APPLICATION FOR A BLOOD ESTABLISHMENT AUTHORISATION

(Complete in conjunction with guidance notes)

All information sought in this form except that in those sections marked with an asterisk (*) is mandatory. However, completion of those sections marked with an asterisk will assist MHRA to process the application.

Section 1 – Background Information

Licence/Authorisation number(s)

If the company/organisation making the application already holds or has previously held an existing licence and/or authorisation from the MHRA please enter the licence/authorisation number(s) below.

Number:		**Number:**	
Number:		**Number:**	

Other Licences/Authorisations Held

If the company/organisation making the application already holds a licence and/or authorisation issued by MHRA please identify it by completing the grid below. To ensure clarity please enter 'yes' or 'no' against each licence/authorisation type in the appropriate column

	Yes	No
Manufacture/Importer licence - (MIA)		
Manufacturer's 'Specials' Licence - (MS)		
Manufacturer's Licence (Investigational Medicinal Products) - MIA(IMP)		
Wholesale Distribution Authorisation – WDA(H)		
Marketing Authorisation (Product Licence)		
Other (if yes specify below)		

Section 2 – Applicant Details

*Blood Establishment Name:	
*Applicant:	
*Trading As:	
*Address:	
*Postcode:	
*Telephone:	
*Mobile:	
*Fax:	
*Email:	

If you are applying on behalf of the Proposed Authorisation Holder **(e.g. if you are a consultant/representative)** please tick here ☐

Contact Details for Communications (if different from above)

*Contact Name:	
*Company Name:	
*Address:	
Postcode:	
*Telephone:	
*Mobile:	
*Fax:	
*Email:	

Section 2 – Applicant Details (continued)

Address for Invoicing Purposes (if different from above)

All charges will be sent to the authorisation holder unless alternative details are given below.

*Contact Name:	
*Company Name:	
*Address:	
Postcode:	
*Telephone:	
*Mobile:	
*Fax:	
*Email:	

Please note – this application form is divided into nine sections. Sections 1 and 2 and the final section (9) must only be completed once per authorisation being applied for. For sections 3 – 8 one set of these sections must be completed for each site that the applicant wishes to include on the authorisation being applied for e.g. if the application is to cover two sites, two sets of sections 3 – 8 must be submitted, one for each site. The requirement to submit a separate set of sections 3 – 8 for each site applies to contract sites also. Please make additional copies of Sections 3 – 8 as necessary to ensure you provide MHRA with one set of sections 3 – 8 per site.

When complete please return the form to the Process Licencing Team

Email: PCL@mhra.gov.uk

Section 3 – Site Information

Please make additional copies of this form as required

*Site Number†	
Site Name:	
Trading as:	
Site Address:	
Postcode:	
Site Contact Name:	
*Telephone:	
*Mobile:	
*Fax:	
*Email:	

† **If known**

SITE ACTIVITY – Please detail below site activity, for clarity please write 'Yes' or 'No' against each proposed activity type.		
	YES	**NO**
Collecting blood		
Testing blood		
Storing blood		
Distributing blood		
Processing blood into blood components		
Storage of blood components		
Distribution of blood components (ref Section 7)		

Section 4 – Site Processes

Site Name		Postcode		Site Number	

Please make additional copies of this form as required

Proposed Processes to be Conducted at this Site - Please write Yes or No as required in the relevant column for each of the processes proposed to be conducted

	Yes	No
Whole blood collection		
Autologous whole blood collection		
Testing donor samples		
Apheresis collection of components		
Please specify apheresis component type collected:		
Whole Blood Processing into:		
Red cells		
Platelets		
Granulocytes		
Fresh frozen plasma		
Recovered plasma (for discard)		
Cryoprecipitate		
Cryoprecipitate depleted plasma		
Buffy coats		
Other (please specify):		

Continued

Section 4 – Site Processes (continued)

Site Name		Postcode		Site Number	

Please make additional copies of this form as required

Proposed Processes to be Conducted at this Site (continued)

	Yes	No
Components Processed into:		
Methylene blue treated plasma		
Irradiated components		
Washed components		
Splitting into small volume packs		
Pooling cryoprecipitate		
Manipulation of haematocrit		
Other (please specify):		

Section 5 – Site Personnel

Please list below the names of each Responsible Person (Blood) on the submission for **this site**. In the right hand column enter the person's MHRA person number.

Name	MHRA Number

† If known

For each person named above a copy of section 6 of this form (Responsible Person (Blood) – Details) must be submitted.

Section 6 – Responsible Person (Blood) - Details

Site Name		Postcode		Site Number	

Please make additional copies of this form as required

All applications for a person to be named as a Responsible Person (Blood) on a Blood Establishment Authorisation must be **signed by both the applicant and the person being nominated** and must be **accompanied by a relevant curriculum vitae** for the person being nominated.

Nominee as a Responsible Person (Blood)	
Title:	
First name(s):	
Surname:	
Business Address:	
*Telephone:	
*Mobile:	

Status – tick as appropriate the status of the nominee at the site			
Permanent employee		Consultant	

Consultant – If consultant was ticked above	
What is the distance from your base to site?	(miles)
How frequently will you visit the site?	
Briefly specify below what are your arrangements for dealing with routine and urgent activities when you are not at the site?	

Section 6 – Responsible Person (Blood) – Details (continued)

Site Name		Postcode		Site Number	

Please make additional copies of this form as required

Qualifications – enter in the box below details of your educational qualifications

Experience – enter in the box below details of your practical post-graduate experience relevant to the responsibilities of a Responsible Person (Blood) at least 2 years in an authorised UK blood establishment

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

Signed (Nominee): _____ Date:_____

Print Name:_____

Signed (Applicant): _____ Date:_____

Print Name:

Section 7 - Hospitals and blood banks supplied

Site Name		Postcode		Site Number	

Please make additional copies of this form as required

DETAILS OF HOSPITALS AND BLOOD BANKS SUPPLIED (UK & OVERSEAS)

HOSPITAL NAME: ADDRESS:	
POSTCODE:	
COUNTRY	

HOSPITAL NAME: ADDRESS:	
POSTCODE:	
COUNTRY	

HOSPITAL NAME: ADDRESS:	
POSTCODE:	
COUNTRY	

If further copies of this page are made (or a separate list is provided) please write the **total** number of pages submitted (i.e. the original plus the additional pages) in this box

Section 8 - Further information

Site Name		Postcode		Site Number	

Please make additional copies of this form as required

Facilities on Site

- On a separate sheet of paper please provide a brief description (approximately 500 words) of the facilities available for the collection, testing, processing, storage and distribution of blood and blood components.

Additional Information

- Below you are invited to provide any other information that may support your application

Additional Information
(Please continue on a separate sheet if necessary)

Section 9 - Declaration

I/we apply for the grant of a Blood Establishment Authorisation to the proposed holder named in this application form in respect of the activities to which the application refers.

Signed_____ Date:_____

Print Name:_____
(Block Capitals)

State capacity in
which signed: _____