FACILITATING THE AUTHORISATION OF

PREPARATION PROCESS FOR BLOOD, TISSUES AND CELLS

ANNOUNCEMENT

2021 Advanced training course on common approaches to preparation process authorisation (PPA) in the blood, tissues & cells, and MAR sectors

Co-funded by the Health Programme of the European Union

This report is part of the project/joint action '785269/GAPP' which has received funding from the European Union's Health Programme (2014-2020). The content of this report represents the views of the author only and is his/her sole responsibility; it can

To the national Competent Authorities (CAs) for blood, tissues and cells

GENERAL OBJECTIVE OF GAPP JOINT ACTION

The main objective is to facilitate the development of a common and optimal approach to assess and authorise preparation processes in blood and tissues establishments giving particular attention to innovative processes under development. Therefore, GAPP aims to ensure that blood and tissue and cell products and related processes are subject to European safety and quality requirements considering that, at present, there is not a full harmonisation among the Member States.

Based on the recognition of the common principles of quality and safety of blood and blood components, tissues and cells, the harmonisation of some of the guidance and training tools at the European level should be considered as a strategic step to ensure a high level of the protection for patients and donors.

GENERAL OBJECTIVE OF THE ADVANCED TRAINING COURSE

Due to the epidemiological contingency, the training course will be delivered remotely.

The target audience are experienced inspectors/assessors for blood establishments (BEs) and tissue establishments (TEs) processing reproductive cells for medically assisted reproduction (MAR) and non-reproductive tissues and cells.

The main reference document will be the “Overall Guidance on organization of PPA system” and the following technical annexes:

- Annex I – authorisation of changes in donation, procurement and collection, processing, preservation, storage and distribution;
- Annex II – assessing the quality and safety for donor/donation testing, pathogen reduction and sterilisation steps as part of PPA process;
- Annex III assessing clinical data as part of PPA;

In addition, a concept of a knowledge sharing platform on PPA between European Union CAs will be presented. The platform allows for a standardised, electronically supported assessment of quality, safety and efficacy of blood, cells and tissues, in the case of state-of-the-art as well as innovative processing procedures

LEARNING OUTCOMES OF THE TRAINING

The participants will:

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- gain the skill to perform risk assessment for the novel BTC and changes in their preparation processes, using the EuroGTP II risk assessment methodologies;
- learn how to define the extent of the required information for PPA based on the level of risk related to the novel BTC or change in the preparation process;
- know what to take into account when assessing the aspects affecting the microbiological quality and safety of blood, tissues and cells (BTC), including
    - competence of laboratories performing donor/donation infectious disease testing and microbiological testing of BTC,
    - reliability of the donor/donation infectious disease marker test kits,
    - effectiveness of pathogen reduction during BTC processing,
    - effectiveness of sterilisation methods during BTC processing,
    - microbiological status of final BTC products;
- know how to evaluate the clinical component of the Preparation Process Dossier (PPD);
- get to know the WP9 platform supporting the application for PPA and assessment of PPA dossiers;

GENERAL ORGANISATION OF THE COURSE

The maximum number of participants is 100: each EU MS CA, including Serbia and Moldova can enrol one inspector/assessor per field of the SoHO (blood, tissues & cells, MAR).

The course will be delivered through the support of the Medical University of Warsaw platform.

The training course will provide successful participants with No. 4 ECTS (European Credit Transfer and Accumulation System).

PARTICIPANTS SELECTION CRITERIA

The CAs will be responsible to nominate the applicants, who should have completed their basic training, should be approved as (lead) inspectors/assessors for one of the specific fields of blood, T&C and/or MAR in their CAs. Moreover, they should have inspection/assessment experience and knowledge of:

- EU Directives and the EDQM Blood and T&C Guides ;
- Inspection Guidelines for EU competent authorities responsible for the inspection and authorisation of blood and tissue establishments;
- Principles of quality assurance and quality management system, principles of good manufacturing procedures (GMPs), Good Practices for blood, tissues and cells (GPBTCs).

The previous participation in other European courses (e.g. VISTART, EUBIS, EUSTITE) and/or similar initiatives (e.g. CATIE) is highly recommended.

TIMEFRAME

Opening of the platform: 21/06/2021

The course will be composed of 3 parts:

- **E-LEARNING PART** (module 1-5) open from 28/06/2021 to 31/08/2021 for all the 100 participants
    - Quizzes after each module must be completed before starting next module.
    - All quizzes must be completed by participants within 31/08/2021
- **LIVE SESSIONS** (module 6 – 1 week) – 2 editions, 50 participants each:
    - 1st edition 20/09/ - 24/09/2021
    - 2nd edition 27/09/ - 1/10/2021
- **Q&A (FORUM), FINAL EXAM AND COURSE CLOSING** (module 7 – 1 week)
    - Forum all participants: 4/10 – 7/10/2021
    - Final exam for all participants: 8/10/2021

TOPICS

E-LEARNING

- **MODULE 1:**
    - Introduction to the course
    - Preparation Process Authorization (PPA) system – general remarks – on the basis of WP5 deliverables
- **MODULE 2:**
    - Authorisation of changes in donation, procurement and collection, processing, preservation, storage and distribution (including labelling and package inserts) – on the basis of WP6 deliverables
- **MODULE 3:**
    - Assessing the quality and safety of donor/donation testing, pathogen reduction and sterilisation steps as part of PPA – on the basis of WP7 deliverables
- **MODULE 4:**
    - Assessing clinical data as part of PPA authorisation – on the basis of WP8 deliverables
- **MODULE 5:**
    - The concept of a PPA platform – on the basis of WP9 deliverables

LIVE SESSIONS

- **DAY 1:** Practical exercise in working groups (case-study) on Blood (novel product or process) through the Euro-GTPII platform
- **DAY 2:** Practical exercise in working groups (case-study) on T&C (novel product or process) through the Euro-GTPII platform

- **DAY 3:** Practical exercise in working groups (case-study) on MAR (novel product or process) through the Euro-GTPII platform
- **DAY 4:** Demonstration on the online platform for an electronically supported preparation process authorisation (PPA) for blood, T&C and MAR (WP9)

REGISTRATION PROCEDURES

In order to register, applicants are kindly requested to duly fill in the dedicated form attached to the present Announcement. The applicant, who will be asked to express a preference on the edition of the live session in which he/she would like to participate[1], will have to send the registration form to Livia Cannata (livia.cannata@iss.it - cc: margherita.gentile@iss.it) **within and no later than May 28, 2021.**

No registration fees are foreseen.

ADDITIONAL INFORMATION

For further information, please do not hesitate to contact:

Izabela Tyszkiewicz at izabela.tyszkiewicz@kcbtik.pl (National Centre for Tissue and Cell Banking, Poland)

Livia Cannata at livia.cannata@iss.it (Italian National Blood Centre, Rome)

Margherita Gentile at margherita.gentile@iss.it (Italian National Transplant Centre, Rome)

[1] The final distribution will be up to the organisers.