

Good Tissues and Cells Practices and EuroGTP



*Agence française
de sécurité sanitaire
des produits de santé*



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Joint GP for tissues and cells **Introduction**



- ✓ **AFSSAPS** is the Competent Authority in charge of drafting and publishing good practices
- ✓ after the approval of the Biomedicine Agency



Joint GP for tissues and cells **Introduction**



- Biomedicine Agency is the Competent Authority in charge of drafting the good practices for Organs
- after the approval of Afssaps

Joint GP for tissues and cells

Context of the regulations



1. European Union :

- Directive 2004/23/CE 31 March 2004
- Directive 2006/17 CE 8 February 2006
- Directive 2006/86/CE 24 October 2006





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Context of the regulations



2. France :

- Law on Bioethics, 6 August 2004
- Decree on Biovigilance, 12 December 2003
- Decree on Good practices for tissues procurement,
1st April 1997

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Context of the regulations



- Good practices for the procurement, transport, processes and storage of cells for human application (Decree 16 December 1998)
- Good practices for storage, processes and transport of tissues for human application (Decree 29 December 1998)





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Context of the regulations



Other regulations :

- Requirement for authorization of tissue establishment activities (Decree 30 August 1999)
- Requirement for authorization of cells establishment activities (Decree 1st October 2001)
- Rules related to the traceability of tissues and cells (Decree 9 October 1995)



Joint GP for tissues and cells

Aim of the revision



- To transpose the EU directive 2004/23/CE and the technical directives
- To take into account :
 - the 11 years experiences of the inspections of tissue and cell establishments (feed back)
 - the development of standards and technical practices applying to these activities :
 - lightening requirements which do not fit with current practices
 - Strengthening requirements which have more impact on the safety/quality of the products



Joint GP for tissues and cells

Justification of the merge



1. Possibility to merge both ?

- Common requirements relating to quality management, personnel, premises, equipment, transport, documentation and information system (IT system)
- Only some characteristics are specific to the nature of the products, tissues or cells

2. 2004/23/EC directive applies to both tissues and cells



Joint GP for tissues and cells

Presentation of the text



1. Framework

- Good practices apply to processes, storage, transport and distribution of tissues and cells for human application
- Procurement is excluded

Joint GP for tissues and cells

Presentation of the text



GTCP apply to clinical trials as mentioned by whereas

11 of the Directive 2004/23/EC laid down that :

«Only those cells and tissues that in clinical trials are applied to the human body should comply with the quality and safety standards laid down in this

Directive »



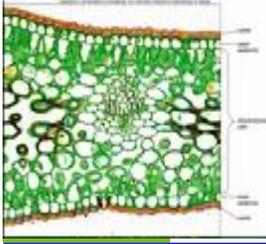
Joint GP for tissues and cells

Presentation of the text



2. New format of the text :

- I. Personnel
- II. Facilities
- III. Activities
- IV. Quality Control
- V. Third parties
- VI. Packaging



Joint GP for tissues and cells

Presentation of the text



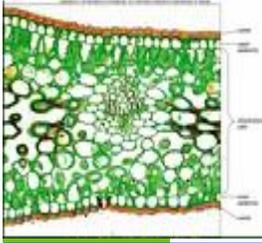
VII. Labelling

VIII. Transport

IX. Documentation

X. IT systems

XI. Management of the non compliance,
biovigilance, complains

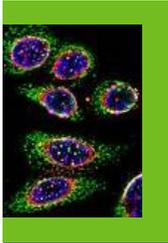


Joint GP for tissues and cells **Presentation of the text**



Advantages of the new format :

- better readability
- gathering the requirements by subjects
- avoiding to go back and forth between general and specific provisions



Joint GP for tissues and cells **modifications**

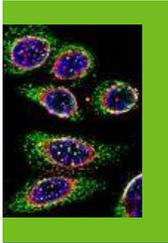


- 1- New format
- 2- Three big chapters : quality management, facilities, activities
- 3- Precisions/distinctness on the role, missions and qualifications of people involved in the tissue and cell banks (new)
- 4- Precision on the required condition for the storage of contaminated products and those pending for validation

Joint GP for tissues and cells modifications of the text



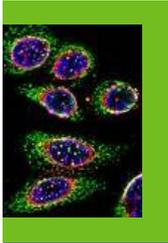
- 5- Revision of the different levels of processes for tissues and cells (1, 2, 3) : only 2 levels have been identified (open versus closed system) *(new)*
- 6- Revision of the air quality required for the processing of tissues and cells (according with the European GMP) *(new)* maintaining the required air quality with some reminds according with ISO methods *(new)*



Joint GP for tissues and cells **modifications of the text**



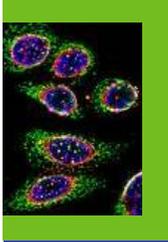
- 7- More details about the requirements for cleaning the facilities and the equipment (biocleaning) *(new)*
- 8- Specifications on the microbiological controls of the air and surfaces according to ISO standards (reenforcement by new requirement) *(new)*
- 9- Clearer, better focused and more appropriate labelling regarding the French Decree of 1995 and the EU directives



Joint GP for tissues and cells **modifications of the text**



- 10- More details about requirements relating to cryogenic area (facilities containing tanks with nitrogen liquid) **(new)**
- 11- Increased accuracy about the controls to be performed for the quality/safety of tissues and cells **(new)**
- 12- details about the conditions of termination of activities of a tissue establishment (as mentioned in the directive art 21) **(new)**
- 13- More details about the prevention of contamination during the process **(new)**



Joint GP for tissues and cells **modifications of the text**



- 14- Details about the analytical control methods to be used for the QC (new)
- 15- Details about the primary packaging which does not have any CE mark
- 16- Details about the equipment entering into contact with tissues and cells
- 17- Details about biovigilance, non compliance and complains (and how to manage the recall of the products)

Joint GP for tissues and cells



Thank you for your attention