Importation of Medical Devices with Biological Material Guideline

National Health Regulatory Authority (NHRA)

Kingdom of Bahrain

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Contents

1. Introduction

This guideline is intended to guide through the process and requirements of importing medical devices utilizing human/animal tissues and their derivatives. The process and requirements differ from the active medical device importation due to the risk of disease transmission from animals to humans.

2. Medical Device utilizing human origin product

Devices manufactured utilizing derivatives of tissues or cells of human origin which are non-viable or are rendered non-viable.

Requirements for importation and registration:

In addition to NHRA checklist of registration, the below documents are required:

- Statement issued from the manufacturer that the final product is tested and found to be free of communicable diseases.
- Methods of traceability system issued and clarified by the manufacturer.
- Accreditation Certificate from the Certified Tissue Bank (AATB, EATB or Similar).
- Tissue Establishment License.

3. Blood/ Plasma derived devices.

Human plasma is a source of important medical device which are obtained by a combination of large-scale processing steps called “fractionation”. It is important that these products have an appropriate quality and safety profile.

Plasma is the liquid portion remaining after separation of the cellular elements from blood collected in a receptacle containing an anticoagulant, or separated by continuous filtration or centrifugation of anticoagulated blood in an apheresis procedure.

Ex: Hemeostatic sponges, fibrin/thrombin sealant, heparin coated devices.

Requirements for importation and registration:

In addition to NHRA checklist of registration, the below documents are required:

- Plasma Master File including:
  - Quality assurance certificate for collection.
  - Blood/plasma collection establishments license.
  - Post collection information system.
  - Specification for bags for collection & storage of blood & plasma.
  - Storage & transport of plasma.
- Certificate that the product is free from all types of relevant communicable diseases.
- IQPP certificate of Plasma storage centers and Plasma Banks.

Please refer to below glossary for more information and clasrification.

4. Medical Devices manufactured from or incorporated animal tissue/derivatives.

Animal tissues and their derivatives are used in the design and manufacture of medical devices to provide performance characteristics that have been chosen for advantages over non-animal-based materials. The range and quantities of materials of animal origin in medical devices vary. These materials can comprise a major part of the device (e.g. bovine/porcine heart valves, bone substitutes for use in dental or orthopedic applications, haemostatic devices), can be a product coating or impregnation (e.g. collagen, gelatin, heparin), or can be used in the device manufacturing process.

Requirements for importation and registration:

In addition to NHRA checklist of registration, the below documents are required:

- Quality assurance certificate ISO 22442.
- Certificate that the product is free from all types of relevant communicable diseases.
- Accreditation Certificate from the Certified Tissue Bank (AATB, EATB or Similar).
- Tissue Establishment License.

5. Labelling Requirements

The label shall include the following information:

Where applicable, an indication that the device contains or incorporates:

- tissues or cells, or their derivatives, of human origin.
- tissues or cells, or their derivatives, of animal origin.

The instructions for use shall contain the following particulars:

Information that allows the user and/or patient to be informed of any warnings, precautions, contra - indications, measures to be taken and limitations of use regarding the device. This information shall cover, where appropriate:

- if the device is intended to administer tissues or cells, or their derivatives, of human or animal origin or biological substances, any limitations or incompatibility in the choice of substances to be delivered;

6. Glossary

No.	Terminology	Definition
1	**Medical Device**	means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of: 1. Diagnosis, prevention, monitoring, treatment or alleviation of disease, 2. Diagnosis, monitoring, treatment, alleviation of or compensation for an injury, 3. Investigation, replacement, modification, or support of the anatomy or of a physiological process, 4. Supporting or sustaining life, 5. Control of conception, 6. Disinfection of medical devices, 7. Providing information by means of in vitro examination of specimens derived from the human body; 8. And does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.
2	**Non-viable**	means having no potential for metabolism or multiplication.
3	**Derivative**	substance obtained from an animal material by a manufacturing process. (ex: Hyaluronic acid, collagen, gelatin, monoclonal antibodies, chitosan, albumin.)
4	**Tissue**	organization of cells and/or extra-cellular constituents
5	**Transmissible agents**	bacteria, mould, yeast, parasites, viruses, TSE agents and unclassified pathogenic entities

No.	Terminology	Definition
6	**International Quality Plasma Program (IQPP)**	To improve the quality and safety of source plasma, PPTA (Plasma Protein Therapeutics Association) developed the International Quality Plasma Program (IQPP). IQPP provides independent, third-party evaluation and recognition of a center's adherence to global industry standards for source plasma. IQPP certification is available to plasma collectors worldwide that have been licensed by a competent national regulatory authority.
7	**Plasma**	The liquid portion remaining after separation of the cellular elements from blood collected in a receptacle containing an anticoagulant, or separated by continuous filtration or centrifugation of anticoagulated blood in an apheresis procedure.
8	**Plasma master file (PMF)**	A document which provides all relevant detailed information on the characteristics of the entire human plasma used by a fractionator as starting material and/or raw material for the manufacture of sub-intermediate or intermediate plasma fractions, constituents of the excipient and active substance(s), which are part of a medicinal product/Medical Device incorporating stable derivatives of human blood or plasma.
9	**Plasmapheresis**	Procedure in which whole blood is removed from the donor, the plasma is separated from the cellular elements and at least the red blood cells are returned to the donor.
10	**Blood/plasma collection establishments**	Information on centers or establishments in which blood/plasma collection or processing is carried out, including inspection and approval, and epidemiological data on blood transmissible infections.
11	**Suitability of donors & the screening of donation**	Donors should be in good health at the time of donation and free of infections transmissible by blood.
12	**Post collection information system**	This includes a contract between the manufacturer of the plasma-derived product and the manufacturer of the finished medicinal product or the medical device in which maintenance of traceability records for at least 30 years after the time of donation is specified.

No.	Terminology	Definition
13	**Specification for bags for collection & storage of blood & plasma**	Information should be provided on the bags used for the collection of blood and plasma donations. This include the following: the name of the bag; composition of bag and its specification; its manufacturer; description of sterilization procedure and site where sterilization performed; the nature and composition of the anticoagulant solution; confirmation of compliance of bag and solution with European Pharmacopoeia requirements: the CE marking and a summary of any other licensing or registration (competent authority and type of licensing/registration).
14	**Storage & transport of plasma**	The procedure for collection, storage and transport of source materials should be described in the Plasma Master File. Maximum storage time should be stated. Information about the how storage conditions are maintained from the collection center to the manufacturer