removal or addition of Person Responsible for Quality Control for existing Site/included for new Site* |  |  |
|  |  |  |
|  |  |  |  |
| *h)* | *Removal or addition of Contract Laboratory for existing Site/included for new Site* |  |  |
|  |  |  |  |
| *i)* | *Removal or addition of Storage and Handling Site for existing Site/included for new Site* |  |  |
|  |  |  |
|  |  |  |  |
| *j)* | *Removal or addition of Contract Manufacturing Site for existing Site/included for new Site* |  |  |
|  |  |  |  |
| *k)* | *Other, please state reason:* |  |  |

5. **Background for Change**

*Please give brief background explanation for the proposed change to your Authorisation.*

|  |
| --- |
|  |

|  |  |
| --- | --- |
| **Current** | **Proposed** |

**6. Named Persons**

 *(Please indicate below how many of the following types of personnel you have working at this site following approval of this variation)*

|  |  |
| --- | --- |
| **Personnel** | **Number** |
| Qualified Person (QP) |  |
| Production Manager/Supervisor (PM) |  |
| Person Responsible for Quality Control (QC) |  |

7. **Declaration**

I hereby make an application for the above ManA to be varied in accordance with the proposals given above. I declare that there are no other changes than those identified in this application.

|  |  |  |  |
| --- | --- | --- | --- |
| Signature: |  | Status: |  |
|  |  |  |  |
| Name in **BLOCK LETTERS**: |  | Date: |  |
|  |  |  |

**Please delete any Sections not required before submitting your Application Form**

**Please complete the Checklist on the last page of this form to ensure that you have submitted all necessary information, signatures and supporting documentation**

**Section 1: Site Information**

**1.1 Site Details**

**You will need to complete one copy of Section 1 for each manufacturing and/or assembly and/or importation site that you wish to include on the Authorisation.**

|  |  |
| --- | --- |
| Site Name: |  |
|  |  |
| Address: |  |

|  |  |
| --- | --- |
| Postcode: |  |

|  |  |
| --- | --- |
| Contact Name: |  |
|  |  |  |  |
| Telephone: |  |
|  |  |  |  |
| Mobile: |  |
|  |  |  |  |
| Email: |  |

**1.2 Use of Products at Site**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Are the products for administration to animals? |  | Yes |  | No |

**Section 2: Site Type and Manufacturing Operations**

**WHERE TICK BOXES ARE PROVIDED, PLEASE INDICATE ADDITION BY A TICK AND DELETION BY A CROSS.**

**2.1 Site Types**

|  |  |  |  |
| --- | --- | --- | --- |
| Manufacture |  | Assembly and Packaging |  |
|  |  |  |  |
| Batch Certification |  | QC Testing |  |
|  |  |  |  |
| Biological |  | Non-biological |  |
|  |  |  |  |
| Export |  | Import |  |
|  |  |  |  |
| Storage and Handling |  | Other, please specify |  |

**2.2 Site Functions**

***Part 1 – MANUFACTURING OPERATIONS***

* authorised manufacturing operations include total and partial manufacturing (including various process of dividing up, packaging or presentation), batch release and certification, importation, storage and distribution of specified dosage forms unless informed to the contrary;
* quality control testing and/or release and batch certification activities without manufacturing operations should be specified under the relevant items;
* if the company is engaged in manufacture of products with special requirements e.g. radiopharmaceuticals or products containing penicillin, sulphonamides, cytotoxics, cephalosporins, substances with hormonal activity or other potentially hazardous active ingredients this should be stated under the relevant product type and dosage form (applicable to all sections of Part 1 apart from sections 1.5.2 and 1.6).

**PLEASE INDICATE ADDITION BY A TICK AND DELETION BY A CROSS**

|  |  |  |
| --- | --- | --- |
| **1.1** | **Sterile Products** | **Manufacture** |
| **1.1.1** | **Aseptically Prepared (processing operations for the following dosage forms)** |  |
|  | 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 |  |

|  |  |  |
| --- | --- | --- |
| ***1.1.2*** | ***Terminally Sterilised (processing operations for the following dosage forms)*** | **Manufacture** |
|  | 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  |  |
| ***1.1.3*** | ***Batch certification***  |  |

|  |  |  |
| --- | --- | --- |
| **1.2** | **Non-sterile products** | *Manufacture* |
| ***1.2.1*** | ***Non-sterile products (processing operations for the following dosage forms)*** |  |
|  | 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 |  |
|  | 1.2.1.16 Veterinary premixes |  |
|  | 1.2.1.17 Other non-sterile medicinal product |  |
| ***1.2.2*** | **Batch certification**  |  |

|  |  |  |
| --- | --- | --- |
| **1.3** | **Biological medicinal products** | **Manufacture** |
| ***1.3.1*** | ***Biological medicinal products (list of product types)*** |  |
|  | 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 |  |
|  | 1.3.1.8 Other biological medicinal products |  |
| ***1.3.2*** | ***Batch certification (list of product types)*** |  |
|  | 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 |  |
|  | 1.3.2.8 Other biological medicinal products |  |

