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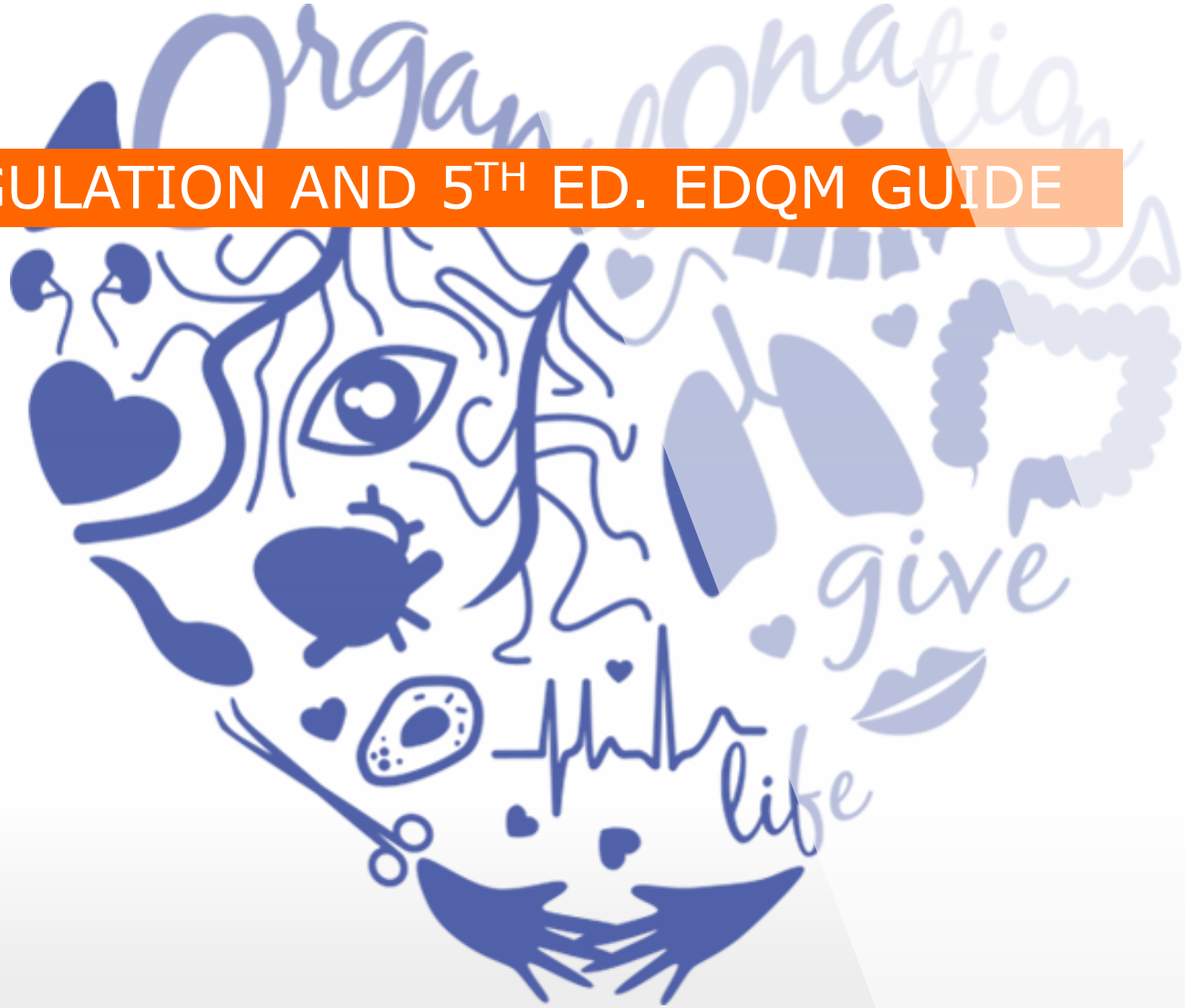
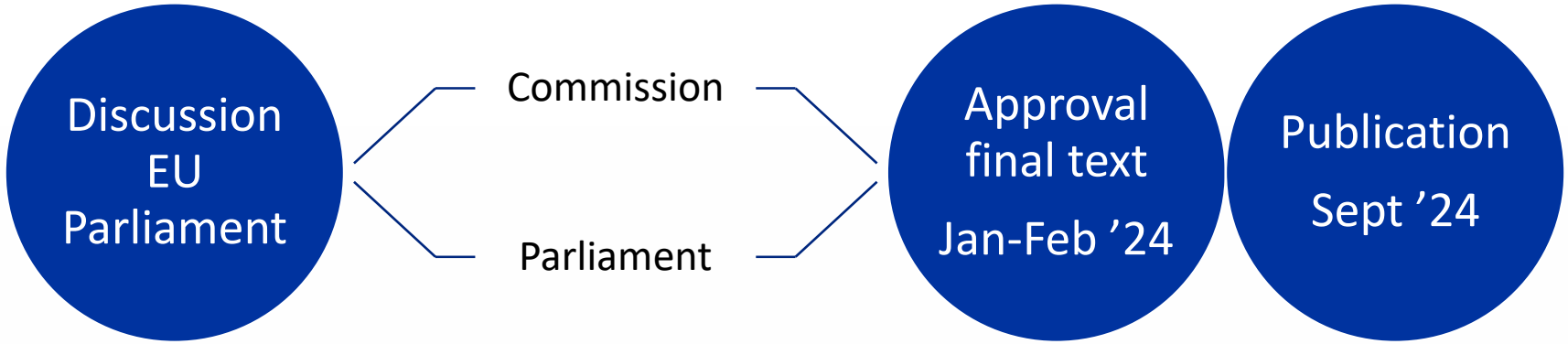
IMPACT COMING EU REGULATION AND 5TH ED. EDQM GUIDE

