Irish Blood Transfusion Service
Seirbhís Fuilaistriúcháin na hÉireann

Document Detail

Type: QA IBTS QM
Document No.: IBTS/QA/QM/0001[4]
Title: **IBTS QUALITY MANUAL**
Owner: QA DOC CON QA DOC CONTROL
Status CURRENT
Effective Date: 04-Mar-2025
Expiration Date: 04-Mar-2027

Review

Review: IBTS DOC REVIEW AND APPROVAL

Level	Owner Role	Actor	Sign-off By
1	DOCUMENT CONTROLLER	REBECCA WALDEN	REBECCA WALDEN
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3	QUALITY ASSURANCE REVIEWER IBTS	COLIN O'LEARY	
4	DIRECTOR OF QUALITY	KAREN BYRNE	

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Valid on Day of Printing, Verify Current Version
Printed By: **Date:**

Document Detail

Change Orders

Changes as described on Change Order:	Change Order No.

Change Orders - Incorporated

Changes as described on Change Order:	Change Order No.
	IBTS/CO/0059/25

Valid on Day of Printing, Verify Current Version

Printed By: **Date:**

TITLE: IBTS QUALITY MANUAL

Change Description:

1. Update format, grammar and language throughout.
2. Add reference to IVDR legislation and requirements.
3. Add reference to Quality, Regulatory & Safety Governance Group and change MAC to MSAC
4. Change DOP to include DSL & DPHS and associated responsibilities. Add QSDM to responsibilities. Update org chart in Att.10.3
5. Check internal document reference throughout and update. Add or amend references to risk logs, PMFs, GDEs, PMX, TMX, POLs, BCPs, and SOPs.
6. Remove ref to documents not in place such as IBTS/MBG/LM/0001, IBTS/QA/QM/0002, IBTS/QA/QM/0004.
7. Update Quality Policy in section 1.0 and Att. 10.1
8. Update all regulatory requirements and other external references. Display as table in Section 4
9. Update section 8.4 for responsible/designated personnel. Add accreditation refs to 10.2 and remove accreditation to ISO15189

Reason for Change:

1. As per IBTS/QA/SOP/0143 and to aid in clarity of information.
2. Ref CC 082/24/IBTS
3. Changes to IBTS governance structure and committee names.
4. Reflect current IBTS Org structure.
5. Reflect current documents within IBTS and reference highest level or most relevant docs where possible
6. Docs planned but not yet in place. Will be added in future version.
7. Outline clear policy objectives for IBTS that can be displayed prominently throughout organisation.
8. Ensure accurate referencing to required legislation and guidelines
9. Ensure accuracy in legal requirements for responsible/ designated person. EFI and WMDA accreditations held by IBTS are not listed and CC 050/25/IBTS

Change order No.:

IBTS/CO/0059/25

Referenced Documents

IBTS/ADM/POL/0001	IBTS/EXT/DOC/0013	IBTS/QA/POL/0006	IBTS/QA/VMP/0001
IBTS/DIAG/CM/0001	IBTS/EXT/DOC/0015	IBTS/QA/POL/0007	IBTS/QA/VMP/0006
IBTS/DP/POL/0002	IBTS/EXT/DOC/0016	IBTS/QA/POL/0011	IBTS/QAV/SOP/0001
IBTS/DP/POL/0018	IBTS/EXT/DOC/0017	IBTS/QA/POL/0012	IBTS/QAV/SOP/0002
IBTS/IT/QM/0001	IBTS/EXT/DOC/0021	IBTS/QA/QM/0003	IBTS/RCI/LM/0001
IBTS/EXT/DOC/0001	IBTS/EXT/DOC/0033	IBTS/QA/SOP/0014	IBTS/RR/BCP/0003
IBTS/EXT/DOC/0002	IBTS/EXT/DOC/0071	IBTS/QA/AUTH/0001	IBTS/RR/BCP/0004
IBTS/EXT/DOC/0003	IBTS/EXT/DOC/0083	IBTS/QA/AUTH/0002	IBTS/RR/POL/0001
IBTS/EXT/DOC/0004	IBTS/QA/POL/0001	IBTS/QA/AUTH/0003	IBTS/RR/POL/0002
IBTS/EXT/DOC/0005	IBTS/QA/POL/0002	IBTS/QA/AUTH/0004	IBTS/RR/POL/0003
IBTS/EXT/DOC/0006	IBTS/QA/POL/0003	IBTS/QA/AUTH/0007	
IBTS/EXT/DOC/0007	IBTS/QA/POL/0004	IBTS/QA/AUTH/0008	
IBTS/EXT/DOC/0012	IBTS/QA/POL/0005	IBTS/QA/LIST/0002	

SmartSolve Roles

QA GEN IBTS	IT EXT L3	IT EXT SD
IT EXT CISO	RCI AUDITOR EXT	

Training Type

Read & Understand for all roles

SmartSolve Document Category

Category	Mobile	Cryobiology	Website	GDP
Yes / No	Yes	Yes	Yes	Yes

TABLE OF CONTENTS

TITLE: IBTS QUALITY MANUAL

1 QUALITY POLICY*

The IBTS is committed to providing to all donors, patients, hospital scientific and clinical staff the highest quality in;

- blood and tissue products
- diagnostic and distribution services
- consultative services

The Quality Objectives, through which this quality policy is implemented, are to;

- comply with all relevant legislation, standards and guidelines.
- operate an effective quality management system, the purpose of which is to maintain and improve the quality and safety of the products and services provided.
- continuously improve the quality management system to ensure efficiency and ease of use by all.
- train IBTS staff in the quality management system to ensure consistency, effectiveness and user satisfaction.
- uphold professional values, good professional practice and embed a quality culture in line with IBTS values.

*A copy of this policy is also available as attachment 10.1 of this document. This copy is available for printing and displaying in IBTS business areas

2 INTRODUCTION

2.1 The IBTS

The Irish Blood Transfusion Service (IBTS) is a public sector body responsible for collecting, processing, testing, storage and distributing blood and blood products in Ireland.

The IBTS processes and distributes corneas, heart valve, directed cord blood, ocular tissue, allogeneic serum eye drops and skin.
The IBTS orders, stores and distributes licensed medicinal products for the treatment of blood disorders.

The IBTS operates as a Blood Establishment under the terms of SI 360/05 (Authorisation # BE - 002)

The IBTS operates as a Tissue Establishment under the terms of SI 158 / 06 (Licence # TE - 012).

The IBTS operates as a Manufacturing Authorisation Holder (Authorisation No.M11514 /00001) under the terms of S.I. No. 539 of 2007.

The IBTS operates as a Distributor of Medicinal Products (Wholesale Distribution Authorisation No. W00011/00001) under the terms of S.I. No. 538 of 2007.

