Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

**Guidance for completing an application form for a Blood Establishment Authorisation (BEA)**

These notes have been developed in order to assist you with filling in the application form. The form should be completed taking into account the operations to be conducted at the establishment for which the authorisation is intended.

## Section 1 - Background Information

**Licence Number Box** If the company/organisation making the application already holds or has previously held an existing licence and/or authorisation from the MHRA the number should be indicated in the licence number box (see the example below).

| **Licence/Authorisation number(s)** | | | |
|---|---|---|---|
| **Number:** | 1234 | **Number:** | 1234 |
| **Number:** | 1234 | **Number:** | 1234 |

The reason we ask for this information is that MHRA uses a system of unique numbers to identify those companies, organisations etc. with which it deals. Providing any number(s) that we have previously allocated will assist MHRA to ensure new applications are properly associated with previous applications made to the Agency (including those submitted to different divisions) and may assist MHRA staff during data processing when queries arise. Where an applicant has more than one number this should also be included when completing the table.

If an applicant does not have an existing number leave this section blank and proceed to Section 2.

**Other Licences/Authorisations Held** If an applicant already holds a licence and/or authorisation issued by MHRA please identify it by completing the grid in this section. To ensure clarity please enter ‘yes’ or ‘no’ in the appropriate column (see example below where the applicant does hold a full Manufacturer’s Licence, a Wholesale Dealer’s Licence and a Marketing Authorisation but does not hold any other licences or authorisations):

| | ***Yes*** | ***No*** |
|---|---|---|
| Manufacture/Importer licence – (MIA) | Yes | |
| Manufacturer's (Specials) Licence – (MS) | | No |
| Manufacturer's Licence (Investigational Medicinal Products) – MIA(IMP) | | No |
| Wholesale Distribution Authorisation – WDA(H) | | No |
| Marketing Authorisation (Product Licence) | Yes | |
| Other (if yes specify below) | | No |

## Section 2 - Applicant Details

### Blood Establishment name

- Enter the name of the blood establishment[1]. This will be the name of the company (e.g. commercial organisation) or organisation (e.g. NHS Trust, Blood Service, Hospital) to which the authorisation is to be issued.

### Applicant

- Enter the name of the individual who will be responsible for the Blood Establishment Authorisation. The individual making the application (applicant) will be subsequently named as the Authorisation Holder on the Blood Establishment Authorisation where one is issued.

### Trading As

- On occasions a company (more usually) or organisation (rarely) operates under a trading name or trading style e.g. XYZ PLC trading as (t/a) ABC Enterprises. If a trading name is entered in this box on the application form it will subsequently be included on the Blood Establishment Authorisation where one is issued.

### Address/postcode

- Enter the details pertaining to the Establishment Name (above).

### Telephone, Mobile, Fax, Email

- This information is for MHRA business use and will aid MHRA in administration and communications and assist in the speedy processing of the application.

**If you are applying on behalf of the Proposed Authorisation Holder**

- If the application form is completed by a third party on behalf of the applicant e.g. a regulatory consultant, please place a tick in the box.

**Contact details for communications**

- If no information is entered here all correspondence relating to the application for a Blood Establishment Authorisation, including queries, will be directed to the person named as the Authorisation Holder (above) at the address given for that person. Similarly, where an authorisation is issued, it will be sent to the named Authorisation Holder. If the applicant wishes correspondence, queries and any issued authorisation to go elsewhere i.e. to an administrative function, the relevant details should be entered in the boxes below "Contact Details for Communications".

**Address for Invoicing Purposes**

- If no information is entered here the invoice relating to MHRA activities for the application for a Blood Establishment Authorisation will be directed to the person named as the Authorisation Holder (above) at the address given for that person. If the applicant wishes the invoice to be sent elsewhere i.e. to a Finance Department, the relevant details should be entered in the boxes below "Address for Invoicing Purposes".

**Please Note**

The application form is divided into nine sections. The information provided in sections 1, 2 and 9 should only be sent once to MHRA with each application form submitted. The information to be provided in the remaining parts of the application form (sections 3-8) is **site specific**. Consequently, if the application for the Blood Establishment Authorisation is to name more than one site (including contract sites[2]) **one set of sections 3-8 will have to be submitted for each site to be named on the Authorisation**. Please make additional copies of sections 3-8 as necessary to ensure you provide MHRA with one set per site.