Johan Guns



COMING EU REGULATION

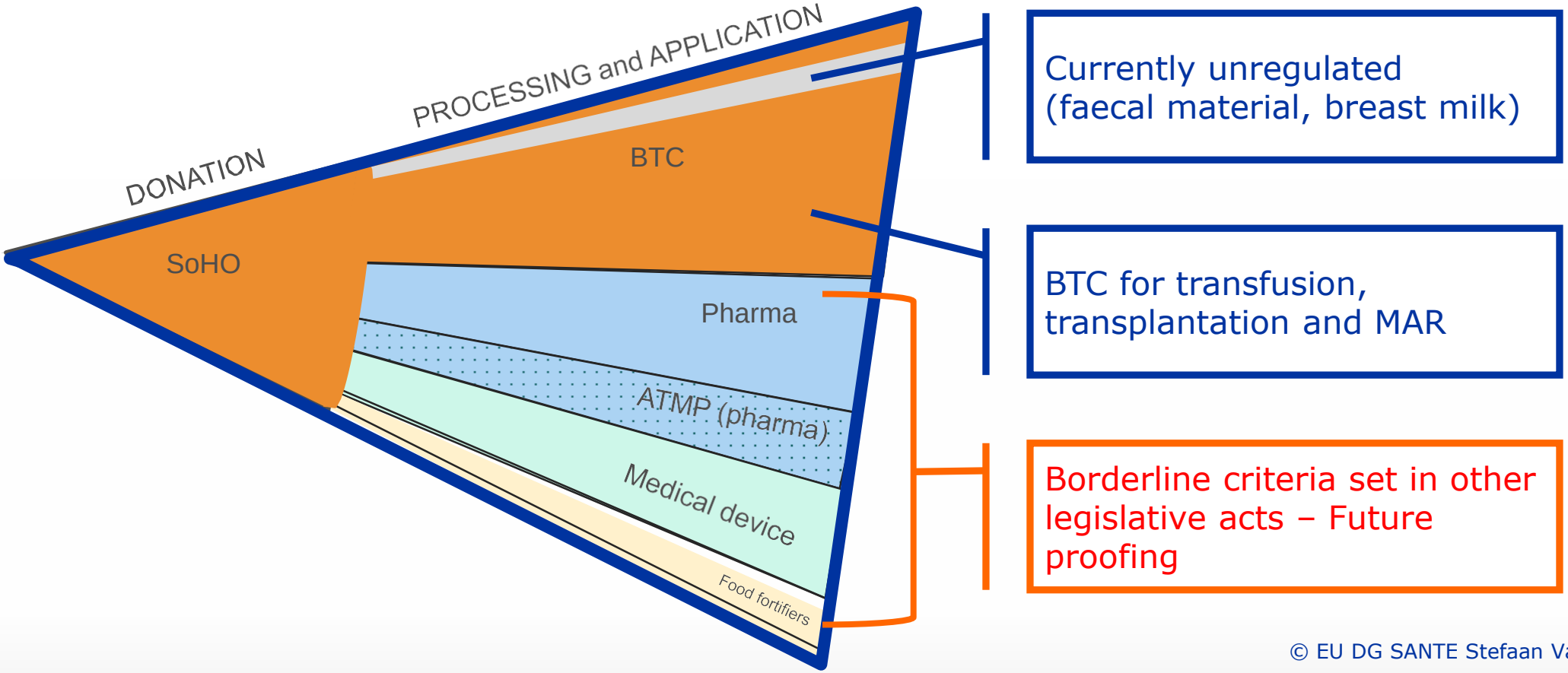
Optimistic predetermined timeline



2 years time for implementation → end 2026

SCOPE OF THE COMING EU REGULATION