2.2 Legal Description

The legal description of the IBTS is described in Statutory Instrument No. 22 of 2000 as follows;

The Functions of the Irish Blood Transfusion Service under Statutory Instrument No. 78 of 1965 as amended are:

- *to organise and administer a blood transfusion service including the processing or supply of blood derivatives or other blood products, and also including blood groups and other tests in relation to specimens of blood received by the Board.*
- *to make available blood and blood products.*
- *to make available equipment or reagents suitable for use in relation to the service*
- *to furnish advice, information and assistance in relation to any aspect of the service to the Minister, any health authority or any hospital authority.*
- *to make any necessary provision for publicity in relation to the service.*
- *to organise, provide, assist or encourage research and the training of persons in matters relating to blood transfusion and preparation of blood products.*
- *to co-operate with other bodies with analogous scientific functions.*

- *to organise and administer a service for obtaining and assessing reports of unexpected or undesirable effects of transfusion of blood or blood components made available by the Board, including the furnishing to the Health Products Regulatory Authority (HPRA) of reports of any unexpected or undesirable effects of any transfusion of such blood or blood components.*

2.3 Corporate Governance

Compliance with the code of practice for the governance of state bodies

The IBTS Board is committed to complying with the relevant provisions of the code of practice for the Governance of state bodies, Department of Public Expenditure and Reform in 2016. The IBTS Board review reports on internal controls during the year along with regular reviews of the reports of the Health Products Regulatory Authority (Competent Authority for Blood, Tissue and GDP in Ireland) on operational and compliance controls and risk management. The board will continue to review these reports and to work closely with the HPRA to ensure the highest international standards.

Workings of the Board

The board is comprised of twelve members including a non-executive chairperson appointed by the Minister of Health. The board meets 6 times a year. All members receive appropriate and timely information, to enable the board to discharge its duties. The board takes appropriate independent, professional advice as necessary.

Medical and Scientific Advisory Committee

The Medical and Scientific Advisory Committee (MSAC) reports to the Board of the IBTS and is comprised of the medically qualified members of the Board and the medical consulting staff. The Medical Advisory Committee meets on a monthly basis. Its function is to monitor developments and develop policies relevant to the field of transfusion medicine and related fields and to inform the board of any such developments and to advise the board on appropriate action. Items from the IBTS National Consultant meetings and Infection Sub-group are brought to the MSAC where required.

The Quality Regulatory and Safety Governance Group

The Quality Regulatory and Safety Governance Group (QRSGG) reporting to the Executive Management Team, is directly concerned with establishing, developing and implementing organisational wide quality, regulatory and safety processes, standards, structures and oversight across the service.

- Oversee the development and implementation of the Quality, Regulatory and Safety monitoring systems and programmes that support a culture of continuous quality improvement.
- Recommend policies and processes that clearly articulate responsibility, authority and accountability for quality, regulatory, safety, risk management, incident reporting/management and improvement across the IBTS.
- Application of appropriate governance structures and processes (e.g. risk escalation) including monitored outcomes through quality indicators and outcome measures for the relevant IBTS divisional areas.
- Assure that services are conforming to regulatory and legal requirements.
- Review of relevant risks and updating risk register on an on-going basis

2.4 Quality Manual Documentation Structure

The IBTS Quality Manual defines at a high level the agreed strategy for the execution of the IBTS approach to a Quality Management System. The IBTS Quality Manual has been developed under the authorisation of the Director of Quality and Compliance. The hierarchical Quality Management System documentation structure is outlined in **Figure 1** below.

This Quality Manual describes the overall IBTS quality management system to meet the requirements of Blood Establishment Good Practice Guidelines (EU Directive 2016/1214) and the document is structured using the Good Practice headings. This is chosen as the most appropriate structure as the IBTS primarily operates as a Blood Establishment.

This IBTS quality manual falls within the document hierarchy as a policy level document. The IBTS Quality Manual is the highest level policy document. Further IBTS manuals and policies, referenced within, contain the detailed and specific descriptions with reference to further regulatory or accreditation requirements. The policy level hierarchy of documents is expanded in Figure 2.

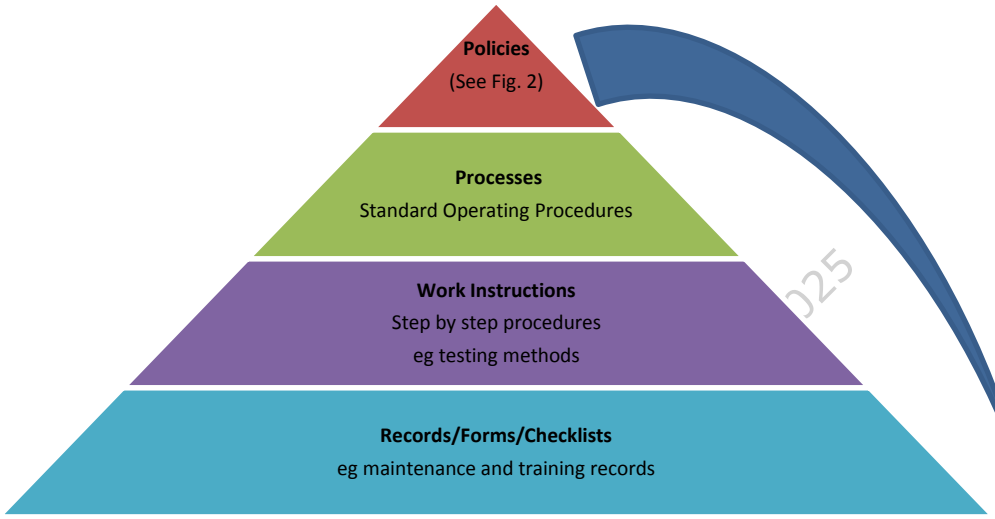

Fig. 1: Overall Documentation Hierarchy

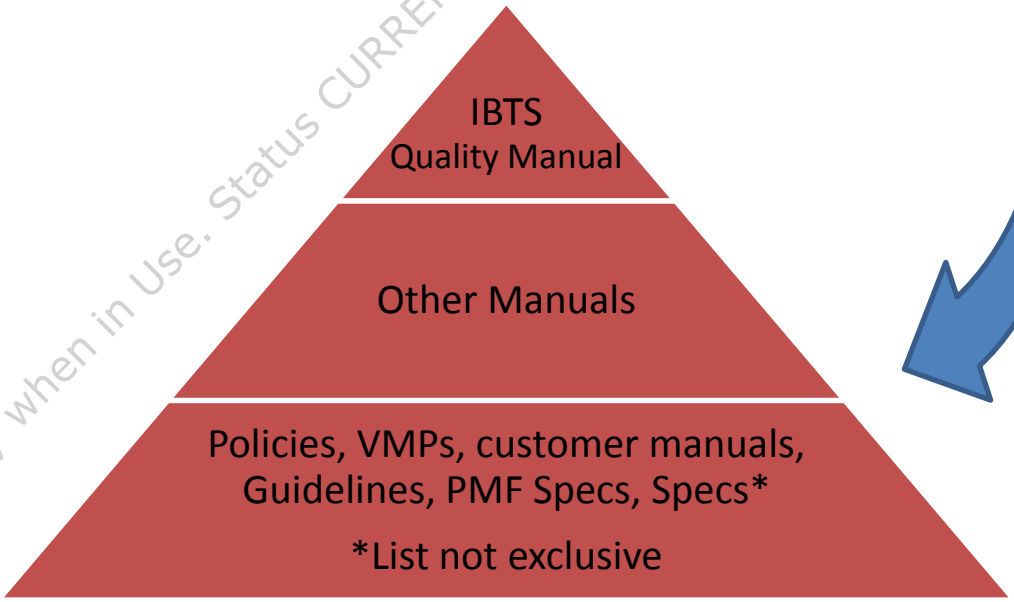

Fig. 2: Expansion of Policies Level from Fig 1

3 OBJECTIVES

The following are the objectives of the IBTS Quality Manual:

