e-form

Application for a Blood Establishment Licence

PLEASE COMPLETE ALL RELEVANT SECTIONS IN THIS FORM
TYPED OR IN BLOCK CAPITALS LEGIBLY USING BLUE/ BLACK INK (Complete in conjunction with guidance notes).

Section 1- Background Information

Licence number(s)

If the company/organization making the application already holds or has previously held an existing license from the Medicines Authority please enter the license number(s) below.

Number:		Number:	
Number:		Number:	

Other Licences Held

If the company/ organisation making the application already holds a licence issued by The Medicines Authority please identify it by completing the grid below. to ensure clarity please enter 'yes' on 'no' against each licence type in the appropriate column.

Manufacturer's Licence:	
Manufacturer's (Assembly Only) Licence:	
Wholesale Dealer's Licence:	

Import Licence:

Manufacturer's Licence (Investigational Medicinal Products):	
Marketing Authorisation:	
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 Licence 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 licence holder unless alternative details are given below.

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 licence 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 licence 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 Medicines Authority with one set of sections 3-8 per site.

Section 3- Site Information

Please make additional copies of this form as required.

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

SITE ACTIVITY- Please detail below site activity, for clarity please write 'Yes' or 'No' against each proposed activity type.

Collecting blood:	
Testing blood:	
Storing blood:	
Distributing blood:	
Processing blood into blood components:	
Storage of blood components:	
Distributing of blood components (ref Section 7):	

Section 4 - Site Processes

Site name:

Postcode:

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.

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):

Buffy coats:

Cryoprecipitate depleted plasma:

Other (please specify):

Section 4 – Site Processes (continued)

Site name:

Postcode:

Please list below the names of each Responsible Person (Blood) on the submission for this site.

Components Processed into:

Methylene blue treated plasma:

Irritated 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.

Name:

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

Section 6 – Responsible Person (Blood) - Details

Site name:	Postcode:

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 Licence 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.

Nominance as a Responsible Person (Blood)

Title:	
First Name(s):	
Surname:	
Business Address:	
Telephone:	
Mobile:	
Fax:	
Email:	

Status – tick as appropriate the status of the nominee at the site.

Permanent employee:	
Consultants:	

Consultant - If consultant was ticked above.

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:

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) for at least 2 years in at least an establishment licence in any Member State of the EU.

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

Signed (Nominee):

Print Name:

Date:

Signed (Applicant):

Print Name:

Date:

Section 7 – Hospitals and blood banks supplied

Site name:	Postcode:

Please make additional copies of this form as required.

DETAILS OF HOSPITALS AND BLOOD BANKS SUPPLIED (Malta & 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:

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 information that may support your application.

(Please continue on a separate sheet if necessary)

Section 9 –Declaration

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

Signed:	
Print Name:	
State capacity in which signed:	
Date: