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.

---

6. Provisions

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

(b) Additional conditions

(i)

(ii)

SECTION 1 (continued)

7. Authorisation Holder

(a) BEA Number: BEA 21314 has been granted to –

NAME:	MS JULIA IRVING
COMPANY:	FUTURE HEALTH TECHNOLOGIES
TRADING AS:	
ADDRESS:	UNIT 10 FARADAY BUILDING, UNIVERSITY BOULEVARD, NOTTINGHAM SCIENCE & TECHNOLOGY PARK, NOTTINGHAM, NG7 2QP, UNITED KINGDOM

(b) This authorisation permits the holder 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, at the premises and using the personnel in accordance with Sections 3 and 4 of this authorisation.

(c) This authorisation will continue to remain in force unless suspended or revoked by the Competent Authority or relinquished by the authorisation holder.

(d) Date granted - 28/01/2011

(e) Authorised by -

Name: Sean Kaiser

(A person authorised to approve on behalf of the Secretary of State for Health.)

Date: 28/01/2011

MHRA

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

Blood Establishment Authorisation

SECTION 2

VARIATION HISTORY

This page will be amended if the authorisation is varied.

Date	Variation Detail
28/01/2011	Initial Application

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

Blood Establishment Authorisation

SECTION 3

RESPONSIBLE PERSON

NAME:	ADDRESS:
MRS BEVERLEY LANCASHIRE-HUNTER	UNIT 10 FARADAY BUILDING, UNIVERSITY BOULEVARD, NOTTINGHAM SCIENCE & TECHNOLOGY PARK, NOTTINGHAM, NG7 2QP, UNITED KINGDOM

Has been designated the Responsible Person(s) for BEA Number:
BEA 21314

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

Blood Establishment Authorisation

SECTION 4 – SITE INFORMATION

The premises –

SITE NAME:	FUTURE HEALTH TECHNOLOGIES
ADDRESS:	UNIT 10 FARADAY BUILDING, UNIVERSITY BOULEVARD, NOTTINGHAM SCIENCE & TECHNOLOGY PARK, NOTTINGHAM, NG7 2QP, UNITED KINGDOM
MHRA SITE NUMBER:	2014532

is named on BEA Number: BEA 21314

The following are authorised at the named premises:

1. Those operations specified at Part A of this section of the authorisation
2. Analytical Testing at those sites named in Section 5 of this authorisation
3. Supply of materials to those Hospitals, Blood Banks and Facilities named in Appendix A of this authorisation
4. Site specific conditions:

SECTION 4 – SITE INFORMATION (continued)

Part A – Proposed processes to be conducted at this Site

A.1.1	**Blood Collected**	
A.1.1.1	Whole Blood Collection	Authorised
A.1.1.2	Autologous whole blood collection	Authorised
A.1.1.3	Testing Donor Samples	Authorised
A.1.1.4	Apheresis collection of components	Not Authorised
	Apheresis component type collected:	
A.1.2	**Whole Blood Processing Information**	
A1.2.1	Red Cells	Not Authorised
A1.2.2	Platelets	Not Authorised
A1.2.3	Granulocytes	Not Authorised
A1.2.4	Fresh frozen plasma	Not Authorised
A1.2.5	Recovered plasma (for discard)	Not Authorised
A1.2.6	Cryoprecipitate	Not Authorised
A1.2.7	Cryoprecipitate depleted plasma	Not Authorised
A1.2.8	Buffy Coats	Authorised
A1.2.9	Other:	
A.1.3	**Components processed into:**	
A1.3.1	Methylene blue treated plasma	Not Authorised
A1.3.2	Irradiated components	Not Authorised
A1.3.3	Washed components	Not Authorised
A1.3.4	Splitting into small volume packs	Not Authorised
A1.3.5	Pooling cryoprecipitate	Not Authorised
A1.3.6	Manipulation of haematocrit	Not Authorised
A1.3.7	Other:Isolation of buffy coat, in order to cryopreserue the immune cells and stem cells	

Safeguarding public health

MHRA

Ms Julia Irving
FUTURE HEALTH TECHNOLOGIES
UNIT 10 FARADAY BUILDING
UNIVERSITY BOULEVARD
NOTTINGHAM SCIENCE & TECHNOLOGY PARK
NOTTINGHAM
NG7 2QP
UNITED KINGDOM

Medicines and Healthcare products Regulatory Agency
151 Buckingham Palace Road London SW1W 9SZ
T 0203 080 6000 www.mhra.gov.uk