- To define and develop the IBTS Quality System to comply with regulatory requirements
- To define the IBTS Organisational Structure with respect to Quality Management System and Regulatory Requirements
- To define the roles / responsibilities of the IBTS Personnel associated with the Quality Management System
- To define the IBTS Quality System Methodology

4 REGULATORY REQUIREMENTS

Irish Blood Transfusion Service Legal Description (IBTS/EXT/DOC/0083)	
Legislation Title	**S.I. Number**
The Blood Transfusion Service Board (Establishment) Orders	SI 22/2000- The Blood Transfusion Service Board (Establishment) Order, 1965 (Amendment) Order, 2000 SI 78/1965- The Blood Transfusion Service Board (Establishment) Order, 1965

Good Practice Guidelines and Associated Legislation (IBTS/EXT/DOC/0001)	
Legislation Title	**S.I. Number**
Commission Directive (EU) 2016/1214 of 25 July 2016 amending Directive 2005/62/EC as regards quality system standards and specifications for blood establishments	S.I. No. 180/2018 - European Communities (Quality System for Blood Establishments) (Amendment) Regulations 2018 with reference to principal regulation S.I. No. 562 of 2006 S.I. No. 562/2006 - European Communities (Quality System for Blood Establishments) Regulations 2006

Blood Legislation – European Commission Directives & Statutory Instruments (IBTS/EXT/DOC/0012)	
Legislation Title	**S.I. Number**
Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (Primary Medicinal Product legislation)	S.I. No. 360/2005 - European Communities (Quality and Safety of Human Blood and Blood Components) Regulations 2005S.I. No. 179/2008* *Amended by S.I. No. 179/2008 - European Communities (Quality and Safety of Human Blood and Blood Components) (Amendment) Regulations 2008
Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components	S.I. No. 360/2005 - European Communities (Quality and Safety of Human Blood and Blood Components) Regulations 2005S.I. No. 179/2008
Directive 2005/61/EC of the European	S.I. No. 547/2006 - European Communities

Commission implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and specifications relating to traceability requirements and notification of serious adverse reactions and events	(Human Blood and Blood Components Traceability Requirements and Notification of Serious Adverse Reactions and Events) Regulations 2006
Directive 2005/62/EC of the European Commission implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for blood establishments	S.I. No. 562/2006 - European Communities (Quality System for Blood Establishments) Regulations 2006
Commission Implementing Directive 2011/38/EU of 11 April 2011 amending Annex V to Directive 2004/33/EC with regards to maximum pH values for platelets concentrates at the end of the shelf life and for the purpose of giving further effect to Directive 2002/98/EC of the European Parliament and of the Council of 27 January 20032 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC	S.I. No. 329/2011 - European Communities (Quality and Safety of Human Blood and Blood Components) (Amendment) Regulations 2011.
Commission Directive 2014/110/EU of 17 December 2014 amending Directive 2004/33/EC as regards temporary deferral criteria for donors of allogeneic blood donations	S.I. No. 494/2015 - European Communities (Quality and Safety of Human Blood and Blood Components) (Amendment) Regulations 2015

Tissue Legislation – European Commission Directives & Decisions & Statutory Instruments (IBTS/EXT/DOC/0013)	
Legislation Title	**S.I. Number**
Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells	S.I. No. 158/2006 - European Communities (Quality and Safety of Human Tissues and Cells) Regulations 2006
Directive 2006/86/EC implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells	S.I. No. 598/2007 - European Communities (Human Tissues and Cells Traceability Requirements, Notification of Serious Adverse Reactions and Events and Certain Technical Requirements) Regulations 2007
2010/453/EU: Commission Decision of 3 August 2010 establishing guidelines concerning the conditions of inspections and control measures, and on the training and qualification of officials, in the field of human tissues and cells provided for in Directive 2004/23/EC of the European Parliament and of the Council (notified under document C(2010) 5278)	N/A
Commission Directive 2012/39/EU of 26 November 2012 amending Directive 2006/17/EC as regards certain technical requirements for the testing of human tissues and cells Text with EEA relevance	S.I. No. 209/2014 - European Communities (Quality and Safety of Human Tissues and Cells) (Amendment) Regulations 2014.
Commission Directive (EU) 2015/565 of 8 April 20151 amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cell	S.I. No. 32/2019 - European Communities (Human Tissues And Cells Traceability Requirements, Notification Of Serious Adverse Reactions And Events And Certain Technical Requirements) (Amendment) Regulations 2019
Commission Directive (EU) 2015/566 of 8 April 2015 implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells	SI 33/2019 giving effect to Commission Directive (EU) 2015/5661 of 8 April 2015 implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells.

Medicinal Products Legislation & Regulations & Statutory Instruments (IBTS/EXT/DOC/0015)	
Legislation Title	**S.I. Number**
Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use* *Medicinal Products (Control of Manufacture) Regulations 2007 to 2013	S.I. No. 539/2007 - Medicinal Products (Control of Manufacture) Regulations 2007 Consolidated 2022 S.I. No. 3/2009 - Medicinal Products (Control of Placing On the Market) Regulations 2007 (Amendment) Regulations 2009 S.I. No. 4/2009 - Medicinal Products (Control of Manufacture) Regulations 2007 (Amendment) Regulations 2009 S.I. No. 553/2009 - Medicinal Products (Control of Placing On the Market) Regulations 2007 (Amendment) (No. 2) Regulations 2009 S.I. No. 43/2022 - Medicinal Products (Control of Manufacture) (Amendment) Regulations 2022
Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use	S.I. No. 270/2022 - Medicinal Products (Safety Features on Packaging) Regulations 2022
Commission Regulation (EC) No 668/2009 of 24 July 2009 implementing Regulation (EC) No 1394/2007 of the European Parliament and of the Council with regard to the evaluation and certification of quality and non-clinical data relating to advanced therapy medicinal products developed by micro, small and medium-sized enterprises	S.I. No. 3/2009 - Medicinal Products (Control of Placing On the Market) Regulations 2007 (Amendment) Regulations 2009
Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products	S.I. No. 553/2009 - Medicinal Products (Control of Placing On the Market) Regulations 2007 (Amendment) (No. 2) Regulations 2009

