

# **Application Form Manufacturer's/Importer's Authorisation (ManA) (Products for Veterinary Use only)**

Please indicate the type(s) of authorisation you wish to apply for:

- Manufacturer & Assembly Authorisation – (products for veterinary use only)**
- Assembly Only Authorisation – (products for veterinary use only)**
- Import Authorisation – (products for veterinary use only)**  
[This application is for authorised medicinal products which are to be imported from outside the EEA.]

**Note:**

- i) If you wish to apply for a Manufacturer's/Importer's Authorisation (for human products), please complete the relevant MIA application form for human products, this will be processed by the MHRA.**
- ii) If you wish to apply for a Manufacturer "Specials" authorisation (for veterinary products) please complete the ManSA application form, this will be processed by the VMD for a vet only site.**

**Please note – the application form is structured into sections and should be completed as follows:**

**Sections 1, 6 and 7 only need to be completed once per application.**

**Sections 2 and 3 – one copy will need to be completed for each manufacturing and/or assembly and/or importation site to be included on the authorisation. This should not include sites/companies that already hold authorisations of their own.**

**Section 4 – one copy will need to be completed for each Contract Laboratory to be included on the authorisation.**

**Section 5 – One copy will need to be completed for each Storage and Handling site to be included on the authorisation**

**Please make additional copies of Sections 2-5 as necessary to ensure you provide the VMD with one set per site.**

**When complete please return the form to**

For attention of:

**Miss Sam Ward  
Licensing Services Section**

VMD  
Woodham Lane  
New Haw  
Addlestone  
Surrey  
KT15 3LS

s.ward@vmd.defra.gsi.gov.uk

# Veterinary Medicines Directorate

## Manufacturer's/Importer's Authorisation Application Form (ManA)

**PLEASE COMPLETE ALL RELEVANT SECTIONS IN THIS FORM TYPED OR IN BLOCK CAPITALS LEGIBLY USING BLACK INK**

### Section 1: Administrative Data

#### 1.1 Applicant's Details

Authorisation Number (if known):

Company Name:

Trading Style(s):

Applicant's Name:

Address:

Postcode:  Telephone:

Mobile:  Fax:

Email:

Are you applying on behalf of the Proposed Authorisation Holder? (e.g. if you are a consultant/representative) if YES please fill out section 1.2

Yes

No

### 1.2 Contact Details for Communication (if different from the applicant address)

Contact Name

Company Name:

Address:

Postcode:  Telephone:

Mobile:  Fax:

Email:

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

Contact Name:

Company:

Address:

Postcode:  Telephone:

Mobile:  Fax:

Email:

## Section 2: Site Information

### 2.1 Site Details

You will need to complete one copy of Sections 2 & 3 for each manufacturing and/or assembly and/or importation site that you wish to include on the Authorisation.

Site ID: (Variation only)	<input type="text"/>		
Site Name:	<input type="text"/>		
Address:	<input type="text"/>		
Postcode:	<input type="text"/>		
Contact Name:	<input type="text"/>		
Telephone:	<input type="text"/>	Fax:	<input type="text"/>
Mobile:	<input type="text"/>		
Email:	<input type="text"/>		

### 2.2 Use of Products at Site

Are the products for administration to animals?

Yes

No

### 2.3 Site Types

Manufacture	<input type="checkbox"/>	Assembly and Packaging	<input type="checkbox"/>
Batch Certification	<input type="checkbox"/>	QC Testing	<input type="checkbox"/>
Biological	<input type="checkbox"/>	Non-biological	<input type="checkbox"/>
Export	<input type="checkbox"/>	Import	<input type="checkbox"/>
Storage and Handling	<input type="checkbox"/>	Other, please specify	<input type="checkbox"/>

Site ID:  
(Variation only)

Site Name:

## 2.4 Site Functions

### Part 1 – MANUFACTURING OPERATIONS

- manufacturing operations include total and partial manufacturing (including various processes of dividing up, packaging or presentation), batch certification, importation, storage and distribution of specified dosage forms unless informed to the contrary;
- batch certification activities and/or quality control testing without other manufacturing operations should be specified under the relevant items/or section 4;
- if the company is engaged in manufacture of products with special requirements e.g. products containing penicillin, sulphonamides, cytotoxics, cephalosporins, substances with hormonal activity or other or 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 tick each of the site functions proposed to be conducted.**

1.1	Sterile Products	Manufacture (Please Tick)
1.1.1	Aseptically Prepared (list of 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 (please specify)	

Site ID:  
(Variation only)

Site Name:

1.1.2	Terminally Sterilised	Manufacture (Please Tick)
	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 only	

1.2	Non-sterile products	Manufacture (Please Tick)
1.2.1	Non-sterile products (list of 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	

Site ID:  
(Variation only)

Site Name:

	<b>Non-sterile products</b>	<b>Manufacture (Please Tick)</b>
	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 products (please specify)	
<b>1.2.2</b>	<b>Batch certification only</b>	

Site ID:  
(Variation only)

Site Name:

1.3	Biological medicinal products	Manufacture (Please Tick)
1.3.1	<b>Biological medicinal products</b>	
	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 Other biological medicinal products (please specify)	
1.3.2	<b>Batch certification only</b>	
	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 Other biological medicinal products (please specify)	

Site ID:  
(Variation only)

Site Name:

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).	Manufacture (Please Tick)
1.4.1	<b>Manufacture of:</b>	
	1.4.1.1 Herbal products	
	1.4.1.2 Homoeopathic products	
	1.4.1.3 Biological active starting materials	
	1.4.1.4 Other (please specify)	
1.4.2	<b>Sterilisation of active substances/excipients/finished product:</b>	
	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 (please specify)	

Site ID:  
(Variation only)

Site Name:

1.5	Packaging only	Packaging (Please Tick)
1.5.1	<b>Primary packing</b>	
	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)	
1.5.2	<b>Secondary packing</b>	

Site ID:  
(Variation only)

Site Name:

1.6	Quality control testing	Manufacture related (Please Tick)
	1.6.1 Microbiological: sterility	
	1.6.2 Microbiological: non-sterility	
	1.6.3 Chemical/Physical	
	1.6.4 Biological	

Site ID:  
(Variation only)

Site Name:

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

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

<b>2.1</b>	<b>Quality control testing of imported medicinal products</b>	<b>Import (Please tick)</b>
	2.1.1 Microbiological: sterility	
	2.1.2 Microbiological: non-sterility	
	2.1.3 Chemical/Physical	
	2.1.4 Biological	
<b>2.2</b>	<b>Batch certification of imported medicinal products</b>	
<b>2.2.1</b>	<b>Sterile Products</b>	
	2.2.1.1 Aseptically Prepared	
	2.2.1.2 Terminally Sterilised	
<b>2.2.2</b>	<b>Non-Sterile Products</b>	
<b>2.2.3</b>	<b>Biological Medicinal Products</b>	
	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 Other biological medicinal products (please specify)	

Site ID:  
(Variation only)

Site Name:

2.2.4	Other importation activities (any other relevant importation activity that is not covered above e.g. importation of radiopharmaceuticals, medicinal gases, herbal or homeopathic products, etc.)	Import (Please Tick)
	2.2.4.1 Radiopharmaceuticals/Radionuclide generators	
	2.2.4.2 Medicinal gases	
	2.2.4.3 Herbal products	
	2.2.4.4 Homoeopathic products	
	2.2.4.5 Biological active starting materials	
	2.2.4.6 Other (please specify)	

Site ID:  
(Variation only)

Site Name:

## 2.5 Products to be Imported

Please answer the question below to indicate importation activities proposed to be conducted at the site.

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 EU/VM authorised products.

