



DOC. TYPE: FORM		
DOC NO.: FDA/VBP/FOR – 30		
age 1 of 16 Ver No :03		

Effective Date: 05/09/2025

TITLE: APPLICATION FORM FOR LICENSING BLOOD FACILITIES AND BLOOD PRODUCTS LISTING

APPLICATION FORM FOR LICENSING BLOOD FACILITIES AND BLOOD PRODUCTS LISTING

(To be submitted in duplicate electronic copies. Please complete all relevant sections)

Cover letter addressed to:

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

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

SUBMISSION SHOULD ALWAYS BE DONE BY A COMPETENT TECHNICAL OFFICER

Section 1 – Background Information

Reasons for submission

Fresh Application	
Application renewal	

^{*}tick appropriately (✓)

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

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



TYPE OF OWNERSHIP

FOOD AND DRUGS AUTHORITY

DOC. TYPE: FORM

DOC NO.: FDA/VBP/FOR - 30

Page **2** of **16**

Ver. No.:03

Effective Date: 05/09/2025

TITLE: APPLICATION FORM FOR LICENSING BLOOD FACILITIES AND BLOOD PRODUCTS LISTING

SOLE PROPRIETORSHIP PARTNERSHIP CORPORATION PROFIT ☐ / NON-PROFIT ☐ COOPERATIVE ASSOCIATION □ HOSPITAL (Religious body) □ GOVERNMENT HOSPITAL □ PRIVATE HOSPITAL □ 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: Email: **Contact person's information**





DOC. TYPE: FORM

DOC NO.: FDA/VBP/FOR - 30

Page 3 of 16 Ver. No.:03

Effective Date: 05/09/2025

TITLE: APPLICATION FORM FOR LICENSING BLOOD FACILITIES AND BLOOD PRODUCTS LISTING

Name:	
Email:	
Telephone:	
f you are an agent applying on beh Please tick here ──	nalf of the proposed license holder,
Contact details for communication	ons (if different from above)
Contact person's name:	
Company name:	
Telephone:	
Mobile:	
Email:	
Contact person's signature:	

Please note – this application form is divided into nine sections. Sections 1 and 2 and the final section 10 must only be completed once per licensure being applied for.

For sections 3-9 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 3-9 must be submitted, one for each site.

The requirement to submit a separate set of sections 3 - 9 for each site applies to contract sites also. Please make additional copies of Sections 3 - 9 as necessary to ensure you provide FDA with <u>one set of sections 3 - 9 per site.</u>

Section 3 - Product listing: Products manufactured and / or stored at the Site



DOC. TYPE: FORM

DOC NO.: FDA/VBP/FOR - 30

Page **4** of **16 Ver. No.:03**

Effective Date: 05/09/2025

Please specify by ticking in the box		
☐ Manufacture		
☐ Storage		
□Whole blood		
☐ Red Blood Cells		
☐ Fresh Frozen Plasma		
□ Platelets		
☐ Cryoprecipitate		
☐ Frozen RBC		
☐ Washed RBC		
□ Leukocytes		
☐ Leukoreduced RBC		
□ Recovered Plasma		
☐ Irradiated Blood		
☐ Fibrin Glue		
☐ Granulocytes		
☐ Buffy coats		
□ Serum Albumin		
☐ Coagulation factors		
☐ Immunoglobulins		
☐ Other (Please specify):		



DOC. TYPE: FORM

DOC NO.: FDA/VBP/FOR - 30

Page **5** of **16 V**

Ver. No.:03

Effective Date: 05/09/2025

Section 4 – Si	te Information
TYPE OF BLO	OOD FACILITY (Check appropriate type)
□Product Test a)Indep	Non-hospital) Blood bank ing Laboratory
+	Hospital Blood bank
<u></u>	Hospital Transfusion Service
	Oonor Center
⊢ ⊢ F	Perioperative Autologous Collection / Administration
⊢ ⊢ F	Plasmapheresis Centre
	Component Preparation Facility
<u></u> ⊢	Hematopoietic Progenitor Cells (HPC)
	Cord Blood Processing
	Collection Centre
	Blood Distribution only
	Blood Storage Only
	Emergency Transfusion only (Ambulatory Surgery Centre)
I	ndustrial Manufacturer (whole blood/ plasma for further manufacture)
	Other (specify):
Please make a	additional copies of this section as required