Medicinal Products Legislation & Regulations & Statutory Instruments (IBTS/EXT/DOC/0015)	
Legislation Title	**S.I. Number**
Regulation (EC) No 1394/2007 of the European Parliament and of the council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004	S.I. No. 3/2009 - Medicinal Products (Control of Placing On the Market) Regulations 2007 (Amendment) Regulations 2009 S.I. No. 4/2009 - Medicinal Products (Control of Manufacture) Regulations 2007 (Amendment) Regulations 2009
Regulation (EU) No 1235/2010 of the European Parliament and of the council of 15 December 2010 amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, and Regulation (EC) No 1394/2007 on advanced therapy medicinal products	S.I. No. 272/2012 - Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2012.
Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004	S.I. No. 3/2009 - Medicinal Products (Control of Placing On the Market) Regulations 2007 (Amendment) Regulations 2009
Directive 2011/62/EU amending Directive 2001/83/EC on the community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products.	S.I. No. 162/2013 - Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2013. S.I. No. 164/2013 - Medicinal Products (Control of Wholesale Distribution) (Amendment) Regulations 2013.

Medical Devices Regulation (EU) (IBTS/EXT/DOC/0071)	
Legislation Title	**S.I. Number**
Regulation (EU) 2017/745 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.	S.I. No. 261/2021 – Medical Devices Regulations 2021.

Good Manufacturing Practice (GMP) Guidelines and Legislation (IBTS/EXT/DOC/0006)	
Legislation Title	**S.I. Number**
Commission Directive (EU) 2017/1572 of 15 September 2017 supplementing Directive 2001/83/EC of the European Parliament and of the Council as regards the principles and guidelines of good manufacturing practice for medicinal products for human use.	S.I. No. 43/2022 - Medicinal Products (Control of Manufacture) (Amendment) Regulations 2022.

EU Legislation on In vitro Medical Devices (IVDR) (IBTS/EXT/DOC/0016)	
Legislation Title	**S.I. Number**
Regulation (EU) 2017/746 of the European Parliament and of the council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU	S.I. No. 547/2017 - European Union (Medical Devices and In Vitro Diagnostic Medical Devices) Regulations 2017
Regulation (EU) 2022/112 of the European Parliament and of the council of 25 January 2022 amending Regulation (EU) 2017/746 as regards transitional provisions for certain in vitro diagnostic medical devices and the deferred application of conditions for in-house devices	S.I. No. 256/2022- In Vitro Diagnostics Medical Device Regulations 2022

5 AUTHORISATIONS AND ACCREDITIONS

A schedule of appropriate regulatory authorisations and quality system accreditations held by the IBTS is listed in **Attachment 10.2.** The current authorisations are available on SmartSolve.

6 ORGANISATION STRUCTURE

The Organisation Structure of the IBTS is outlined in **Attachment 10.3**.

7 RESPONSIBILITIES

The following are the key organisational roles and their associated responsibility with respect to Quality within the organisation.

Role	Responsibility within the Quality System
Chief Executive	The responsibility of the Chief Executive is to ensure Senior Management commitment to the Quality Management System at the IBTS.
Director of Quality & Compliance	The responsibility of the Director of Quality / Compliance is to ensure that the Quality Management System is implemented across the organisation and that regulatory requirements are met.
Medical and Scientific Director	The responsibility of the Medical and Scientific Director is to ensure the Quality Management System is appropriately supported and implemented in all medical and scientific functions of the IBTS. The further responsibility of the Medical and Scientific Director is to ensure that approved medical policies are implemented consistently across the organisation.
Director of Production and Hospital Services	The Director of Production and Hospital Services is responsible for the management of blood processing departments, hospital services departments, blood component/new product development, supply chain and the transport functions of the IBTS. This position also provides a key point of contact for external colleagues and health care partners, with strong focus on patient care and operational excellence.
Director of Donor Services and Logistics	The responsibility of the Director of Donor Services and Logistics is to ensure that appropriate operational resources are made available to fully implement the Quality Management System in their area of responsibility
Director of Finance	The responsibility of the Director of Finance is to ensure appropriate financial resources are made available to implement the Quality Management System. The further responsibility of the Finance Director is to ensure the Quality Management System is fully implemented in their associated area of responsibility.
Director of Human Resources	The responsibility of the Human Resource Director is to ensure appropriate human resources are made available to implement the Quality Management System. The further responsibility of the Human Resources Director is to ensure the Quality Management System is fully implemented in their associated area of responsibility.

Role	Responsibility within the Quality System
Chief Information Officer	The responsibility of the Chief Information Officer is to ensure appropriate IT resources are made available to implement the Quality Management System. The further responsibility of the Chief Information Officer is to ensure the Quality Management System is fully implemented in their associated area of responsibility.

The following are the key Quality System Management roles and their associated responsibility with respect to Quality within the organisation.

Role	Responsibility within the Quality System
National Quality Assurance Manager	The National Quality Assurance Manager is responsible for the effective implementation of the Quality Management System across the organisation.
Quality Systems Development Manager	The Quality Systems Development Manager is responsible for the development and management of electronic systems for managing the QMS.
Validation Manager	The responsibility of the Validation Manager is to implement the Quality Management System across the organisation with respect to Management of Validation, Equipment Maintenance & Calibration
IT Quality Manager	The responsibility of the IT Quality Manager is to implement the Quality Management System across the organisation with respect to the IT department and computer systems.
Quality Compliance and Regulatory Manager	The responsibility of the Quality Compliance and Regulatory Manager is to ensure the Quality Management System meets international best practice, GMP & regulatory requirements across the organisation. This includes management of Internal and external inspections to drive continuous improvement.
Quality Control Manager	The responsibility of the QC Manager is to implement the Quality Management System across the organisation with respect to Quality Monitoring, Environmental Monitoring and Materials Management.
Risk and Resilience Manager	The responsibility of the RR Manager is to implement the Quality Management System across the organisation with respect to Quality Risk Management.

8 IBTS QUALITY SYSTEM

The IBTS Quality Manual has been subdivided into the following sections to meet the current Regulatory Requirements as described in the Good Practice Guidelines. Each section defines the IBTS quality management system approach. This describes the overall quality management system in the organisation. Detailed and specific aspects of the quality management system for specific areas of IBTS business are described in the relevant referenced documents.

8.1 Quality System– General

The Quality System encompasses the following;

- quality management
- quality assurance
- continuous quality improvement
- personnel
- premises & equipment
- documentation
- collection
- testing
- processing
- storage
- distribution
- quality control including statistical process control
- recall
- external and internal auditing
- contract management
- non-conformance
- self –inspection
- training

8.2 Quality System – Good Practice

Good Practice is the part of Quality Management that ensures that blood, blood components and tissue are produced and controlled consistently to the quality standards appropriate to their intended use. The IBTS operates according to good practice by;

- Clearly defining all processes and ensuring they are reviewed systematically
- Ensuring the requirements for Quality Control are met.
- Performing quality reviews of all blood and tissue products according to defined procedure.

