Application for a Blood Establishment Authorisation

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| section 1: Application details |
| * 1. APPLICANT DETAILS   **For internal use only:**  Draft authorisation no:  Licensing register ref no:  Fee codes:  CWS reference no:  Name of blood establishment:  Address of blood establishment:  Eircode:  Date of application: |
| * 1. RESPONSIBLE PERSON   ‘Responsible Person’ (RP) in relation to a blood establishment means the person who has been designated pursuant to Regulation 8 of the European Communities (Quality and Safety of Human Bloods and Blood Components) Regulations (SI 360 of 2005) as the responsible person for that blood establishment. It is the responsibility of the RP to confirm that the requirements of Regulation 8 are met. The RP’s *curriculum vitae* must be submitted with this application.  Please provide the name and contact details for the RP:  Name of RP:  Contact address:  Eircode:  E-mail:  Telephone:  Fax:  RP 24-hour contact details:  Qualifications:  Please provide the name and contact details for the deputy RP(s):  Name of deputy RP:  Contact address:  Eircode:  E-mail:  Telephone :  Fax :  RP 24-hour contact details:  Qualifications: |

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| Please specify the functions that have been delegated to the above person(s):    Attach the *curriculum vitae* (CVs) of the above names RP and deputy RP(s).  Please tick here to confirm CVs are attached to the application form. |
| * 1. OTHER LICENCES/AUTHORISATIONS HELD   (This is relevant only to other licences/authorisations granted by the Health Products Regulatory Authority.)  Name and address of licensed/authorised establishment:  Licence authorisation number: |
| * 1. SITES AT WHICH ANY PRESCRIBED ACTIVITY IS PERFORMED   ‘Prescribed activity’, as per section 2 of SI No 360 of 2005 is any activity consisting of any aspect of:   * the collection and testing of blood or blood components, whatever their intended purpose, and * the processing, storage and distribution of bloods and blood components when they are intended to be used for transfusion.   Please provide a description of the prescribed activities and the sites at which each prescribed activity shall be carried out:   |  |  | | --- | --- | | **Prescribed activities** | **Name and address of site(s) (include Eircodes) where prescribed activities shall be carried out** | |  |  | |  |  | |  |  | |  |  | |
| * 1. DETAILS OF CONTRACTUAL ARRANGEMENTS WITH ANY PERSON/COMPANY IN RESPECT OF PRESCRIBED ACTIVITIES CONTRACTED OUT   Please provide the name(s) and address(es) (include Eircodes) of any person(s) or company(ies) which shall carry out any prescribed activities on behalf of the blood establishment:   |  |  | | --- | --- | | **Name and address of contract site** | **Prescribed activities** | |  |  | |  |  | |  |  | |  |  | |  |  | |
| * 1. LIST OF HOSPITAL BLOOD BANKS/SITES SUPPLIED BY THE APPLICANT BLOOD ESTABLISHMENT   Please provide a list of the hospital blood banks and/or other sites supplied by the blood establishment:   |  |  | | --- | --- | | **Name of hospital blood bank/site** | **Address of hospital blood bank/site** | |  |  | |  |  | |  |  | |

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| section 2: Description of the quality system in place as per Article 6.4(b) of SI no 360 of 2005 |
| 2.1 ORGANISATION CHART OR SIMILAR DOCUMENTATION  Attach an organisational chart or similar documentation, setting out the responsibilities of the RP(s) and reporting relationships.  Tick here to confirm the required documentation is attached. |
| 2.2 SITE MASTER FILE OR QUALITY MANUAL  Attach a site master file or quality manual, or similar documentation, describing the quality system in place and explaining how it meets the requirements of the annex to Commission Directive 2005/62/EC.  Tick here to confirm the required documentation is attached. |
| 2.3 PERSONNEL  Provide brief details in relation to the number and qualifications of personnel at the blood establishment:  Number of persons:  Qualifications: |
| 2.4 DETAILS OF HYGIENE PROVISIONS  Provide brief details of the hygiene provisions in place at the blood establishment: |
| 2.5 DETAILS OF PREMISES AND EQUIPMENT  Provide brief details of premises and equipment available at the blood establishment: |
| 2.6 LIST OF SOPS  Attach a list of SOPs for:   * recruitment, retention and assessment of donors * processing, testing, distribution and recall of blood and blood components * reporting and recording of serious adverse reactions and events.   Please tick to confirm attached. |
| 2.7 COPIES OF SOPS  Attach copies of SOPs for   * recall of blood and blood components * the reporting and recording of serious adverse reactions and events   Please tick to confirm attached. |
| section 3: fees |
| An application fee must be submitted with each request for an authorisation. Please refer to the ‘Guide to Fees for Human Products’ on the ‘Publications and Forms’ section of [www.hpra.ie](http://www.hpra.ie) and complete the fee application form.  Tick to confirm that the fee application form has been completed and submitted with this application.  Tick to confirm that the appropriate fee has been attached. |
| Section 4: declaration |
| In the event of the authorisation being granted, I undertake to ensure fulfilment of the obligations arising by virtue of the terms and conditions of the authorisation and declare that the above particulars are, to the best of my knowledge and belief, correct.  **Signature**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:**  (Responsible Person)  **Print name**:       **Title/position:**  **Signature**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:**  (CEO/Medical Director)  **Print name**:       **Title/position:** |

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