

**FOOD AND DRUGS AUTHORITY**

**APPLICATION FORM FOR A VARIATION TO A LINCENSED BLOOD FACILITY**

**Document No. : FDA/SMC/BPD/AP-BFV/2021/10**

**Date of First Adoption : 4th January, 2021**

**Effective Date : 4th January, 2021**

**Version No. : 01**

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| **SECTION 1: APPLICATION DETAILS** |
| **1.1 APPLICANT DETAILS** |
| Name of Blood Facility: |
| Physical and Postal Address: |
| Site Number: |
| License Number: |
| Date of Application: |
|  |
|  |
| **1.2 RESPONSIBLE PERSON** |
| Name: |
| Contact address:  E-mail:  Telephone :  Designation: |

**SECTION 2: PROPOSED VARIATION TO THE AUTHORISATION**

**2.1 TYPE OF VARIATION**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **A = Administrative** | **T = Technical** | **Please** |  | **Supporting Documentation Required** | **Please** |
|  |  |  | **Tick (√)** |  |  | **tick (√) if** |
|  |  |  |  |  |  | **supplied** |
| A | Change in name of the Blood Facility | |  | 1 | Letter confirming change in name. |  |
|  |  |  |  |  | Copy of company registration certificate |  |
|  |  |  |  |  |  |  |
| T | Change in address of the Blood Facility | |  | If new premises: | |  |
|  |  |  |  | 1 | Letter confirming change of address |  |
|  |  |  |  | 2 | Copy of company registration certificate |  |
|  |  |  |  | 3 | GhanaPost GPS address of new location |  |
|  |  |  |  | 4 | Details of suitability of premises and equipment |  |
|  |  |  |  | If administrative change in address: | |  |
|  |  |  |  | 1 | Letter confirming change of address |  |
|  |  |  |  | 2 | Copy of company registration certificate |  |
|  |  |  |  |  |  |  |
| A | Change in name of site carrying out a prescribed | |  | 1 Letter confirming change in name | |  |
|  | activity |  |  |  |  |  |
| T | Change in address of site carrying out a prescribed | |  | If new premises: | |  |
|  | activity |  |  | 1 | Letter confirming change of address |  |
|  |  |  |  | 2 | Details of suitability of premises and equipment |  |
|  |  |  |  | If administrative change in address: | |  |
|  |  |  |  | 1 | Letter confirming change of address |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **A = Administrative** | **T = Technical** | **Please** | **Supporting Documentation Required** | | **Please** |
|  |  |  | **Tick (√)** | **tick (√) if** |
|  |  |  |  | **supplied** |
| T | Addition of a Responsible Person | |  | 1 | CV of Responsible Person. |  |
| A | Deletion of a Responsible Person | |  | 1 | Explanation for deletion of Responsible Person |  |
| T | Replacement of a Responsible Person | |  | 1 | Explanation for replacement of Responsible Person |  |
|  |  |  |  | 2 | CV of replacement Responsible |  |
| A | Addition of a hospital blood bank supplied by the licensed Blood Facility | |  | 1 | Copy of contract or Memorandum of Understanding (MoU) between the Blood Facilities |  |
| T | Addition of a new blood component produced by the Blood Facility | |  | 1 | Appropriate validation data |  |
| A | Deletion of a named blood component  produced by the blood facility | |  | 1 | Explanation for deletion of named blood component from the |  |
|  |  |  | licensure and confirmation that blood component will no longer |  |
|  |  |  | be produced by the blood facility |  |
|  |  |  |  |  |
| T | Addition of a site and/or prescribed activity | |  | 1 | Appropriate validation data |  |
|  |  | |  |  |  |  |
| A | Deletion of a site and/or prescribed activity | |  | 1 | Explanation for deletion of site and / or prescribed activity from |  |
|  |  |  |  |  | the licensure and confirmation that site will not be used and / or |  |
|  |  |  |  |  | prescribed activity will not be carried out. |  |
|  |  |  |  |  |  |  |

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| --- | --- | --- | --- | --- | --- | --- |
|  | **A = Administrative** | **T = Technical** | **Please** | **Supporting Documentation Required** | | **Please**  **tick (√) if**  **supplied** |
|  |  |  | **Tick (√)** |
|  |  |  |  |
| T | Changes in relation to the import and / or  export of blood and blood products | |  | 1 | Details of arrangements in place surrounding the import |  |
|  |  |  | /export of blood and blood components. |
|  |  | 2 | Contracts / memorandum of understanding in place with |
|  |  |  | import/export site. |
|  |  | 3 | Statement by RP that imported/ exported blood |
|  |  |  |  |
| T | Variation to equipment  (Inclusion or Exclusion of equipment like centrifuges (table top and ultracentrifuge), freezers, weighing balance, etc) | |  | 1  2 | Statement by the RP on the need of inclusion or exclusion  Validation data |  |
| T | Other variation to the content of the  Licensure.  Please specify: | |  | 1 | Appropriate validation data if applicable |  |
|  |  | 2 | Other information as deemed necessary |
|  |  |  |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of variation**  **A = Administrative T = Technical** | | **Please**  **Tick (√)** | **Supporting Documentation Required** | | **Please**  **tick (√) if**  **supplied** |
| T | Change(s) at the site(s) at which the Blood Facility operates or to the prescribed activities carried out at each site(s) that may impact the quality and safety of blood.  Please specify: |  | 1 | Appropriate validation data as relevant  Note: This change may not result in a change to the content of the licensure but is required to be notified to the FDA in writing. |  |
| T | Change(s) which would result in a failure to comply with the FDA Blood Regulatory Framework  Please specify: |  | 1 | Appropriate justification / explanation for change  Note: This change may not result in a change to the content of the licensure but is required to be notified to FDA in writing. |  |
| T | Change(s) to the quality system likely to have a  substantial impact on the conduct of, or might  compromise the safety of, any of the prescribed  activities which the blood facility hasbeen licensed to undertake as per the terms  of the licensure.  Please specify: |  | 1  2 | Updated Quality Manual or Site Master File  Appropriate validation data  Note: This change may not result in a change to the content of the licensure but is required to be notified to the FDA in writing. |  |

**2.2 BACKGROUND**

Please give a brief background explanation for the proposed variation to your licensure or for the proposed change (attach additional supporting data as necessary).

**3.0 SECTION 3: DECLARATION**

I hereby make application for the above authorization to be varied and / or to notify the FDA in relation to the above changes in accordance with the proposals given above, and certify that the changes will not adversely affect the quality, efficacy or safety of any blood or blood product produced. I declare that amended documents have been supplied and that the supporting information is correct. I declare that all changes have been identified and that there are no other changes in the amended documentation.

**Name: Signature**: **Date:**

(Responsible Person)

**Name: Signature**: **Date:**

(Medical Director)