DOCUMENT 5
Sample/Template Application Form: New Wholesale Dealer's Licence (Human use)

Persons completing the application form

Title

First Name(s)

Surname

Contact Details

Telephone

Mobile

E-mail

Are you a consultant / representative applying on behalf of the proposed Licence Holder? YES ☐ NO ☐

Application Date		Purchase Order Number	

Type of Application

Application for Wholesale Dealer's licence (WL)

Application for Wholesale Dealer's licence General Sales List only (GSL)

Checklist

- ☐ Completed Application Form
- ☐ Payment Confirmation
- ☐ Section 1 - need only be completed once per application.
- ☐ Section 2 - one copy for each new site to be named.
- ☐ Section 3 - one copy for each third-party site to be named.
- ☐ Section 4 - one copy for each new Responsible Person to be named, signed and dated.
- ☐ Section 5 - one copy for each current Responsible Person to be named, signed and dated.
- ☐ Section 6 - need only be completed once per application, signed and dated.

General Information

Is your business a registered pharmacy? ☐

If 'Yes' does wholesale dealing form less then 15% of annual turnover? ☐

If 'No', is your annual turnover by way of wholesale dealing less than £35,000? ☐

Section 1: Administrative

1.1 Company Information

1.1.1 Licence Holder (Registered Company Name)

1.1.2 Trading Style(s)

1.1.3 DUNS Number

1.1.4 Company Contacct Person

Title

First Name(s)

Surname

1.1.5 Contact Details

Telephone

Mobile

E-mail

Fax

1.1.6 Company Address

Name of department

Building Name

Industrial Complex

Unit Number(s)

Street Number

Street Name

Town

Country

Postcode

Section 1: Administrative Data

1.2 Company Information

1.2.1 Address for Communication (Where your licence/post should be sent) and/or address for Invoicing (Where your invoices should be sent).

1.2.1.1 Add a new address for communication ☐

1.2.1.2 Add a new address for invoicing ☐

1.2.1.3 Persons your communication should be addressed to:

Title

First Name(s)

Surname

1.2.1.4 Company Name (If different to proposed licence holder)

1.2.1.5 Address to be used Communication

Name of department

Building Name

Industrial Complex

Unit Number(s)

Street Number

Street Name

Town

Country

Postcode

Section 2: New Site Information

2.1 Site Details

Site Number _____ Postcode _____

This is the main site? YES ☐ NO ☐

2.2 Site Name

_____

2.3 Site Address

Name of department _____

Building Name _____

Industrial Complex _____

Unit Number(s) _____

Street Number _____

Street Name _____

Town _____

Country _____ Postcode _____

2.4 DUNS Number

☐☐ ☐☐☐ ☐☐☐☐

2.5 Company Contacct Person

Title _____

First Name(s) _____

Surname _____

2.5.1 Contact Details

Telephone _____ Mobile _____

E-mail _____ Fax _____

Site Name of Number		Postcode	

Section 2: Site Activities

2.6.1 Use of Products at Site

Are the products for administration to human beings? YES ☐ NO ☐

2.6.1 Aminal Human Origin Products at Site

Products of Animal Human Origin (AHO) are present at this site? YES ☐ NO ☐

2.6.3 Site Types

Procurement/Administration only (no storage) # ☐

Procurement and Administration ☐

Storage and Handling (Picking of Goods) ☐

Other (Specify) ☐

2.6.4 Categories of Products Handled at this Site

General Sales List (GSL) ONLY* ☐
*Wholesale Dealer's General Sales list (GSL) only licence; this is the only category which may be selected

Prescription Only (POM) ☐

Pharmacy ☐

General Sales List (GSL) ☐

Traditional Herbal Medicinal Products ☐

Biologicals ☐

2.6.5 Specific Site Activities

Are "special" manufactered products handled at this site? ☐

Are unlicensed medicinal prodcuts imported from other EEA member states handled at this site? ☐

Are parallel imported medicinal products handled at this site? ☐

Site Name of Number		Postcode	

2.7 Product Classes Handled at this Site

Small volume streile liquids (includes eye drops) ☐

Other sterile products **(Must be specified)** ☐

Solid sterile dosage forms (includes sterile powders) ☐

Non-sterile liquids (includes solutions, syrups,and suspensions)* ☐

Solid non-sterile dosage forms (includes tablets, capsules, suppositories & poweders)* ☐

Semi-solid non-sterile dosage forms (includes non-sterile creams and ointments)* ☐

