**Wholesale Distribution Authorisation (WDA-V) Application Form – Products for Veterinary use**



 Sections 1 - 4 (Part A) only need to be completed once per application.

 Sections 2 - 3 (Part B) one copy will need to be completed for each site to be

included on the authorisation

**2.0 New Site Information**

****Is this a new site (Not named on any MHRA authrisation)

[ ]  Yes [ ]  No

****Is this the main site

[ ]  Yes [ ]  No

This is a third-party site, owned by another company/legal entity holding a current live

MHRA Authorisation.

[ ]  Yes [ ]  No

|  |  |
| --- | --- |
| **Site Name:** | Click or tap here to enter text. |
| **Site id (if known)** |  |

|  |  |
| --- | --- |
| **Address 1:**  | Click or tap here to enter text. |

|  |  |
| --- | --- |
| **Address 2:**  | Click or tap here to enter text. |

|  |  |
| --- | --- |
| **Town/City:** | Click or tap here to enter text. |

|  |  |
| --- | --- |
| **Postcode:** | Click or tap here to enter text. |

|  |  |
| --- | --- |
| **Country:** | Click or tap here to enter text. |

|  |  |
| --- | --- |
| **DUNS Number:** | Click or tap here to enter text. |

**2.1 Site Contact Person**

|  |  |
| --- | --- |
| **Name (including Title)**: | Click or tap here to enter text. |

|  |  |
| --- | --- |
| **Primary Telephone Number:** | Click or tap here to enter text. |

|  |  |
| --- | --- |
| **Secondary Telephone Number:** | Click or tap here to enter text. |

|  |  |
| --- | --- |
| **Email Address:** | Click or tap here to enter text. |

**2.2 Site Activities**

**2.2.1 Use of Products at Site**

Are the products for administration to animals?

[ ]  Yes [ ]  No

**2.2.2 Animal Human Origin Products at Site**

Products of Animal Human Origin (AHO) are present at this site?

[ ]  Yes [ ]  No

**2.2.3 Site Types**

|  |  |
| --- | --- |
|  |  |
| [ ]  | Procurement |
| [ ]  | Storage |
| [ ]  | Distribution |
| [ ]  | Other **(This must be specified, or it will not appear on the licence)** |

|  |
| --- |
| Click or tap here to enter text. |

**2.2.4 Categories of Products Handled at this Site**

|  |  |
| --- | --- |
|  |  |
| [ ]  | Prescription Only Medicines – Veterinary (POM-V)  |
| [ ]  | Prescription Only Medicines – Veterinary, Pharmacy, Suitably Qualified Person (POM-VPS) |
| [ ]  | Non-Food Animal – Veterinary, Pharmacy, Suitably Qualified Person (NFA-VPS)  |
| [ ]  | Authorised Veterinary Medicines – General Sales List (AVM-GSL) |
| [ ] [ ]  | Unlicensed Veterinary Medicinal ProductsCold Chain Products |
| [ ]  | Schedule 6 Products (products marketed under the Exemptions of Small Pet Animals) |
| [ ]  | Veterinary Homeopathic Remedies |

**2.2.5 Specific Site Activities**

|  |  |
| --- | --- |
|  |  |
| [ ]  | Are Parallel Imported Veterinary Medicinal Products imported at this site? |
| [ ]  | Are Veterinary Medicinal Products requiring refrigeration or low temperature storage handled at this site? |
| [ ]  | Controlled Drugs (Licensed by the Home Office) are handled at this site? |
|  |

**2.3 Premises**

|  |  |  |
| --- | --- | --- |
| Are the premises sound and secure?  | [ ]  Yes | [ ]  No |
| Do you have a lease/freehold for the premises named?  | [ ]  Yes | [ ]  No |

In the space below provide details of the security arrangements for the premises

|  |
| --- |
| Click or tap here to enter text. |

Provide in the space below a definitive statement that the premises are complete and

fully prepared for wholesale dealing activities. This must include a description of

what storage facilities are in place including shelving/racking, lockable storage etc?