Substances of Human Origin (SoHO), except organs and research



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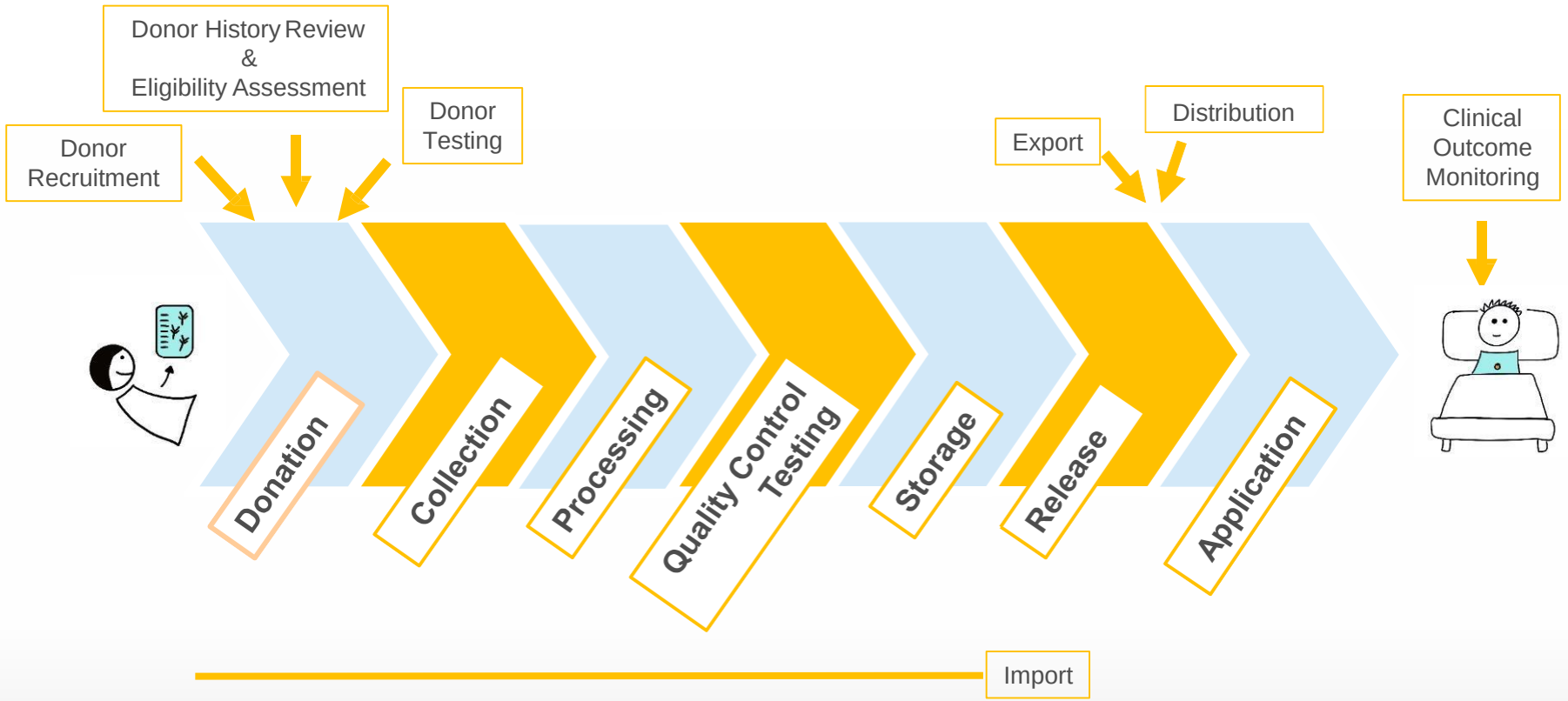
KEY DISCUSSION POINTS

