Application Form for Licensing Blood Facilities in Ghana

(To be submitted in duplicate, one comb-bound hard copy and one electronic copy. Please complete all relevant sections)

COVER LETTER ADDRESSED TO:

THE CHIEF EXECUTIVE
FOOD AND DRUGS AUTHORITY
P. O. BOX CT 2783
CANTONMENTS-ACCRA
GHANA.

RETURN COMPLETED FORM TO:

CHIEF EXECUTIVE OFFICER
FOOD AND DRUGS AUTHORITY
17 SOUTH LEGON COMMERCIAL
AREA, SHIASHIE
ACCRA

All information sought in this form shall be provided to enable the FDA process the application

SUBMISSION SHOULD ALWAYS BE DONE BY A COMPETENT TECHNICAL OFFICER

FACILITY TYPE	ACTIVITIES/PROCESSES					
	Collection	Testing	Processing/ Packaging & labelling	Storage & release/ distribution	Further Manufacturing	Cross-matching
Area Blood Center						
Broker/Warehouse						
Collection facility						
Community (non-Hospital) blood banks						
Hospital Blood Banks						
Component preparation facility						
Distribution centre						
Plasmapheresis center						
Product testing laboratory						
Others						

*tick appropriately (✔)

SPECIFY CLASS OF BLOOD FACILITY

FEES AND CHARGES

CLASS	ACTIVITIES / PROCESSES
CLASS I	STORAGE AND DISTRIBUTION FOR TRANSFUSION AND FURTHER MANUFACTURE
CLASS II	STORAGE, CROSS-MATCH AND DISTRIBUTION FOR TRANSFUSION AND/OR FURTHER MANUFACTURE
CLASS III	COLLECTION, TESTING, PROCESSING, PACKAGING / LABELLING, STORAGE, RELEASE AND DISTRIBUTION TO OTHER BLOOD FACILITIES AND HEALTH CENTERS
CLASS IV	TESTING, PROCESSING INTO BLOOD PRODUCTS, PACKAGING / LABELLING, STORAGE, RELEASE AND DISTRIBUTION TO HEALTH CENTERS AND MEDICAL STORES

PLEASE PRINT CLASS OF FACILITY: _____

BI-ANNUAL FACILITY COMPLIANCE FEE (see fee schedule)

NOTE: To maintain your license status, the facility shall be inspected annually to ensure that the facility remains in compliance with the license requirements.

Section 1 – Background Information

License number(s)

If the blood facility making the application already holds or has previously held an existing license from the FDA please enter the license number(s) below

Year of issuance:		**License number:**	
Year of issuance:		**License number:**	
Year of issuance:		**License number:**	

Other Licences held

If the blood facility making the application already holds a license issued by FDA, please identify it by completing the grid below. To ensure clarity please enter 'yes' or 'no' against each license type in the appropriate column

	YES	**NO**
Collection		
Testing		
Processing		
Packaging and Labelling		
Release and Distribution		
Further Manufacture		
Other (if yes specify below)		

Reasons for submission

Initial license	
License renewal	

*tick appropriately (✔)

Section 2 – Applicant Details

TYPE OF OWNERSHIP

1. ☐ SINGLE PROPRIETORSHIP
2. ☐ PARTNERSHIP
3. ☐ CORPORATION profit ☐/ non- profit ☐
4. ☐ COOPERATIVE ASSOCIATION
5. ☐ HOSPITAL (Religious body)
6. ☐ SECURITY SERVICES
7. ☐ HOSPITAL (Government)
8. ☐ HOSPITAL (Private)
9. ☐ OTHER (Specify)_____

Applicant:	
Legal name of blood facility:	
Other names used: (*include trade name, doing-business-as, previous names, etc***.)**	
Trading as:	
Mailing address of applicant: (*Include location of the post office***)**	
Physical Address: (*Include legal name, number, street, city, and district***)**	
Telephone:	
Fax:	
Email:	
Contact person's information	

Legal name: **Email:** **Telephone:**	
Contact person's signature:	

If you are an agent applying on behalf of the proposed license holder, please tick here ☐

Contact details for communications (if different from above)

Contact person's name:	
Company name:	
Telephone:	
Mobile:	
Email:	

Section 2 – Applicant Details (continued)

Address for invoicing purposes (if different from above)
All charges/fees will be sent to the license holder unless alternative details are given below.

Name:	
Company name:	
Physical address:	
Telephone:	
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 licensure being applied for. For sections 3 – 8 one set of these sections must be completed for <u>each site</u> that the applicant wishes to include on the license 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 FDA with <u>one set of sections 3 – 8 per site.</u>

Section 3 – Site Information

TYPE OF BLOOD FACILITY (Check appropriate type)

☐ Area Blood Center
☐Community (Non-hospital) Blood bank
☐Product Testing Laboratory
a) ____ Independent
b) ____Associated with community or hospital blood bank
☐ Hospital Blood bank
☐ Hospital Transfusion Service
☐Donor Center
☐Perioperative Autologous Collection / Administration
☐Plasmapheresis Center
☐ Component Preparation Facility
☐Hematopoietic Progenitor Cells (HPC)
☐ Cord Blood Processing
☐ Collection Centre
☐ Blood Distribution only
☐Blood Storage Only
☐ Emergency Transfusion only (Ambulatory Surgery Centre)
☐ Industrial Manufacturer (whole blood/ plasma for further manufacture)
☐ **Other (specify):_____**

Please make additional copies of this section as required

Site Number:	
Site Name:	
Site Address: (*Include legal name, number, street, city, and district***)**	
Site contact person's name:	
Telephone:	
Mobile:	
Fax:	

Email:	