DOC. TYPE: FORM

DOC NO.: FDA/VBP/FOR – 30

Page **6** of **16 Ver. No.:03**

Effective Date: 05/09/2025

Site Name:		
Site Address: (Include legal name, number, street, city, and district)		
Site contact person's name:		
Telephone:		
Mobile:		
Email:		
ITE ACTIVITY – Please detail b		ease indicate ' Yes ' or
ITE ACTIVITY – Please detail b No' against each proposed activi		
		ease indicate ' Yes ' or YES / NO
lo ' against each proposed activi		
No' against each proposed activically against each proposed	ty type	
No' against each proposed activition collecting blood esting blood rocessing whole blood into blood	ty type	
No' against each proposed activition collecting blood esting blood rocessing whole blood into blood ackaging and labelling	d components	
collecting blood esting blood rocessing whole blood into blood rackaging and labelling storage of whole blood, blood cor	d components	
collecting blood esting blood rocessing whole blood into blood ackaging and labelling torage of whole blood, blood cor	d components mponents and blood products	
No' against each proposed activi	d components mponents and blood products blood (ref Section 8)	





Site name:

FOOD AND DRUGS AUTHORITY

DOC. TYPE: FORM

DOC NO.: FDA/VBP/FOR – 30

Page **7** of **16**

Ver. No.:03

Effective Date: 05/09/2025

Physical address: (Include			
legal name, number, street,			
city, and district)			
,			
Site number:			
Please make additional copies	s of this section as required		
	1		
Processes conducted at this S		•	
relevant column for each of the	processes proposed to be con-		
		YES / NO	
WHOLE BLOOD COLLECTIO	N SERVICES		
Pleas	e specify by ticking in the bo	X	
☐ 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:			



DOC. TYPE: FORM

DOC NO.: FDA/VBP/FOR - 30

Page 8 of 16

Ver. No.:03 **Effective Date: 05/09/2025**

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)





DOC. TYPE: FORM

DOC NO.: FDA/VBP/FOR - 30

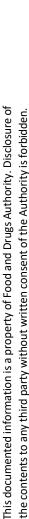
Page **9** of **16 Ver. No.:03**

Effective Date: 05/09/2025

TITLE: APPLICATION FORM FOR LICENSING BLOOD FACILITIES AND BLOOD PRODUCTS LISTING

□HBsAg		
•		
□HBcAb		
□HIV I / II		
□HTLV-I / II		
□HCV		
☐ Syphilis		
☐ NAT Testing		
Site name: Physical address: (Include		
Section 5 – Site Processes (co	ontinued)	
legal name, number, street,		
city, and district)		
Site number:		
Please make additional copies of this section as required		
Processes conducted at this Site (continued)		
COMPONENTS PROCESSED	INTO:	YES /NO

Methylene blue treated plasma Irradiated components Washed components Splitting into small volume packs





DOC. TYPE: FORM

DOC NO.: FDA/VBP/FOR – 30

Ver. No.:03

Page 10 of 16

Effective Date: 05/09/2025

TITLE: APPLICATION FORM FOR LICENSING BLOOD FACILITIES AND BLOOD PRODUCTS LISTING

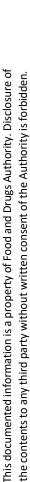
Haematocrit determination		
Other (please specify):		
Section 5 – Site Processes (co OTHER PROCESSES	ontinued)	
SITE NAME:	SITE ADDRESS	
		•

Section 6 – Site Personnel

Pooling cryoprecipitate

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)





 DOC. TYPE: FORM

 DOC NO.: FDA/VBP/FOR – 30

 Page 11 of 16
 Ver. No.:03

Effective Date: 05/09/2025

TITLE: APPLICATION FORM FOR LICENSING BLOOD FACILITIES AND BLOOD PRODUCTS LISTING

For each person named above a copy of section 7 of this form must be submitted.