8.3 Quality System – Quality Risk Management

The Executive Management Team (EMT) has the overall responsibility for all aspects of Risk Management in the IBTS. The appointed Risk and Resilience Manager provides the necessary guidance and support to fulfil these requirements. The IBTS Risk Management policy (IBTS/RR/POL/0002) describes:

- the objectives of IBTS risk management arrangements;
- compliance with risk management;
- risk management principles;
- roles and responsibilities;
- escalation, reporting and review of risks, and;
- risk appetite statement.

In addition quality risk management is embedded in all areas of the quality system and is described in the individual policies and procedures that cover each area. E.g. Quality Risk Management in Change Management is described in IBTS/QA/POL/0001

The risk and resilience manager maintains a corporate risk log for the management and control of risk at a high level.

8.4 Personnel & Organisation

The Human Resources Department of the IBTS has in place personnel and recruitment policies. Refer to IBTS HR Policies and Procedures Manual located at: \\nbcfileprintsvr.ibts.local\IBTS_HR_Policies&Procedures$

The IBTS ensures that all Personnel are sufficiently qualified and trained for tasks they are expected to perform. Job descriptions are developed to individually define the high level responsibilities. Additional specific detailed responsibilities are defined in the specific plans / standard operating procedures in which the personnel are trained.

The IBTS ensures that at a minimum procedural based training is conducted and where necessary competency based training. This is described in IBTS/QA/POL/0007.

8.4.1. Responsible Person (Blood)

The IBTS designates a person who is responsible for the following functions (Ref Directive 2002/98/EC):

- ensuring that every unit of blood or blood components has been collected and tested, whatever its intended purpose, and processed, stored, and distributed, when intended for transfusion, in compliance with the laws in force in the Member State.

- providing information to the competent authority in the designation, authorisation, accreditation or licensing

procedures as required in Article 5.
- implementing the requirements of Articles 10, 11, 12, 13, 14 and 15 in the blood establishment.

8.4.2. Responsible Person (Tissue)

The IBTS designates a person who is responsible for the following functions (Ref Directive 2004/23/EC)**:**

- ensuring that human tissues and cells intended for human applications in the establishment for which that person is responsible are procured, tested, processed, stored and distributed in accordance with this Directive and with the laws in force in the Member State.
- providing information to the competent authority or authorities as required in Article 6.
- implementing the requirements of Articles 7, 10, 11, 15, 16 and 18 to 24 within the tissue establishment.

8.4.3. Responsible Person (GDP)

The IBTS designates a person who is responsible for the following functions:

- Ensuring that a quality management system is implemented and maintained.
- Focusing on the management of authorised activities and the accuracy and quality of records.
- Ensuring that initial and continuous training programmes are implemented and maintained.
- Coordinating and promptly performing any recall operations for medicinal products.
- Ensuring that relevant customer complaints are dealt with effectively.
- Ensuring that suppliers and customers are approved.
- Approving any subcontracted activities which may impact on GDP.
- Ensuring that self-inspections are performed at appropriate regular intervals following a prearranged programme and necessary corrective measures are put in place.
- Keeping appropriate records of any delegated duties.
- Deciding on the final disposition of returned, rejected, recalled or falsified products.
- Approving any returns to saleable stock.
- Ensuring that any additional requirements imposed on certain products by national law are adhered to.

8.4.4. The IBTS ensures that the responsible person(s) fulfils the regulatory requirement for qualifications, experience and knowledge.

8.4.5. In the absence of the responsible person the IBTS has nominated a delegate.

8.4.6. The Responsible Person(s) and delegate(s) are listed in the relevant authorisations. The list of authorisations is contained in Attachment 6.2.

8.4.7. Laboratory Director Red Cell Immunohaematology Laboratory
The IBTS designates a person with the competence and delegated responsibility for the services provided. This is further described in IBTS/RCI/LM/0001.

8.4.8. Laboratory Director Molecular Biology and Genetics Laboratory
The IBTS designates a person with the competence and delegated responsibility for the services provided.

8.5 Premises

The IBTS ensures that Premises / Facilities is located, designed, constructed, adapted and maintained to suit the operations to be carried out. The IBTS ensures where possible the layout and design aims to minimise the risk of errors and permit effective cleaning and maintenance in order to avoid any adverse effect on blood component, tissue and cell product.

8.6 Equipment & Materials

The IBTS ensures that Equipment / Systems are located, designed, constructed, adapted and maintained to suit the operations carried out. The IBTS ensures where possible the layout and design aims to minimise the risk of errors and permit effective cleaning and maintenance in order to avoid any adverse effect on tissue and cell product.

8.6.1 Data processing systems (Computerised Systems)

Where computerised systems are used, software, infrastructure and back-up procedures are checked regularly to ensure reliability, are validated before use, and are maintained in a validated state. Infrastructure and software are protected against unauthorised use or unauthorised changes. The back-up procedure prevents loss of or damage to data at expected and unexpected down-times or function failures (Directive/2005/62/EC/Annex 4.5).

The IBTS ensures computer systems are properly maintained at all times with a documented maintenance strategy. All changes to computerised systems are validated and maintained in a validated state.

The IBTS ensures data is protected with safeguards in place to prevent unauthorised additions, deletions or modifications of data and transfer of information are in place to resolve data discrepancies, and to prevent unauthorised disclosure of such information.
There is a hierarchy of permitted user access to enter, amend, read or print data. To prevent unauthorised access, there are personal passwords in place on computer systems that are changed regularly. Further information is described in the IT Manual (IBTS/IT/QM/0001).

8.6.2 Qualification & Validation

The IBTS identifies all equipment / systems / processes which have a direct or indirect impact on Blood / Tissue product quality that require validation.
The IBTS has developed a Validation Master Plan (IBTS/QA/VMP/0001) and associated Validation Matrix to validate all equipment / systems / processes identified as having a direct or indirect impact on Blood / Tissue product quality.
The IBTS has developed a Calibration / Maintenance Master Plan (IBTS/QA/VMP/0006) to ensure the validated state of equipment / systems are maintained.

8.6.3 Process Validation

The IBTS has a system in place to cover the initial validation of new processes, subsequent validation of modified processes or site transfers for maintaining of the validated state (on-going process verification) with reference to the validation master plan (IBTS/QA/VMP/0001). Process validation of new blood components or tissue covers all intended processes and sites of manufacture. During process validation the IBTS establishes whether all quality attributes and process parameters, which are considered important for ensuring the validated state and acceptable blood component or tissue quality, can be consistently met by the process. Ref to the processing matrix (IBTS/SSCD/PMX/0001).

8.6.4 Validation of test methods

The IBTS ensures all analytical test methods used in qualification or validation exercises are validated with an appropriate detection and quantification limit as described in the validation master plan (IBTS/QA/VMP/0001).
When microbial testing of blood components or tissue is performed, the method is validated to confirm that the product or residues, e.g. antibiotics, do not interfere with the analysis and influence the recovery of microorganisms.