Other non-sterile products **(Must be specified)*** ☐

Medicinal Gases ☐

Semi-solid sterile dosage forms (includes sterile creams and ointments) ☐

Large volume sterile liquids ☐

2.8 Specific Site Activities

Controlled Drugs (Licensed by the Home Office) are handled at this site? ☐

Do you supply stock which requires refrigeration or low temperature storage? ☐

*Wholesale Dealer's General Sales list (GSL) only licence; these are the only category which may be selected

Site Name of Number		Postcode	

Section 2: Information

Section B: Inspectorate Information

1. Premises

1.1 Are the premises sound and secure? YES ☐ NO ☐

1.2 Do you have a lease/freehold for the premises named? YES ☐ NO ☐

1.3 Are the premises sound and secure? YES ☐ NO ☐

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

1.5 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.

Site Name of Number		Postcode	

Section 2: Site Information

Section B: Inspectorate Information

2. Equipment/facilities on site

2.1 In the space below provide a drawing of your facilities. Alternativley, supply the information on additional pages.

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

Site Name of Number		Postcode	

Section 2: Site Information

Section B: Inspectorate Information

3. Procedures

Quality Systems

Note: This 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 assesment will not proceed.

3.1 I confirm that these procedures apply to all sites. ☐

3.2 Is a Quality System in place? YES ☐ NO ☐

3.3 Are there Standard Operating Procedures (SOPs) available for the distribution business processes? YES ☐ NO ☐

3.4 Are these SOPs tailored for the business and premises named in the application form submitted to MHRA? YES ☐ NO ☐

Note: commercially sourced generic SOPs that have not been tailored to the business and premises named in the application form will not be acceptted.

3.5 Do SOPs include details of defined stall roles and responsibilites? YES ☐ NO ☐

4. Transport and Distribution

4.1 Will you distribute products using postal services? YES ☐ NO ☐

4.2 Will you distribute products using a third party courier/van service? YES ☐ NO ☐

4.3 Will you distribute products using your own courier/van service? YES ☐ NO ☐

4.4 Will you distribute products using customer collection? YES ☐ NO ☐

4.5 Has provision been made for refrigerated products and has the proposed delivery system been tested? YES ☐ NO ☐

Site Name of Number		Postcode	

5.1 Are draft or signed Technical Agreements in place with third party contractors? YES ☐ NO ☐

5.2 Supply copies of contacts for services supplied by third parties
e.g. purchasing, invoicing, RP services, storage, distribution, etc. You must supply requited information.

Documentation	The documentation required in 5.2 is attached	☐

6.1 Are maximum/minimum temperatures recorded in all areas Using calibrated monitoring devices? YES ☐ NO ☐

Site Name of Number		Postcode	

Section 3: Site Personel

New Responsible Persons

This is a new nominated Responsible Person, not named on any current live MHRA licences.

This nominated Responsible Person is already named on a licence issued by the MHRA and has undergone the neccessary security checks (i.e. has provided copies of documentation such as utility bills and the passport information page and/or photo card drivers licence).

Note: Responsible Persons named on licences prior to 2006 (when the new system was Introduced) who have not yet provided this information will be expected to provide this before they may be named on new sites or licences. If you are unsure please email pcl@mhra.gsi.gov.uk and we will confirm.

3.1 Nominated Responsibility Person

Title	
First Name(s)	
Surname	

3.1.1 Contact Details

Telephone		Mobile	
E-mail		Fax	

3.1.2 Person Number

1.1.6 Company Address

Building Name			
Industrial Complex			
Unit Number(s)			
Street Number			
Street Name			
Town			
Country		Postcode	

Site Name of Number		Postcode	

Section 3: Site Personel

Section 3B: Inspectorate Information

1. Status

1.1 Will you be a permanent employee of the proposed licence holder? YES ☐ NO ☐

1.2 If the answer to 1.1 is 'no', will you be a consultant/contract Ressponsible Person? YES ☐ NO ☐

1.3 If the answer to 1.2 is 'no', is a technical agreement/contract between you and the licenceholder in place? YES ☐ NO ☐

1.4 If the answer to 1.2 is 'yes', please ensure a copy is supplied as part of the information submitted with this form, also complete 1.4.1 below.

Documentation	A copy of the technical agreement is attached.	☐

1.4.1 Indicate itn the box below below the frequency that you intend to visit the site(s) to carry out RP duties (e.g. full-time, twice a week, once a month etc.)