SITE ACTIVITY – Please detail below site activity for clarity. Please indicate '**Yes**' or '**No**' against each proposed activity type	
	YES / NO
Collecting blood	
Testing blood	
Processing whole blood into blood components	
Packaging and labelling	
Storage of whole blood, blood components and blood products	
Further Manufacture	
Release and Distribution of whole blood (ref Section 7)	
Distribution of blood components (ref Section7)	

Section 4 – Site Processes

Site name:	
Physical address: (*Include legal name, number, street, city, and district***)**	
Site number:	

Please make additional copies of this section as required

Processes conducted at this Site - Please indicate '**Yes'** or '**No'** as required in the relevant column for each of the processes proposed to be conducted

	YES / NO
WHOLE BLOOD COLLECTION SERVICES	
Please specify by ticking in the box ☐ On-Site ☐ Mobile Site ☐ Allogeneic ☐ Autologous whole blood collection ☐ Family replacement	
APHERESIS	
Please specify APHERESIS component type collected by ticking in the box ☐Plasmapheresis ☐Leukapheresis ☐Plateletpheresis ☐ Erythrocytapheresis	
PROCESSING WHOLE BLOOD INTO:	

Please specify by ticking in the box

☐ Red Blood Cells

☐ Fresh Frozen Plasma

☐ Platelets

☐ Cryoprecipitate

☐ Frozen RBC

☐ Washed RBC

☐ Leukocytes

☐ Leukodepleted RBC

☐ Recovered Plasma

☐ Irradiated Blood

☐ Fibrin Glue

☐ Granulocytes

☐ Buffy coats

☐ Other (Please specify):_____

TESTING OF DONOR SAMPLES	

Please specify by ticking in the box

Testing (Routine)

☐ ABO

☐ Rh

☐ Antibody detection

☐ Antibody ID

☐ Cross matching

Testing (Special)

☐HBsAg

☐HBcAb

☐ HIV I / II

☐ HTLV-I / II

☐ HCV ☐ Syphilis ☐ NAT Testing

Section 4 – Site Processes (continued)

Site name:	
Physical address: (*Include legal name, number, street, city, and district***)**	
Site number:	

Please make additional copies of this section as required

Processes 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	
Haematocrit determination	
Other (please specify):	

Section 4 – Site Processes (continued)

OTHER PROCESSES

SITE NAME:	**SITE ADDRESS:**
☐Manufacturer ☐ Ambulatory Surgery Centre ☐ Dialysis Service ☐Plasmapheresis Centre ☐ Broker ☐Other, (Please Specify):_____	

Section 5 – Site Personnel

Please provide information, including name(s) of responsible person(s) involved in the operational activities for **this site**.

Legal name of responsible person	Designation / Qualification	Contact information (Tel. phone and Email)

For each person named above a copy of section 6 of this form must be submitted.

Section 6 – Responsible person - Details

Site name:	
Physical address: (*Include legal name, number, street, city, and district***)**	
Site number:	
Signature of responsible person	

Please make additional copies of this section as required

Note. All applications for a person to be nominated as a responsible person in a blood facility must be signed by both the **APPLICANT** and the **RESPONSIBLE PERSON.**

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

Designation – tick as appropriate the designation of the nominated responsible person 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– Details (continued)

Site name:	
Physical address: (*Include legal name, number, street, city, and district***)**	
Postal address:	
Site number:	

Please make additional copies of this section 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 for at least 2 years in at least a blood facility licensed / authorized in Ghana

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

Signed (Nominated person):_____ Date:___/___/_____

Print Name (Nominated person):_____

Signed (Applicant):_____Date:___/___/_____

Print Name (Applicant):_____

Section 7 –Other blood facilities and Hospitals supplied

Site name:	
Physical address: (*Include legal name, number, street, city, and district***)**	
Postal address:	
Site number:	

Please make additional copies of this section as required

DETAILS OF OTHER BLOOD FACILITIES AND HOSPITALS SUPPLIED WITH BLOOD/BLOOD COMPONENTS/BLOOD PRODUCTS

Legal name of hospital / blood facility:	
Physical address: (*Include legal name, number, street, city, and district***)**	
Postal address:	
Responsible Area Blood Center: (Southern, Central, or Northern**)**	

Legal name of hospital / blood facility:	
Physical address: (*Include legal name, number, street, city, and district***)**	
Postal address:	
Responsible Area Blood Center: (Southern, Central, or	

Northern**)**	

Legal name of hospital / blood facility:	
Physical address: (*Include legal name, number, street, city, and district***)**	
Postal address:	
Responsible Area Blood Center: (Southern, Central, or Northern**)**	

Legal name of hospital / blood facility:	
Physical address: (*Include legal name, number, street, city, and district***)**	
Postal address:	
Responsible Area Blood Center: (Southern, Central, or Northern**)**	

Legal name of hospital / blood facility:	
Physical address: (*Include legal name, number, street, city, and district***)**	
Postal address:	
Responsible Area Blood Center: (Southern, Central, or	

Northern**)**	

If further copies of this page are made (or a separate list is provided), please provide the **TOTAL** number of pages submitted (*i.e*. the original plus the additional pages):

Section 8 - Further information

Site name:	
Physical address: (*Include legal name, number, street, city, and district***)**	
Postal address:	
Site number:	

Please make additional copies of this section as required

Facilities on Site

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

Additional Information

•You are invited to provide any other information that may support your application in the space below

Section 9 - Declaration

I/we apply for the license for a blood facility to the proposed holder named in this application form in respect of the activities to which the application refers.

I declare that the information provided with this application is complete and correct.

Signed: _____ Date: ____/____/_____

Print name (Block Capital): _____

State capacity in which signed: _____