When microbial testing of surfaces is carried out, validation is performed on the test method to confirm that sanitising agents do not influence the recovery of microorganisms.

8.6.5 Change Control

The IBTS ensures the change management process describes the actions to be taken if a planned change is proposed for a starting material, blood component specification, tissue specification, process, equipment, environment (or site), product range, method of production or testing or any other change that may affect donor safety, blood or tissue component quality or reproducibility of the process. This is further described in IBTS/QA/POL/0001.

Quality risk management is used to evaluate planned changes to determine the potential impact on blood component or tissue quality, the blood or tissue establishment's quality systems, documentation, validation, regulatory status, calibration, maintenance on any other system to avoid unintended consequences and to plan for any necessary process validation, verification or requalification efforts.

8.6.6 Control of equipment & materials

The IBTS ensures there is a documented system for purchasing equipment and materials as per specific departmental operating procedures. The specific requirements for establishing and reviewing contracts for the supply of both equipment and materials are described in IBTS/ADM/POL/0001.

The calibration and maintenance of equipment is defined in IBTS/QA/VMP/0006 and specific departmental operating procedures and requalification documents.

8.6.7 Materials Management

The IBTS operates a system of Materials Management. Requirements will be defined in specific departmental operating procedures.

Testing and management of critical materials for blood and tissues is defined in dedicated standard operating procedure(s) and critical starting material lists with reference to Material Specifications.

The In Vitro Device Regulation (IVDR), outlines that in-house In Vitro Devices (IVDs) can be made and used by IBTS Laboratories to address an unmet clinical need where CE marked alternatives are not available or suitable for the patient population. Guidance for the implementation of the requirement of

Regulation (EU) 2017/746 is described in IBTS/QA/POL/0012 and implemented in specific testing laboratory operating procedures.

8.7 Documentation

8.7.1 Required good practice documentation

The IBTS ensures current documents exist that set out specifications, procedures and records covering each activity undertaken in the blood and tissue establishment The IBTS documentation and record management policies are described in IBTS/QA/POL/0002 and IBTS/DP/POL/0018.
The IBTS document policies describe both the control of internal and external documentation

8.7.2 Generation & Control of documentation

The IBTS establishes a system of document control, through which the IBTS takes all necessary measures to ensure that the quality system includes at least documentation on the following:

- Laboratory and Department manuals
- Policies
- SOPs
- Guidelines
- User guides
- Customer manuals, Lab Manuals, Dept Manuals
- Training and reference manuals,
- Reporting forms,
- Donor records, and
- Information on the final destination of blood products, tissues and cells.

The IBTS ensures that this documentation is readily available for inspection by the Competent Authority.

8.7.3 Good documentation practice

The IBTS follows good documentation practice in all areas of the IBTS as laid out in IBTS/QA/POL/0002 and associated standard operating procedures.

8.7.4 Retention of documents

The IBTS prescribes to a defined system for the retention and control of documentation as described in IBTS/DP/POL/0002.

8.7.5 Specifications

The IBTS ensures there are current, authorised specifications for starting and packaging materials, as well as finished tissue, blood and blood components. The finished tissue and blood components specifications are detailed in the.

8.7.6 Preparation Instructions

The IBTS ensures there are approved written instructions for preparation of each blood components and tissue / cell that is produced

8.7.7 Labelling

Through the use of product master file specifications the IBTS ensures that labelling should identify the individual components and their nature clearly at all stages of production.

8.7.8 Procedures & Records

With departmental operating procedures the IBTS ensures there are written procedures and records for the receipt of each delivery of materials and reagents that can impact on the quality and safety of blood and blood components and tissues / cells.
The Materials Management department manages operating procedures and starting materials lists for the internal labelling, quarantine and storage of starting materials, packaging materials and other materials.
The Tissue Bank in conjunction with the Materials Management department manages operating procedures and starting materials lists for the internal labelling, quarantine and storage of starting materials, packaging materials and other materials relating to Tissues and cells.

8.7.9 Sampling

The IBTS ensures that procedures exist for the following;

- Sampling
- Quality monitoring
- Testing of materials, blood components, tissues and cells at different stages of processing.

8.7.10 Other

The IBTS ensures the following are available;

- Procedures for release and rejection of blood, blood components, tissue and cells.
- Records of the distribution of blood, blood components, tissue and cells and medicinal products to facilitate any necessary recall with reference to IBTS/QA/POL/0005.
- Records are kept for major or critical analytical testing, processing equipment, and areas where blood components or Tissue and cells have been processed.

The IBTS ensures the non conformance policy (IBTS/QA/POL/0003), and associated SOPs allow recording of actions and conclusions reached where there have been issues with any of the following;

- Validation and qualification of processes, equipment and systems.
- Equipment assembly and calibration.
- Maintenance, cleaning and sanitation.
- Personnel matters, including signature lists, training in Good Practice and technical matters, clothing and hygiene, and verification of the effectiveness of training.
- Environmental monitoring.
- Pest control.
- Complaints.
- Recalls.
- Returns.
- Change control.
- Investigations of deviations and non-conformances.
- Audits of compliance with internal quality/Good Practice;
- Summaries of records, where appropriate (e.g. review of the quality of blood components).
- Supplier audits.

8.8 Blood and Tissue / Cells collection, testing & processing

8.8.1 Donor selection and eligibility

The IBTS ensures donor selection and eligibility for blood components is performed as described in relevant Medical Guidelines.

8.8.2 Collection of blood & blood components & Tissue / Cells

The IBTS ensures the collection and processing of blood & blood components & Tissue / Cells is performed.

8.8.3 Laboratory testing

The IBTS maintains policies / standard operating procedures for quality control testing for blood products and tissue.

8.8.4 Testing for infectious markers

The IBTS maintains policies / standard operating procedures for blood products and tissue for the following;

- Viral Screening of virology markers
- NAT testing of virology markers
- Bacterial screening tests

8.8.5 Blood group serological testing of donors & donations

The IBTS maintains policies / standard operating procedures for Donor Grouping Testing for blood products.

8.8.6 Processing & validation

The IBTS ensures the following as described in IBTS/QA/VMP/0001 and IBTS/SSCD/PMX/0001;

- All equipment is used according to validated procedures
- Processing of blood components, tissue and cells is performed using appropriate and validated procedures
- Closed systems are used for processing where possible
- Freezing processes are validated according to worst case scenarios
- Sterile connecting devices are used according to the validated procedures.

8.8.7 Labelling

The IBTS maintains policies / standard operating procedures for blood products and tissue, labelling and packaging.

8.8.8 Release of blood & blood components and Tissue

The IBTS maintains policies / standard operating procedures for the release of blood products and tissue.

8.9 Storage & Distribution

The IBTS maintains policies / standard operating procedures for blood products and tissue storage, that will ensure;

- that personnel directly involved in activities relating to the storage of blood products and tissue are qualified to perform such tasks and shall be provided with the appropriate training
- that all procedures associated with the storage of products are documented in the standard operating procedures and that the storage conditions comply with predetermined acceptance criteria
- procedures for the control of packaging and storage areas, in order to prevent any situation arising that might adversely affect the functioning or integrity of blood products and tissue

The IBTS maintains policies / standard operating procedures for management of blood products and tissue distribution.

8.10 Outsourced Activities Management

The IBTS establishes written agreements with a third party each time an external activity takes place which influences the quality and safety of blood products and tissue processed in cooperation with a third party, and in particular in the following circumstances with reference to IBTS/ADM/POL/0001;

- Where the IBTS entrusts one of the stages of blood products or tissue processing to a third party,
- Where a third party provides goods and services that affect blood products or tissue quality and safety assurance, including their distribution,
- Where the IBTS distributes blood products or tissue processed by third parties.
- Where the IBTS provides blood products / tissue to hospitals
- Where the third party provides referral testing services for patient service testing.

8.10.1 The contract giver

The IBTS evaluates and selects third parties on the basis of their ability to meet the standards laid down in the appropriate EU Blood and Tissue Directives.

The IBTS keeps a complete list of the agreements that they have established with third parties.

The IBTS ensures all relevant information is provided to the contract acceptor to ensure contracted operations are performed as required in the contract.

8.10.2 The contract acceptor

Where the IBTS entrusts a third party to carry out work on their behalf they ensure the contract acceptor has adequate premises, equipment, knowledge, experience and competent personnel.

The contract acceptor will not pass to a third party any of the work entrusted under the contract without prior evaluation and approval of the arrangements by the IBTS. Arrangements made between the contract acceptor and any third party should ensure that the relevant blood or tissue collection, processing and testing information is made available in the same way as between the original contract giver (IBTS) and contract acceptor.

8.10.3 The contract

The IBTS ensures that all contracts with third parties specify their respective responsibilities relating to the contracted operations.

The contract ensures all arrangements for blood or tissue collection, processing and testing are in compliance with the requirements of Good Practice and regulatory requirements and agreed by both parties.

The contract specifies detailed procedures for the IBTS and the contract acceptor.

The contract clearly describes who is responsible for purchasing materials, testing and releasing materials, undertaking blood or tissue collection, and for processing and testing (including in-process controls). Where analyses are sub-contracted, the contract states the arrangements for the collection of samples and the contract acceptor understands that they may be subject to inspections by the Competent Authority.

The IBTS ensures any records relevant to assessment of the quality of the blood, tissue or a blood component in the event of complaints or a suspected defect are be accessible and specified in the IBTS defect/recall procedures.

The contract permits the IBTS to audit the facilities of the contract acceptor.

The agreements between the IBTS and third parties are available for examination by the Competent Authority.

8.11 Non-Conformance & Recall

8.11.1 Deviations & CAPA

The IBTS operates an incident reporting system. This is implemented through standard operating procedure with reference to the policy, IBTS/QA/POL/0003. The incident reporting system defines and categorises incidents, manage incident corrective / preventative actions and tracks / trends incident reports.

8.11.2 Complaints

The IBTS operates a complaints system. This is implemented through standard operating procedure with reference to the policy, IBTS/QA/POL/0003. The complaint reporting system defines and categorises complaints, manage associated corrective / preventative actions and tracks / trends complaints. The complaint system operates for donor / service and product complaints.

8.11.3 Serious Adverse Event / Reactions

The IBTS ensures that all serious adverse events and reactions are notified to the competent authority. The IBTS manages this through its vigilance procedures IBTS/QAV/SOP/0001 and IBTS/QAV/SOP/0002. The notification reports;

- Any serious adverse events and reactions which may have an influence on the quality and safety of blood products and tissues and / or which may be attributed to blood products collected, tested, processed, stored and distributed or which may be attributed to the procurement, testing, processing, preservation, storage and distribution of tissues.
- Any serious adverse reactions observed during or after clinical applications, which may be linked to the quality and safety of blood products collected, tested, processed, stored and distributed and tissues tested, processed, preserved, stored or distributed.

8.11.4 Recall

The IBTS operates a system to ensure that an accurate, rapid and verifiable procedure is in place, which enables it to recall from distribution any Blood Products or Tissues that are found to be in non conformance with procedures / specifications. This is implemented through standard operating procedure with reference to IBTS/QA/POL/0005.

The IBTS ensures there is a system in place for the recall of medicinal products as described IBTS/QA/SOP/0014

8.12 Self-inspection, audits & improvement

The IBTS operates an Internal / External Audit Process with reference to IBTS/QA/POL/0006. This is implemented through standard operating procedure. The IBTS creates and executes an Annual Internal / External Audit schedule.

8.13 Quality Monitoring & Control

8.13.1 Quality monitoring

IBTS operates a quality monitoring programme. Specific Quality Monitoring Requirements are listed in the individual blood and tissue components specifications

8.13.2 Quality control

The IBTS operates a system of Quality Control. This is implemented through standard operating procedure(s). The Quality Control procedures define sampling, specifications and testing associated with;

- Blood Products throughout the collection, testing, processing, storage and distribution of human blood and blood products.
- Tissues throughout the procurement, testing, processing, preservation, storage and distribution of tissues and cells.

These are defined in the specific department procedures. Batch acceptance testing and management of critical materials for the blood, tissues are defined in dedicated standard operating procedure(s).

8.14 Quality Management – Change Control

The IBTS operates a Change Management system as described in IBTS/QA/POL/0001.Thisis implemented through standard operating procedure. The change control system ensures that an effective change management process is in place for any significant change requested under the Quality System or any change which has a direct or indirect impact to Product quality.

8.15 Regulatory Authorisation

See section 4 and 5 for description of regulatory requirements and authorisations.

The IBTS provides an annual report to the Competent Authority (HPRA) to comply with authorisation requirements for both the blood and tissue operations.

8.16 Traceability

The IBTS operates a system of traceability, through which the IBTS takes all necessary measures to ensure that;

- all blood and tissues, which it procures, processes, stores or distributes, can be fully identified and traced from donor to end user, or disposal, and vice versa, in accordance with the Irish Regulations. This traceability also applies to all relevant data relating to products and materials coming into contact with these tissues and cells as described in IBTS/DP/POL/0002.
- a donor identification system is in place, which assigns a unique numeric or alphanumeric donation indication, to each of the products associated with it.
- a labelling system is in place that contains the information or references

The IBTS keeps the traceability records and additional records which are necessary as defined in IBTS/DP/POL/0002;

- for the identification and traceability of each single blood component, tissue donation and each single blood component, tissue unit and its products and products coming into contact with these blood products, tissues,
- to ensure full traceability from donation and procurement, processing or storage to the point of delivery to a hospital or site, and at all stages,
- for a period of not less than 30 years after clinical use.