EU/VM Number	Product Name	Country of Origin

Site ID:  
(Variation only)

Site Name:

## 2.6 Other Information

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

### OTHER SPECIFIC PROCESSES/ACTIVITIES

Bulk or partial manufacturing	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Assembly of parallel imported products	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Manufacture and assembly for export	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Assembly for export	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Are materials or products of Animal Human Origin (AHO) present at this site?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No

### LETTING AND/OR ACCEPTING CONTRACTS

Applicants intends to be contract acceptor (i.e. manufactures partially/wholly for others)	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Applicant intends to be contract giver (i.e. uses external manufacturers for total or partial manufacture)	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Applicant intends to be contract acceptor (i.e. carries out testing partially/wholly for others)	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Applicants intends to be contract giver (i.e. uses external test houses for some/all testing)	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No

### SUPPLEMENTARY QC TESTING INFORMATION AT THIS SITE

Stability testing?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Is this site involved in doing finished product testing?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Is this site involved in microbiological testing of finished products and/or raw materials?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
If answer No to above, explain activities:				

Site ID:  
(Variation only)

Site Name:

**OTHER INFORMATION**

Do you, or will you handle medicines which require refrigeration or low temperature storage?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Do you, or will you, import intermediate products for further processing?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Is this site ready for inspection?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Are you conversant with Eudralex – Volume 4: Good Manufacturing Practice (GMP) Guidelines?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Are signed technical agreements available for inspection where applicable?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No

## 2.7 Further information which should be attached

Is the Site Master File submitted as a hard copy or an electronic copy?

Hard Copy  E Copy

### FACILITIES ON SITE

Details should be included in your Site Master File

### EQUIPMENT ON SITE

Details should be included in your Site Master File.

Site ID:  
(Variation only)

Site Name:

**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.

Site ID:  
(Variation only)

Site Name:

### 3.1. Qualified Person

1. Please complete a separate page for each QP.
2. Each QP nomination must be signed by both the nominee and the applicant.
3. All applications by a QP must include a relevant CV and a copy of the nominee's certificate of eligibility from RPSGB, IOB or RSC.

Title:  Person ID:  
(if known)

First name(s):

Surname:

Business Address:

Postcode:  Telephone:

Fax:  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?

Site ID:  
(Variation only)

Site Name:

**Qualifications (relevant to this authorisation)**

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

**Professional Association(s):**

Site ID:  
(Variation only)

Site Name:

**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:** \_\_\_\_\_

Site ID:  
(Variation only)

Site 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:  Person ID:  
(if known)

First name(s):

Surname:

Business Address:

Postcode:  Telephone:

Fax:  Mobile:

Email:

#### Qualifications (relevant to this authorisation)

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

Site ID:  
(Variation only)

Site Name:

**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:** \_\_\_\_\_

Site ID:  
(Variation only)

Site Name:

### 3.3. Person Responsible for Quality Control

Please give the following details of the person(s) with overall responsibility for Quality Control. 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 areas of responsibility.

Title:  Person ID:  
(if known)

First name(s):

Surname:

Business Address:

Postcode:  Telephone:

Fax:  Mobile:

Email:

#### Qualifications (relevant to this authorisation)

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

Site ID:  
(Variation only)

Site Name:

**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: Contract Laboratories

Please complete a copy of section 4 for each contract laboratory you wish to name on this authorisation

Site ID:  
(Variation only)

Site Name:

Address:

Postcode:

Site Contact Name:

Telephone:  Fax:

Mobile:

Email:

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

Quality Control Testing				
Microbiological: sterility	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Microbiological: non-sterility	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Chemical/Physical	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Biological	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Stability testing?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Is this site involved in doing finished product testing?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
Is this site involved in microbiological testing of finished products and/or raw materials?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No
If answer No to above, explain activities:				

## Section 5: Storage & Handling Sites

Please complete a copy of section 5 for each storage and handling site that you wish to include on the authorisation.

Site ID:  
(Variation only)

Site Name:

Address:

Postcode:

Site Contact Name:


Telephone:  Fax:

Mobile:

Email:

## Section 6: Comments

Please provide any other information that may support your application. You can also detail any changes to addresses, person names etc.

A large, empty rectangular box with a thin black border, intended for the user to provide additional information or comments. The box is currently blank.

## Section 7: Declaration

**I/We apply for the grant of a Manufacturer's/Importer's Authorisation (ManA) to the proposed holder named in this application form in respect of the activities to which the application refers.**

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

**7.2 To the best of my knowledge and belief the particulars I have given in this form are correct, truthful and complete.**

**Signed (Applicant):** \_\_\_\_\_

**Date:** \_\_\_\_\_

**Print Name:** \_\_\_\_\_

**State capacity in which signed:**