If possible, provide photographs of premises, facilities etc.

|  |
| --- |
| Click or tap here to enter text. |

**2.3.1 Equipment/facilities on site**

In the space below provide a drawing of your facilities. Alternatively, supply the

information on additional pages.

|  |
| --- |
| Click or tap here to enter text. |

In the space below provide details of your Business Model and/or Business Plan. Alternatively, supply the information on additional pages.

|  |
| --- |
| Click or tap here to enter text. |

**2.3.2 Procedures**

**Quality Systems**



The information sought in this section must be relevant to the site detailed in Section 2:

Site Information. If:

* more than one site is to be named on your submission and
* if the same procedures apply to each of the named sites

This section only needs to be completed for one of the sites.

**Remember,** the information required in this section must be supplied for at least one site, if it

is not the assessment will not proceed.

|  |  |  |
| --- | --- | --- |
| I confirm that these procedures apply to all sites.  |  | [ ]   |
| Is a Quality System in place?  | [ ]  Yes  | [ ]  No |
| Are there Standard Operating Procedures (SOPs) available for the distribution business processes?  | [ ]  Yes  | [ ]  No |
| Are these SOPs tailored for the business and premises named in the application form submitted to MHRA? **Note:** commercially sourced generic SOPs that have not been tailored to the business and premises named in the application form will not be acceptable.  | [ ]  Yes  | [ ]  No |
| Do SOPs include details of defined staff roles and responsibilities?  | [ ]  Yes  | [ ]  No |

**2.3.3 Transport and Distribution**

|  |  |  |
| --- | --- | --- |
| Will you distribute products using postal services?  | [ ]  Yes  | [ ]  No |
| Will you distribute products using a third party courier/van service?  | [ ]  Yes  | [ ]  No |
| Will you distribute products using your own courier/van service?  | [ ]  Yes  | [ ]  No |
| Will you distribute products using customer collection?  | [ ]  Yes  | [ ]  No |
| Has provision been made for refrigerated products and has the proposed delivery system been tested?  | [ ]  Yes  | [ ]  No |

**2.3.4 Contracts**

Are draft or signed Technical Agreements in place with

third party contractors? [ ]  Yes [ ]  No

****Supply copies of contracts for services supplied by third parties e.g. purchasing, invoicing, WQP services, storage, distribution, etc. You must supply required Information.

The documentation required is attached. [ ]

**2.3.5 Temperature Control**

Are maximum/minimum temperatures recorded in all areas

Using calibrated monitoring devices? [ ]  Yes [ ]  No

**3.0 Site Personnel - Wholesale Dealer’s Qualified Person**

This is a new nominated Wholesale Dealer’s Qualified Person, not named on

any current live MHRA Authorisations. [ ]

This nominated Wholesale Dealer’s Qualified Person is already named on a

Authorisation issued by the MHRA [ ]

|  |  |
| --- | --- |
| **MHRA Person ID Number (if known):** | Click or tap here to enter text. |

**3.1 Nominated Wholesale Dealer’s Qualified Person**

|  |  |
| --- | --- |
| **Name**: | Click or tap here to enter text. |

|  |  |
| --- | --- |
| **Primary Telephone Number:** | Click or tap here to enter text. |

|  |  |
| --- | --- |
| **Secondary Telephone Number:** | Click or tap here to enter text. |

|  |  |
| --- | --- |
| **Email Address:** | Click or tap here to enter text. |

**3.1.2 Nominated Wholesale Dealer’s Qualified Person Business Address**

|  |  |
| --- | --- |
| **Company/Site Name:** | Click or tap here to enter text. |

|  |  |
| --- | --- |
| **Address 1:**  | Click or tap here to enter text. |

|  |  |
| --- | --- |
| **Address 2:**  | Click or tap here to enter text. |

|  |  |
| --- | --- |
| **Town/City:** | Click or tap here to enter text. |

|  |  |
| --- | --- |
| **Postcode:** | Click or tap here to enter text. |

|  |  |
| --- | --- |
| **Country:** | Click or tap here to enter text. |

**3.2 Status**

**Will you be permanent employee of the proposed licence holder or a consultant/contract Wholesale Dealer Qualified Person?**

