Good Manufacturing Practice for ATMPs

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Health and Food Safety

1. Legal framework for ATMPs in EU

- ATMPs are regulated as medicinal products:
  - Marketing authorisation granted on the basis of quality, safety and efficacy criteria.
  - Single assessment/authorisation across EU.
  - Specialised committee within EMA: the Committee for Advanced Therapies ("CAT").
  - GMPs and pharmacovigilance obligations apply.

1. Legal framework for ATMPs in EU (cont.)

Because of the novelty, complexity and technical specificity of advanced therapy medicinal products, specially tailored and harmonised rules are needed to ensure the free movement of those products within the Community, and the effective operation of the internal market in the biotechnology sector. (Regulation 1934/2007, recital 5).

- Article 5 of Regulation 1934/2007:

The Commission shall, after consulting the Agency, draw up detailed guidelines in line with the principles of good manufacturing practice and specific to advanced therapy medicinal products.

1. Legal framework for ATMPs in EU (cont.)

- Additional GMP principles for ATMPs were added to Annex 2 of the GMP Guidelines ("Manufacture of biological active substances and medicinal products for human use").
  - Annex 2 does not derogate from the general framework: the general Chapters and other annexes of the GMP guidelines are also applicable to ATMPs.

2. Specific GMPs for ATMPs: Objectives

- Adaptation of GMP requirements to specific characteristics of ATMPs.
- Reduction of burdens.
  - Public health should, however, not be compromised.
- To facilitate the understanding of relevant obligations for ATMP developers.
  - All relevant obligations laid down in a single document.
  - Improve and streamline the text of the Guidelines.

3. The consultation paper

- Paper is intended to seek the views of ATMP developers/manufacturers.
- Combination of two approaches:
  - Open questions on how to address issues not currently addressed in GMP (*e.g.* reconstitution, automated production of ATMPs).
  - Presentation of possible adaptations to current requirements for comments.

3. The consultation paper (cont.)

- **Adaptation to specific characteristics of ATMPs**:
  - Supply chain specific features: role of Tissue Establishments (Sect 7, Q13).
    - Identity testing.
    - Level of supervision.
  - Inherent variability and scarcity of cells/tissues:
    - Testing requirements (sect. 12.3, Q19).
    - Sampling of biological starting materials/ finished product (Sect.12.2,Q19).
    - Validation obligations (Sect. 10, Q16 and Q17).

3. The consultation paper (cont.)

- **Reduction of burdens:**
  - Addressing the situation of ATMPs that do not entail substantial manipulation of cells/tissues (Q3).
  - Possibility to accept clean rooms with a background C or D (Sect. 4.2.2, Q8).
    - This flexibility would not apply for commercial manufacturing or pivotal clinical trials.
  - Additional flexibilities for ATIMPs: *e.g.* no trending.
  - In general, more emphasis on outcome and less detailed requirements:
    - Flexibility for manufacturers to apply measures best suited to the specific product.

3. The consultation paper (cont.)

- **Making GMP requirements more understandable and accessible**:
  - Single document with all requirements relevant to ATMPs.
  - Current provisions streamlined (overlaps, requirements not relevant to ATMPs will be removed).
  - Text drafted with specific focus on ATMPs.

4. Consultation of stakeholders

- We want to hear from you:
  - Do you (dis)agree with the objectives?
  - Are there additional elements that should be addressed?
  - Do you (dis)agree with the specific requirements provided for in the consultation document?
- Comments can be submitted until November,12

http://ec.europa.eu/health/human-use/advanced-therapies/developments/index_en.htm

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Thank you!

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Public Health information:

http://ec.europa.eu/health/index_eu.htm

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