|  |  |  |
| --- | --- | --- |
| ***1.4*** | ***Other products or manufacturing activity***(any other relevant manufacturing activity/product type that is not covered above e.g. sterilisation of active substances, manufacture of biological active starting materials (when required by national legislation), herbal or homeopathic products, bulk or total manufacturing, etc.). | **Manufacture** |
| ***1.4.1*** | **Manufacture of:**  |  |
|  | 1.4.1.1 Herbal products |  |
|  | 1.4.1.2 Homoeopathic products |  |
|  | 1.4.1.3 Other |  |
| ***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** | **Others** |  |

|  |  |  |
| --- | --- | --- |
| ***1.5*** | ***Packaging***  | Manufacture |
| ***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  |  |
| ***1.5.2*** | **Secondary packing** |  |
| ***1.6*** | **Quality control testing** |  |
|  | **1.6.1 Microbiological: sterility** |  |
|  | **1.6.2 Microbiological: non-sterility** |  |
|  | **1.6.3 Chemical/Physical**  |  |
|  | **1.6.4 Biological** |  |

***Part 2 – IMPORTATION OF MEDICINAL PRODUCTS***

* authorised importation activities without manufacturing activity
* authorised importation activities include storage and distribution unless informed to the contrary

**PLEASE INDICATE ADDITION BY A TICK AND DELETION BY A CROSS**

|  |  |  |
| --- | --- | --- |
| ***2.1*** | **Quality control testing of imported medicinal products** | **Import** |
|  | 2.1.1 Microbiological: sterility |  |
|  | 2.1.2 Microbiological: non-sterility |  |
|  | 2.1.3 Chemical/Physical |  |
|  | 2.1.4 Biological |  |
| ***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* |  |
| *2.2.3* | *Biological medicinal products* |  |
|  | 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 medical products |  |
| ***2.3*** | ***Other importation activities***(any other relevant importation activity that is not covered above) |  |
|  | 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 |  |

**IMPORTATION OF MEDICINAL PRODUCTS**

**Products to be Imported**

**2.3 Products to be Imported**

**You will need to complete Section 2.3 if you wish to add or remove any products to be imported.**

**WHERE TICK BOXES ARE PROVIDED, PLEASE INDICATE ADDITION BY A TICK AND DELETION BY A CROSS.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Are authorised veterinary medicinal products from outside the EEA imported at this site? |  | **Yes** |  | **No** |
|  |  |  |  |

If yes, please list below all authorised products imported from outside the EEA including authorised products that you wish to add or remove.

|  |  |  |  |
| --- | --- | --- | --- |
| **Authorisation Number** | **Product Name** | **Country of Origin** | **Enter a Tick or a Cross** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**Section 3: Named Persons**

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

|  |  |
| --- | --- |
| **Personnel** | **Number** |
| Qualified Person (QP) |  |
| Production Manager/Supervisor (PM) |  |
| Person Responsible for Quality Control (QC) |  |

**Please ensure you have included copies of the required documentation.**

**Qualified Persons**

**3.1 Qualified Person**

1. **Please complete a separate page for each proposed Qualified Person (QP).**
2. **Each QP nomination must be signed by both the nominee and the applicant.**
3. **If removing a QP, please state their name in the Background for Change section on page 2.**
4. **ALL APPLICATIONS BY A QP MUST INCLUDE A RELEVANT CV AND A COPY OF THE NOMINEE’S CERTIFICATE OF ELIGIBILITY FROM RPSGB, SOB OR RSC.**

|  |  |  |  |
| --- | --- | --- | --- |
| Title: |  | Person ID:(if known) |  |
|  |  |  |
|  |  |  |  |
| First name(s): |  |
|  |  |  |  |
| Surname: |  |
|  |  |  |  |
| Business Address: |  |
|  |  |  |  |
| Postcode: |  |  Telephone: |  |
|  |  |  |  |
| Mobile: |   |
|  |  |  |  |
| Email: |  |

**Please indicate your status**

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

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)**

|  |
| --- |
|  |

**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 Qualified Person.**

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

**Person Responsible for Production**

**3.2 Person Responsible for Production**

1. **Please complete a separate page for each proposed person responsible for production (PM).**
2. **Each PM nomination must be signed by both the nominee and the applicant.**
3. **If removing a PM, please state their name is the Background for Change section on page 2.**
4. **ALL APPLICATIONS BY A PM MUST INCLUDE A RELEVANT CV WHICH DESCRIBES THE PRODUCTION MANAGER’S EXPERIENCE IN DEALING WITH VETERINARY MEDICINES.**
5. **In what capacity are you signing this? Please indicate in the box below.**

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

|  |  |  |  |
| --- | --- | --- | --- |
| Title: |  | Person ID:(if known) |  |
|  |  |  |
|  |  |  |  |
| First name(s): |  |
|  |  |  |  |
| Surname: |  |
|  |  |  |  |
| Business Address: |  |
|  |  |  |  |
| Postcode: |  |  Telephone: |  |
|  |  |  |  |
| Mobile: |   |
|  |  |  |  |
| Email: |  |