[ ]  Permanent Employee [ ]  No Consultant/Contractor

**Business Address**

The registered business address of the consultant or contractor

|  |
| --- |
| Click or tap here to enter text. |

**3.3 Knowledge of Legislation**

|  |  |  |
| --- | --- | --- |
| Do you have knowledge of the relevant provisions of the current Veterinary Medicines Regulations necessary to carry out the role of WQP?  | [ ]  Yes | [ ]  No |
| Do you have knowledge of the relevant provisions of the Medicines for HumanUse (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005 (SI 2005/2789) necessary to carry out the role of WQP? | [ ]  Yes | [ ]  No |
| Directive 2001/82/EC necessary to carry out the role of WQP?  | [ ]  Yes | [ ]  No |
| Do you have knowledge of Guidelines for Good Distribution Practice of Medicinal products for human use (94/C 63/03) necessary to carry out the roleof WQP? | [ ]  Yes | [ ]  No |

**3.4 Professional Information**

|  |  |  |
| --- | --- | --- |
| Are you a registered pharmacist?  | [ ]  Yes | [ ]  No |
| Are you eligible to act as Qualified Person?  | [ ]  Yes | [ ]  No |
| Are you eligible under the provisions for Transitional Qualified Person (TQP)?  | [ ]  Yes | [ ]  No |
| Are you a member of a professional association? If yes, write the name ofthe association and your registration/certificate number below.  | [ ]  Yes | [ ]  No |

**Name of Professional Association and registration number**

|  |
| --- |
| Click or tap here to enter text. |

|  |  |  |
| --- | --- | --- |
| Have you ever been disciplined and/or struck off a Professional register?  | [ ]  Yes  | [ ]  No |

If you answered ‘yes’ provide details below. If you need more space, please write on additional pages.

|  |
| --- |
| Click or tap here to enter text. |

**3.5 Practical Experience**

****If you are not a pharmacist or eligible to act as Qualified Person, then please confirm that you have at least one-year practical experience in:

|  |  |  |
| --- | --- | --- |
| Handling, storage and distribution of medicinal products.  | [ ]  Yes | [ ]  No |
| Transactions in or selling or procuring medicinal products.  | [ ]  Yes | [ ]  No |
| Managerial experience in controlling and directing the wholesale distribution of medicinal products on a scale similar to the Authorisation being nominated for.?  | [ ]  Yes | [ ]  No |
| A Curriculum Vitae (CV) detailing qualifications and work experience relevant to this Authorisation is attached. | [ ]  |  |

**3.6 Identification**

**To support the addition of a Wholesale Dealer Qualified Person (WQP) to your licence you’ll need to include the follow information with the application of the person being added**

**Passport / Driving Licence**

Photo ID – A copy of a document which may be used to identify the nominated WQP such as the information page from a passport or a photo card driver’s licence. (**Please attach copy with application**)

**Utility Bill**

Proof of Residence – Photocopies, preferably of at least two recent (not older than three months) utility bills to confirm the residential address of the nominated WQP. (**Please attach copy with application**)

[ ]  **Please confirm that the nominated WQP has the right to live and work in the United Kingdom**

****The inspector may request verification when visiting the site.

**Additional Information**

****

If there is any further information you feel may be relevant to the inspector when your

nomination for the role of Wholesale Dealer’s Qualified Person is considered; please supply it

in the box below.

|  |
| --- |
| Click or tap here to enter text. |

Version 2.0 Updated 13/01/2022