2. Knowledge of legislation

2.1 Do you have knowledge of the relavent provisions of the Medicines Act 1968 (as amended) neccessary to carry out the role of RP? YES ☐ NO ☐

2.2 Do you have knowledge of the relevant provisions of the Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous) Regulations 2005 (SI 2005/2789) neccessary to carry out the role RP? YES ☐ NO ☐

2.3 Do you have knowledge of the relevant provisions of Directive 2001/83/EC neccessary to carry out the role of RP? YES ☐ NO ☐

2.4 Do you have knowledge of Guidelines for Good Distribution Practice of Medicinal products for human use (94/C 63/03) neccessary to carry out the role of RP? YES ☐ NO ☐

Site Name of Number		Postcode	

Section 3: Site Personel

Section 3B: Inspectorate Information

3. Professional Information

3.1 Are you a registered Pharmasist?	YES	☐	NO	☐
3.2 Are you eligible to act as a Qualified Person?	YES	☐	NO	☐
3.3 Are you eligible under the provisions for Transitional Qualified Person (TQP)?	YES	☐	NO	☐
3.4 Are you a member of a professional association? If yes, write the name of the association and your registration/certificate number below.	YES	☐	NO	☐

Name of Professional Association	Your registration number

3.5 Have you ever been disciplined and/or struck off a Professional register?	YES	☐	NO	☐

If you answered 'yes' to 3.5 provide details below. If you need more space please write on additional pages.

4. Practical Experience

If you are not a Pharmasist or eligible to act as a Qualified Person then please confirm that you have at least one years practical experience in:

4.1 Handing, storage and distribution of medicimal products.	YES	☐	NO	☐
4.2 Transactions in or selling or procuring medicinal products.	YES	☐	NO	☐
4.3 Managerial experience in controlling and directing the wholesale distribution of medicinal products on a scale similar to the licence being nominated for.	YES	☐	NO	☐
4.4 A Curriculum Vitae (CV) detailing qualifications and work experience relevant to this licence is attached.	YES	☐	NO	☐

Site Name of Number		Postcode	

Section 3: Site Personel

Section 3B: Inspectorate Information

5. Identification

5.1 Photo ID - A copy of a document which may be used to identify the nominated Responsible Person such as the information page from a passport or a photo card driver's licence. ☐

5.2 Proof of Residence - Photocopies of at least two recent (not older than three months) utility bills to confirm the residential address of the nominated Responsible Person. ☐

6. Professional Reference

Provide details of referees who can substantiate the information you have provided. MHRA reserve the right to contact referees to verify the information provided.

Reference 1

Company:	
Posittion you held:	
Period you were in the position:	
Referee's name:	
Position in company held by the referee:	
Referee's email address:	
Referee's telephone number:	

Referee's postal address:

Reference 1

Company:	
Posittion you held:	
Period you were in the position:	
Referee's name:	
Position in company held by the referee:	
Referee's email address:	
Referee's telephone number:	

Referee's postal address:

Site Name of Number		Postcode	

Section 3: Site Personel

Section 3B: Inspectorate Information

6. Professional References

Reference 3

Company:	
Posittion you held:	
Period you were in the position:	
Referee's name:	
Position in company held by the referee:	
Referee's email address:	
Referee's telephone number:	

Referee's postal address:

7. Additional Information

If there is any further information you feel may ve relevant to the inspector when your nomination for that role of Responsible Person is considered; please supply it in the box below.

Site Name of Number		Postcode	

Section 3: Site Personel

8. Declaration

Each new nominee for Responsible Person must complete the details in the declaration box below and sign and date the declaration.

I confirm that the information submitted about me in response to the questions in this form which this declaration forms a part of are to the best of my knowledge and belief correct, complete, true and accuarate. I agree to be nominated as Responsible Person.

Signed (Nominated Qalified Person)		Date	
Print Name			
Signed (Applicant)		Date	
Print Name			

Site Name of Number		Postcode	

Section 4: Declaration

I/We apply for the grant of a Wholesale Dealer's Licence to the proposed holder named in this application from in respect of activities to whichj the application refers,

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

4.2 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			
Capacity in which signed			

Submission Information

Please return the application form along with supporting documentation to :

E-Mail: **pcl@mhra.gsi.gov.uk**

Or paper applications to :

Medicines and Healthcare products Regulatory Agency
Process Licensing, (5Y, Desk 363)
151 Buckingham Palace Road
London
SW1W 9SZ