A **SoHO entity carries out one or more SoHO activities**

A **SoHO establishment** carries out at least **processing and storage**



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KEY DISCUSSION POINTS

SoHO entities shall follow the highest available levels of standards (Art. 56 & 59):

Level 1 Commission Implementing Legislation → "where the Commission deems necessary"

If none:

Level 2 Technical Guidance on the EU SoHO Platform → Published & updated by ECDC/EDQM

OR

"Equivalent" Guidance → Entities shall demonstrate equivalance

If none:

Level 3 Methods based on international standards or scientific evidence → Entities shall demonstrate equivalance

NCA

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KEY DISCUSSION POINTS

Biovigilance

Directive 2004/23/EC

- Serious adverse events
- Serious adverse reactions

Table 17.1. **Severity scale for adverse reactions**

Not reportable	Insignificant	No harm to the recipient or living donor, and considered to be reportable as an event rather than a reaction according to EU directives
	Non-serious	Mild clinical consequences that do not necessitate hospitalisation and/or do not result in long-term disability or consequences for the recipient or living donor
To be reported	Serious	Adverse reaction resulted in: • hospitalisation or prolongation of hospitalisation and/or • persistent or significant disability or incapacity and/or • medical or surgical intervention to preclude permanent damage or impairment of a body function and/or • evidence of a serious transmissible infection and/or • birth of a child with a serious genetic disease after ART with non-partner gametes or donated embryos
	Life-threatening	• The living donor or recipient required major intervention after procurement or application of tissues or cells (vasopressors, intubation, transfer to the intensive care unit) to prevent death and/or • There is evidence of a life-threatening transmissible infection
	Fatal	Death in a living donor or a recipient of tissues or cells

Coming regulation

- Serious adverse occurences

Trigger? → Severity scale (EDQM 5th edition)

EDQM T&C GUIDE REVISION 5TH ED.

"Must" versus "Should"

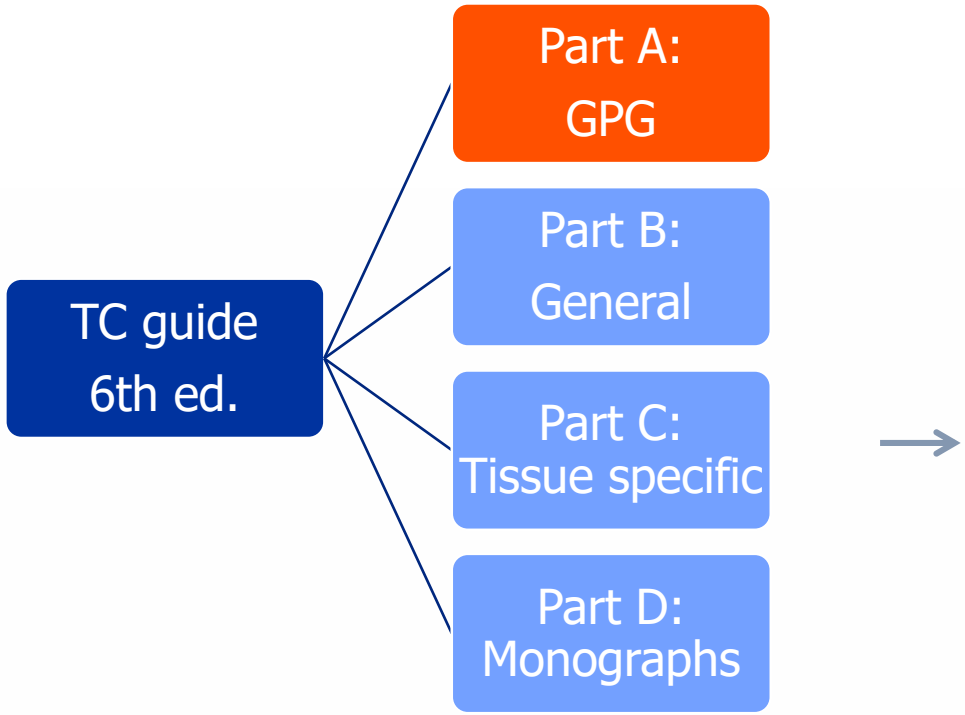
Directive 2004/23/EC

- Must → directives
- Should → good practice (expert committee)