## Section 3 – Site Information

**Definition:** with respect to making an application for a Blood Establishment Authorisation **site** is as defined in the relevant legislation[3].

**Site Number**

- If known, enter the MHRA site number. This is a unique identifier used by MHRA and will assist in processing of the application.

**Site Name**

- If the site has a specific name unique from the address e.g. Something Building, enter the information in the site name box.

***Site Contact Name***

- Enter the name of the person to contact at the site (e.g. for inspection purposes). If no name is entered the contact name provided in section 2 of the application form or, if absent, the authorisation holder name provided in section 2 of the application form will be used by MHRA for site contact purposes.

**Site Address/postcode**

- Enter the details pertaining to the site.

***Site Contact Details, Telephone, Mobile, Fax, Email***

- This information is for MHRA business use and will aid MHRA in administration and communications and assist in the speedy processing of the application.

***Site Usage***

- Complete the grid to specify site usage. For clarity please enter 'Yes' or 'No' as appropriate in the relevant column.

**Section 4 – Site Processes**

**Site Identifier Box**

- At the top of each page of this section is a box for entering site details. Please complete this for each page submitted. The information will assist MHRA to ensure submitted pages do not get mislaid or mixed up, particularly when multiple copies of sections 3 – 8 are submitted.

**Proposed Processes to be Conducted at this Site**

- Complete the grid to specify those processes intended to be undertaken at the site. For clarity please enter 'Yes' or 'No' as appropriate in the relevant column.
- Note, the proposed processes grid extends to a second page. Both pages should be completed even if none of the processes on the second page are to be undertaken.
- Definitions for the processes are defined in the relevant legislation[4].

**Section 5 – Site Personnel**

- Enter in the grid the names of all personnel who will undertake the role of Responsible Person (Blood) **at this site**. Responsible person in relation to a blood establishment means the person who has been designated pursuant to regulation 6 as the responsible person for that blood establishment[5]. The same person may be named in this role at

multiple sites but when this is so that person's name must be added to the separate sets of sections 3 – 8 submitted for each site.

- For each person named please provide the MHRA person number. MHRA uses a system of unique numbers to identify those personnel named on authorisations, licences etc. issued by the Agency. Providing the number that we have previously allocated will assist MHRA to ensure new applications naming personnel are properly associated with previous applications made to the Agency and may assist MHRA staff during data processing when queries arise. If the person number is not known leave the entry blank.

- For each person named at section 5, a copy of section 6 of the application form (Responsible Person (Blood) – Details) must be submitted.

**Section 6 – Details of the Responsible Person (Blood)**

**Site Identifier Box**

- At the top of each page of this section is a box for entering site details. Please complete this for each page submitted. The information will assist MHRA to ensure submitted pages do not get mislaid or mixed up, particularly when multiple copies of sections 3 – 8 are submitted.

**Nominee as a Responsible Person (Blood)**

Enter the title, name and business address and postcode of the person who is being nominated for the role of Responsible Person (Blood) at the site specified at section 3. Providing the telephone, mobile, and fax numbers and email address for the person will aid MHRA in administration and communications and assist in the speedy processing of the application.

**Status**

- Tick whether the person being nominated for the role of Responsible Person (Blood) will be a permanent employee of the Blood Establishment specified at section 2 of the application form or if the person being nominated will be a consultant offering contracted services to the Blood Establishment.

**Consultant**

- If consultant was ticked in the status box (above) please answer the questions in the consultant box. When answering the question about frequency of visiting the site it is important that the information provided is sufficiently detailed and accurate for proper assessment by MHRA.

**Qualifications**

- Only relevant qualifications need be provided. Include membership of relevant professional societies.

**Experience**

- Detail the relevant experience gained in an authorised UK blood establishment that makes the person being nominated as Responsible Person (Blood) suitable to hold the position.

**Signature**

- **Both** the person being nominated for the role of Responsible Person (Blood) **and** the applicant named at section 2 of the form must sign section 6 of the application form. MHRA reserve the right to independently contact the person named as the nominee for the role of Responsible Person (Blood) to verify the voracity of the application.

**Reminder - one copy of section 6 of the application form (Responsible Person (Blood) – Details) must be submitted for each person named at section 5.**

**Section 7 – Hospitals and blood banks supplied**

**Site Identifier Box**

- At the top of each page of this section is a box for entering site details. Please complete this for each page submitted. The information will assist MHRA to ensure submitted pages do not get mislaid or mixed up, particularly when multiple copies of sections 3 – 8 are submitted.

**Details of Hospitals and Blood Banks Supplied**

- Provide the names and addresses of all the hospitals or blood banks supplied with blood or blood components from the site specified at section 3. The list must include not only hospitals and/or blood banks supplied in the UK but also any hospitals and/or blood banks outside the UK that are supplied with blood or blood components. If the number of hospitals and/or blood banks supplied is greater than the number of boxes available in section 7 of the application form please make additional copies of the page. If additional copies are made please write the **total** number of copies of section 7 (including the original) in the box at the bottom of the page. This may be entered in the box on all copies or just the original.

**Section 8 – Further information**

**Site Identifier Box**

- At the top of each page of this section is a box for entering site details. Please complete this for each page submitted. The information will assist MHRA to ensure submitted pages do not get mislaid or mixed up, particularly when multiple copies of sections 3 – 8 are submitted.

**Facilities on Site**

- On a separate sheet of paper provide a brief description (approximately 500 words) of relevant facilities on the site specified at section 3 to support the application for being named on a Blood Establishment Authorisation e.g. the facilities available for collection,

testing and storage of blood, facilities for processing blood and the processing undertaken, facilities for storage and distribution of blood and blood components. Please include at the top of the separate sheet the information held in the Site Identifier Box (as shown at the top of section 8) for the relevant site.

**Additional Information**

- Provide any further information that may assist in supporting and processing the application. If necessary use a separate sheet of paper; if a separate sheet is used please note this fact in the additional information box and include at the top of the sheet the information held in the Site Identifier Box (as shown at the top of section 8) for the relevant site.

**Section 9 – Declaration**

**Declaration**

- The applicant named at section 2 of the application form must sign and date the application form and state in what capacity the form was signed.

When complete send the form to the address given on page 3 of the form. Please remember:

1. The applicant must sign the declaration.
2. For each person to be nominated as a Responsible Person (Blood) **both** the applicant and the person nominated must sign the relevant part of the form (section 7).
3. Information to support the nomination of Responsible Person (Blood) should be provided e.g. copies of relevant certificates (for qualifications or professional societies), copies of a relevant curriculum vitae etc.
4. At the time of inspection the sites to be inspected should be properly prepared for inspection with all required systems and documentation developed and suitable for purpose.
5. Information provided on the application form will be included on the Blood Establishment Authorisation where one is issued. If any of the information subsequently requires changing it is the responsibility of the Authorisation Holder to **inform MHRA in advance of any change** by submitting a variation to the Authorisation.

**References**

[1] Paragraph 3(2) of Statutory Instrument 2005 No. 50 **The Blood Safety and Quality Regulations 2005**, obtainable from the Office of Public Sector Information (http://www.opsi.gov.uk)

[2] Paragraph 4.1.4.a.iii of Statutory Instrument 2005 No. 50 **The Blood Safety and Quality Regulations 2005**, obtainable from the Office of Public Sector Information (http://www.opsi.gov.uk)

[3] Citation, commencement and interpretation 1.3 and paragraph 4.1.4.a.i of Statutory Instrument 2005 No. 50 **The Blood Safety and Quality Regulations 2005**, obtainable from the Office of Public Sector Information (http://www.opsi.gov.uk)

[4] Part 1 – Definitions of Statutory Instrument 2005 No. 50 **The Blood Safety and Quality Regulations 2005**, obtainable from the Office of Public Sector Information (http://www.opsi.gov.uk)

[5] Citation, commencement and interpretation 1.3 of Statutory Instrument 2005 No. 50 **The Blood Safety and Quality Regulations 2005**, obtainable from the Office of Public Sector Information (http://www.opsi.gov.uk)