The IBTS ensures that the labelling, documentation and packaging on all blood and blood products and on each tissue supplied conform to the requirements in SI 360/05 and SI 158/06.
This is implemented through standard operating procedure(s).

8.17 Import / Export

The IBTS ensures that imported blood component products and tissues;

- can be traced in both directions from donor to the recipient in accordance with the requirements in the EU Blood and Tissue Directives
- meet standards of quality and safety equivalent to those laid down in the EU Blood and Tissue Directives and IBTS Quality Standards
- have a clear fating with respect to traceability.

The IBTS;

- verifies and records the fact that the packaging of blood products and tissue complies with the requirements set out in the EU Blood and Tissue Directives and IBTS Quality Standards
- ensures that blood components and tissues that do not comply are appropriately managed.
- documents the acceptance or rejection of received blood products and tissue
- ensures that blood products and tissue are correctly identified at all times. Each delivery or batch of blood products and tissues are assigned an identifying code
- holds blood product and tissue in quarantine until such time as the requirements relating to donation, testing and information have been met in accordance with procedure / specification

The IBTS ensures that exported blood component products and tissues meet standards of quality and safety equivalent to those laid down in the EU Blood and Tissue Directives and IBTS Quality Standards

8.18 Data Protection / Confidentiality

The IBTS through the implementation of IBTS/DP/POL/0001 and associated policies and standard operating procedures ensures that all information, which is collected is held securely so that it is;

- available for the purpose of tracing donations,
- Subject to safeguards against unauthorised additions, deletions or modifications to donor files or deferral records and transfer of information.
- disclosed under identified exceptions

The IBTS ensures that procedures to resolve data discrepancies are in place.

The IBTS ensures that the identity of the recipient of tissue is not disclosed to the donor or his family and vice versa, without prejudice to any national law which may come into force on the conditions for disclosure.

8.19 Business Continuity

The IBTS ensures Business Continuity through the following IBTS Policies and associated Business Continuity Plans;
IBTS/RR/POL/0001
IBTS/RR/POL/0003

8.20 Health and Safety

The IBTS ensures Health and Safety at the Organisation through the Health and safety policies managed by the Health & Safety (H&S) Manager. These are controlled under the direction of the H&S Manager.

8.21 Haemovigilance / Tissue Vigilance

The IBTS operates a Haemovigilance and Tissue Vigilance system with reference to the vigilance procedures, IBTS/QAV/SOP/0001 & IBTS/QAV/SOP/0002. These are managed by the IBTS BioVigilance Officer.

8.22 Therapeutic Services

The IBTS operates a Therapeutic Services in the MRTC region. This is implemented through standard operating procedure(s).

8.23 Contingency Arrangement

The IBTS ensures Business Continuity through the following IBTS contingency plans; IBTS/RR/BCP/0003 and IBTS/RR/BCP/0007

8.24 Import of Rare Blood & Components from non-EEA countries

The IBTS describes the policies relating to import of rare blood components from non-EEA countries in the relevant BE, TE and RCI manuals. IBTS/RR/BCP/0004.

8.25 Patient testing

Red Cell Immunohaematology (RCI) Testing
The IBTS maintains policies / standard operating procedures for RCI patient testing. See IBTS/RCI/LM/0001 for further detail.

Molecular Biology and Genetics (MBG) Testing
The IBTS maintains policies / standard operating procedures for MBG patient testing.

9 REFERENCES

The following references were used in the development of this document:

9.1 Regulatory Requirements as listed in section 4
9.2 ISO 9001 – Quality Management Systems (IBTS/EXT/DOC/0021)
9.3 ISO 15189 - Medical Laboratories – Particular requirement for Quality and Competence (IBTS/EXT/DOC/0033)
9.4 Council of Europe, Guide to the preparation, use and quality assurance of blood components, current edition (IBTS/EXT/DOC/0002)
9.5 Council of Europe, Guide to the quality and safety of tissues and cells for human application, current edition (IBTS/EXT/DOC/0003)
9.6 Guidelines on Good Distribution Practice of medicinal products for human use (IBTS/EXT/DOC/0004)
9.7 Minimum requirements for Blood Bank compliance with article 14 and article 15 of EU directive 2002/98/EC (AML-BB) (IBTS/EXT/DOC/0017)
9.8 Guidelines for the Blood Transfusion Services in the UK, current edition. (IBTS/EXT/DOC/0007)
9.9 PIC/S GMP Guide For Blood Establishments. (IBTS/EXT/DOC/0005)

Definitions are described in IBTS/QA/LIST/0002.

10 ATTACHMENTS

10.1 Quality Policy
10.2 Authorisations/ Accreditations
10.3 IBTS Organisation Chart

IBTS QUALITY POLICY

The IBTS is committed to providing to all donors, patients, hospital scientific and clinical staff the highest quality in;

- blood and tissue products
- diagnostic and distribution services
- consultative services

The Quality Objectives, through which this quality policy is implemented, are to;

- comply with all relevant legislation, standards and guidelines.
- operate an effective quality management system, the purpose of which is to maintain and improve the quality and safety of the products and services provided.
- continuously improve the quality management system to ensure efficiency and ease of use by all.
- train IBTS staff in the quality management system to ensure consistency, effectiveness and user satisfaction.
- uphold professional values, good professional practice and embed a quality culture in line with IBTS values.

Signed_____ **Date**_____

Director of Quality and Compliance

IBTS Authorisations / Accreditations Held

Business Area	Authorisations/ Accreditations	IBTS Doc Ref.
Blood	Blood Establishment (Authorisation No. BE-002) under the terms of S.I. No. 360 of 2005.	IBTS/QA/AUTH/0001
Tissue	Tissue Establishment (Authorisation No. TE-012) under the terms of S.I. No. 158 of 2006.	IBTS/QA/AUTH/0002
	Manufacturing Authorisation Holder (Authorisation No.M11514 /00001) in accordance with 2001/83/EC and under the terms of the Medicinal Products (Control of Manufacture) Regulations 2007 to 2013 and S.I. No. 539 of 2007.	IBTS/QA/AUTH/0003
GDP	Wholesaler at NBC (Wholesale Distribution Authorisation No. W00011/00001) in accordance with 2001/83/EC transposed into the Medicinal Products (Control of Wholesale Distribution) Regulations 2007 to 2013 and S.I. No. 538 of 2007.	IBTS/QA/AUTH/0004
	Wholesaler at MRTC (Wholesale Distribution Authorisation No. W00011/ 00002) in accordance with 2001/83/EC transposed into the Medicinal Products (Control of Wholesale Distribution) Regulations 2007 to 2013 and S.I. No. 538 of 2007.	
IUBMR	WMDA - Full Standards Certification	IBTS/QA/AUTH/0007
MBG – NHIRL	EFI No. 03-IE-002.998, Reference Laboratory (NHIRL) Irish Blood Transfusion Service	IBTS/QA/AUTH/0008

Summary Organogram

Target State (Interim) Organisational Structure 2022 – 2025