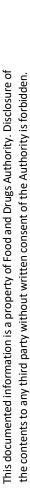
Section 7 – Responsible person - Details

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





DOC. TYPE: FORM

DOC NO.: FDA/VBP/FOR - 30

Page 12 of 16 Ver. No.:03

Effective Date: 05/09/2025

TITLE: APPLICATION FORM FOR LICENSING BLOOD FACILITIES AND BLOOD PRODUCTS
LISTING

person at the site	te the des	ignation of the r	nominated responsible
Permanent employee	Co	onsultant	
	I		
Consultant – If consultant was ti	icked abo	ve	
What is the distance from your basite?	ase to	(miles))
How frequently will you visit the s	site?		
Briefly specify below what are yo	ur arrand	opposite for deal	
activities when you are not at the		ements for deal	ing with routine and urgent
	e site?		ing with routine and urgent
activities when you are not at the	e site?		ing with routine and urgent
activities when you are not at the	e site?		ing with routine and urgent
activities when you are not at the section 7 – Responsible Persor Site name:	e site?		ing with routine and urgent
section 7 – Responsible Persor Site name: Physical address: (Include	e site?		ing with routine and urgent
Section 7 – Responsible Persor Site name: Physical address: (Include legal name, number, street,	e site?		ing with routine and urgent
Section 7 – Responsible Person Site name: Physical address: (Include legal name, number, street, city, and district)	e site?		ing with routine and urgent

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



DOC. TYPE: FORM

DOC NO.: FDA/VBP/FOR - 30

Page **13** of **16 Ver. No.:03**

Effective Date: 05/09/2025

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):



Responsible Regional

Blood Centre:



FOOD AND DRUGS AUTHORITY

DOC. TYPE: FORM

DOC NO.: FDA/VBP/FOR - 30

Page **14** of **16 Ver. No.:03**

Effective Date: 05/09/2025

TITLE: APPLICATION FORM FOR LICENSING BLOOD FACILITIES AND BLOOD PRODUCTS LISTING

Signed (Applicant): ________Date: ___/___/

Print Name (Applicant):	
(
Section 8 – Other blood facilit	ies and Hospitals supplied
Site name:	
Physical address: (Include	
legal name, number, street,	
city, and district)	
Postal address:	
Site number:	
Site number:	
Please make addi	tional copies of this section as required
DETAILS OF OTHER BLOOD F	ACILITIES AND HOSPITALS SUPPLIED WITH
BLOOD/BLOOD COMPONENT	
Legal name of hospital /	
blood facility:	
Physical address: (Include	
legal name, number, street,	
city, and district)	
Postal address:	





DOC. TYPE: FORM

DOC NO.: FDA/VBP/FOR – 30

Ver. No.:03

Effective Date: 05/09/2025

Page **15** of **16**

TITLE: APPLICATION FORM FOR LICENSING BLOOD FACILITIES AND BLOOD PRODUCTS LISTING

Legal name of hospital / blood facility:	
Physical address: (Include legal name, number, street, city, and district)	
Postal address:	
Responsible Regional Blood Centre:	

If further copies of this table are made, please provide the **TOTAL** number of facilities supplied with blood/ components by your facility:

Section 9 - 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.



DOC. TYPE: FORM

DOC NO.: FDA/VBP/FOR - 30

Page **16** of **16 Ver. No.:03**

Effective Date: 05/09/2025

Section 10 - Declaration I/we apply for the license for a blood facility to the proposed holder named in this
I/we apply for the license for a blood facility to the proposed holder named in this
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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:
Deter
Date:/
Print name (Block Capital):
State capacity in which signed: