MHRA

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

Blood Establishment Authorisation

SECTION 1

1. This authorisation is granted in accordance with the provisions of The Blood Safety and Quality Regulations 2005 No.50 (as amended).

2. It permits the authorisation holder named on page 3 of Section 1 to undertake the collection and testing of blood and blood components whatever their intended purpose and the processing, storage and distribution of blood and blood components when they are intended to be used for transfusion.

3. In this document a Blood Establishment Authorisation may be referred to as BEA and the Medicines and Healthcare products Regulatory Agency may be referred to as MHRA.

4. The authorisation holder must inform the MHRA, in advance, of any change to the details submitted by him and/or included in this authorisation. All changes must be approved by the MHRA to have effect. If the business should change hands, the company or person taking over the business will have to obtain a new authorisation before commencing the collection and testing of blood and blood components whatever their intended purpose and the processing, storage and distribution of blood and blood components when they are intended to be used for transfusion.

Attention is drawn to the structure of this authorisation (as detailed on page 2 of Section 1) and to its completeness in accord with that structure. This is of particular relevance where the holder of the authorisation is using it as evidence to a third party in support of claims to carry out those operations and activities to which this authorisation applies on premises and using personnel covered by this authorisation.

SECTION 1 (continued)

5. Authorisation Structure

This authorisation is divided into three sections.

(a) Sections 1 (this section) identifies the authorisation holder and holds the authorising name for the issue of the authorisation. This section would not usually be replaced during routine variations of the authorisation unless the authorisation holder details are varied.

(b) Section 2 lists variations to the authorisation. A replacement section 2 will be issued each time the authorisation is varied.

(c) Section 3 contains the details relating to Responsible Person

(d) Section 4 contains the details relating to each site named on the authorisation. Where there is more than one site there will be more than one part to Section 4. When a variation is made to the details of a named the relevant portion of Section 4 will be replaced.

(e) The authorisation holder is required to attach to his authorisation any replacement pages issued by MHRA and to mark or destroy superseded pages as to render them invalid.

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6. Provisions

(a) The provisions of The Blood Safety and Quality Regulations 2005 No.50 (as amended).

(b) Additional conditions

(i)

(ii)
