

**FOOD AND DRUGS AUTHORITY**

**APPLICATION FORM FOR LICENSING BLOOD**

**FACILITIES**

**Document No. : FDA/SMC/BPD/AP-BFL/2015/06**

**Date of First Adoption :12th March, 2015**

**Effective Date :12th March,2015**

**Version No. :02**

**Application Form for Licensing Blood Facilities**

**(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:**

**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 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 | BLOOD FACILITY | PERMITTED ACTIVITIES / PROCESSES |
| Ia | Hospital Blood Bank | Storage, Compatibility Testing and Issue for Transfusion |
| Ib | Hospital Blood Bank & Collection Area | Donor Management and Collection of Whole Blood (performed by ABC), Storage, Compatibility Testing and Issue for Transfusion |
| II | Collection Site | Donor Management, Collection of Whole Blood |
| IIIa | Area Sub-Centre /sub Zonal Blood Centre | Donor Management, Collection of Whole Blood, Donation Testing and Confirmatory Testing (performed by ABC/ZBC), Processing, Storage, Release/Issue to Hospital Blood Bank |
| IIIb | Area Sub-Centre / sub Zonal Blood Centre | Donor Management, Collection of Whole Blood, Donation Testing (performed in-house), Confirmatory Testing (performed by ABC/ZBC), Processing, Storage, Release/Issue to Hospital Blood Bank |
| IV | Area Blood Centre / Zonal Blood Centre | Donor Management, Collection of Whole Blood, Apheresis, Donation and Confirmatory Testing (performed in-house), Processing, Storage, Release/Issue, Distribution for further Manufacture |
| V | Plasma Fractionation Centre | Receipt of Blood Component for further Manufacture |

* ABC –Area Blood Centre
* ZBC: Zonal Blood Centre
* Donation testing includes; TTI testing, ABO blood typing, RhD typing and confirmation of RhD negative. Donation testing involves initial testing using enzyme immunoassay which include ELISA, repeat testing of initial reactive and confirming repeat reactive.
* Confirmatory testing applies to TTI and RhD typing.

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 each site 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 one set of sections 3 – 8 per site.**

**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**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_