**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 he/she reports:**

|  |
| --- |
|  |

**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:** |  |  |  |
|  |  |  |  |

**Person Responsible for Quality Control**

**3.3 Person Responsible for Quality Control**

1. **Please complete a separate page for each proposed person responsible for quality control (QC).**
2. **Each QC nomination must be signed by both the nominee and the applicant.**
3. **If removing a QC, please state their name in the Background for Change section on page 2.**
4. **ALL APPLICATIONS BY A QC MUST INCLUDE A RELEVANT CV WHICH DESCRIBES THE PERSON RESPONSIBLE FOR QUALITY CONTROL’S EXPERIENCE IN DEALING WITH VETERINARY MEDICINES.**

|  |  |  |  |
| --- | --- | --- | --- |
| Title: |  | Person ID:(if known) |  |
|  |  |  |
|  |  |  |  |
| First name(s): |  |
|  |  |  |  |
| Surname: |  |
|  |  |  |  |
| Business Address: |  |
|  |  |  |  |
| Postcode: |  |  Telephone: |  |
|  |  |  |  |
| Mobile: |   |
|  |  |  |  |
| Email: |  |

**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 he/she reports:**

|  |
| --- |
|  |

**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:** |  |  |  |
|  |  |  |  |

**Section 4: Contact Laboratories**

1. **Please complete a copy of Section 4 for each proposed Contract Laboratory you wish to name on this authorisation.**
2. **If removing a Control Laboratory, please name the laboratory in the Background for Change section on page 2.**

**COPIES OF APPROPRIATE AUTHORISATIONS FOR CONTRACT LABORATORIES SHOULD BE ATTACHED.**

|  |  |
| --- | --- |
| Site Number:(if known) |  |
|  |  |
| Site Name: |  |
|  |  |
| Address: |  |

|  |  |
| --- | --- |
| Postcode: |  |

|  |  |
| --- | --- |
| Site Contact Name: |  |
|  |  |  |  |
| Telephone: |  |
|  |  |  |  |
| Mobile: |  |  |  |
|  |  |  |  |
| Email: |  |

1. **Please indicate the type of testing carried out by ticking the relevant box(es) below.**

|  |
| --- |
| **Quality Control Testing** |
|  |  |  |  |  |
| Microbiological sterility |  | **Yes** |  | **No** |
|  |  |  |  |  |
| Microbiological non-sterility |  | **Yes** |  | **No** |
|  |  |  |  |  |
| Chemical/Physical |  | **Yes** |  | **No** |
|  |  |  |  |  |
| Biological |  | **Yes** |  | **No** |
|  |  |  |  |  |
| Stability testing? |  | **Yes** |  | **No** |
|  |  |  |  |  |
| Is this site involved in doing finished product testing? |  | **Yes** |  | **No** |
|  |  |  |  |  |
| Is this site involved in microbiological testing of finished products and/or raw materials? |  | **Yes** |  | **No** |
|  |  |  |  |

**Section 5: Storage and Handling Site**

1. **Please complete a copy of Section 5 for each proposed Storage and Handling Site that you wish to name on this authorisation.**
2. **If removing a Storage and Handling Site, please name the site in the Background for Change Section on page 2.**

**COPIES OF APPROPRIATE AUTHORISATIONS FOR STORAGE AND HANDLING SITES SHOULD**

**BE ATTACHED.**

|  |  |
| --- | --- |
| Site Number:(if known) |  |
|  |  |
| Site Name: |  |
|  |  |
| Address: |  |

|  |  |
| --- | --- |
| Postcode: |  |

|  |  |
| --- | --- |
| Site Contact Name: |  |
|  |  |  |  |
| Telephone: |  |
|  |  |  |  |
| Mobile: |  |  |  |
|  |  |  |  |
| Email: |  |

**Section 6: Contract Manufacturing Site**

1. **Please complete a copy of Section 6 for each proposed Contract Manufacturing Site that you wish to name on this authorisation.**
2. **If removing a Contract Manufacturing Site, please name the site in the Background for Change Section on page 2.**

**COPIES OF APPROPRIATE AUTHORISATIONS FOR CONTRACT MANUFCTURING SITES SHOULD**

**BE ATTACHED.**

|  |  |
| --- | --- |
| Site Number:(if known) |  |
|  |  |
| Site Name: |  |
|  |  |
| Address: |  |

|  |  |
| --- | --- |
| Postcode: |  |

|  |  |
| --- | --- |
| Site Contact Name: |  |
|  |  |  |  |
| Telephone: |  |
|  |  |  |  |
| Mobile: |  |  |  |
|  |  |  |  |
| Email: |  |

**CHECKLIST OF DOCUMENTS ATTACHED/SIGNATURES**

|  |  |  |
| --- | --- | --- |
| 1. Copies of relevant CVs and qualifications for Named Persons.
 |  |  |
|  |  |  |
| 1. Copy of Site Master File if adding a new Site
 |  |  |
|  |  |  |
| 1. Copies of appropriate authorisations for new contract laboratories, storage

 and handling sites and contract manufacturing sites |  |  |
|  |  |
|  |  |  |
| 1. Named Persons sections signed by both the Nominee and Applicant.
 |  |  |
|  |  |  |
| 1. Declaration signed at page 3.
 |  |  |