Coming regulation

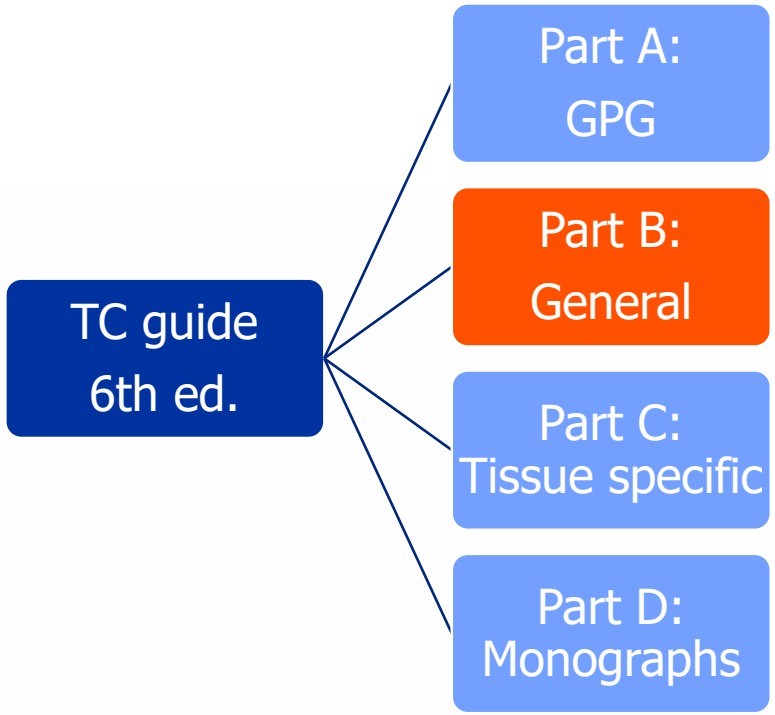
- Must → Regulation
- **Must → expert committee**
- **Should → Good practice (expert committee)**

EDQM T&C GUIDE REVISION 5TH ED.



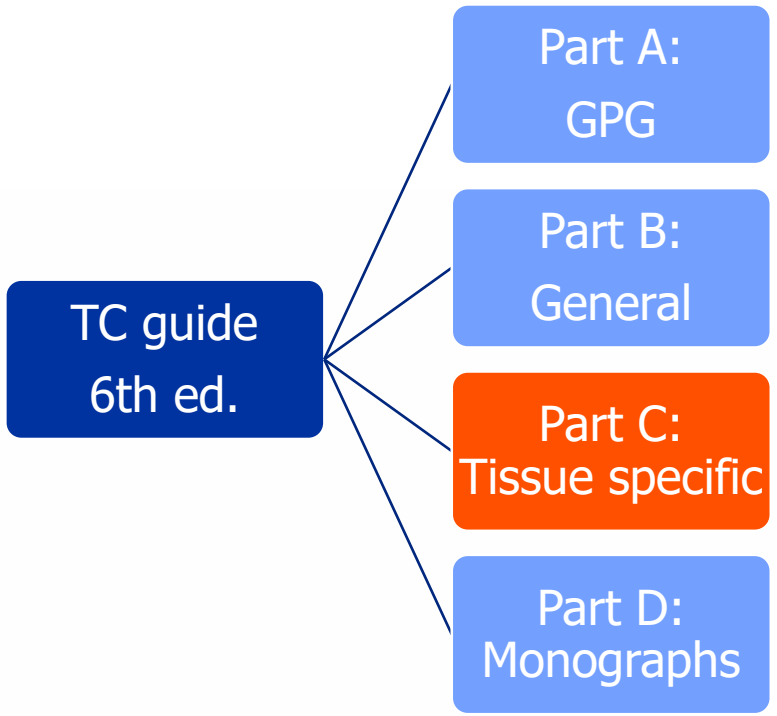
- ✓ TC-GPG describe the standards and specifications of quality systems to be implemented by TE that want to comply with EU requirements
- ✓ Heavily based on Directives, EDQM guide part A, EuroGTPs, JACIE and Blood Guide.
- ✓ The GPG for Tissue Establishments (TC-GPG) have been elaborated following the example of the Blood Guide

EDQM T&C GUIDE REVISION 5TH ED.



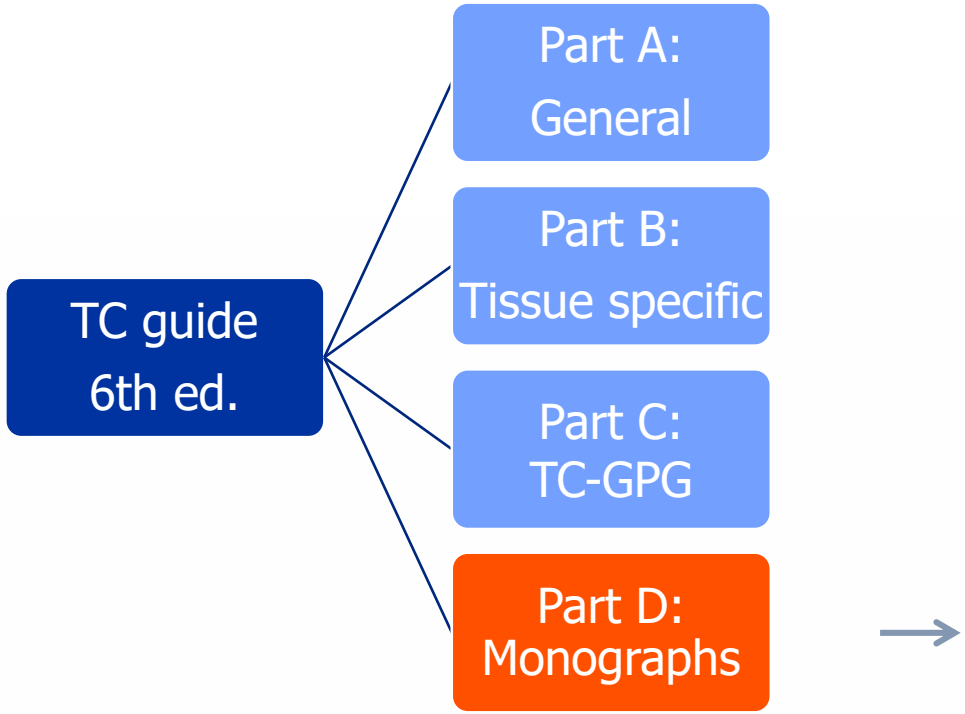
- Introduction
- **Quality management ~~and validation~~**
- **Qualification and validation**
- Risk management
- Recruitment of potential donors, identification and consent
- Donor evaluation
- Donor testing- markers for infectious diseases
- Procurement
- **Premises**
- Processing
- Storage
- Principles of microbiological testing
- Release, distribution and import/export
- Interaction between tissue establishments and Organisations Responsible for Human Application
- Computerised systems
- Coding, packaging and labelling
- Traceability
- Biovigilance
- Introduction of novel processes and clinical applications

EDQM T&C GUIDE REVISION 5TH ED.



- Ocular
- Amniotic membrane
- Skin
- Cardiovascular
- Musculoskeletal
- Haematopoietic progenitor cells
- Umbilical cord blood progenitors
- Pancreatic islets
- **Hepatocytes**
- Adipose tissue
- Medically assisted reproduction
- Fertility preservation
- Human milk
- Intestinal microbiota
- Blood components for topical use or injection
- Tissues and cells as starting materials

EDQM T&C GUIDE REVISION 5TH ED.



- ✓ For well characterised products with well established clinical indications – as long as the established quality criteria are met and the product is used for the appropriate clinical indications. Thus, no need for heavy preparation process authorisation, clinical studies, etc.
- ✓ New processes/products would eventually move to having monographs once they become consolidated by evidence and there was consensus on the release criteria and appropriate clinical indications.

43 Monographs 5th edition

Monographs expanded

BELGIUM

To be expected shortly

1. HGR/CSS – 3 advice documents Biovigilance
    1. General
    2. Replacement tissue and cells
    3. Medical Assisted Reproduction
2. FAGG/ AFMPS
    1. New digital reporting forms (autumn 2023)

HGR - CCS

Published advise documents

1. HGR/CCS 9758 – GDPR and human body material

QUESTIONS

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