Gene therapy and cell therapy: regulation challenges faced by RNAs

Agência Nacional de Vigilância Sanitária- ANVISA
Brasil

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Advanced Therapy Products Regulation from the BRASIL's perspective

CELL THERAPIES

CONVENCIONAL THERAPY

- Blood Transfusion
- Haematopoietic Reconstitution
- Tissues Transplantation
- Cells and tissues germinative for medicine reproductive

ADVANCED THERAPY

- Gene Therapy
- Somatic-cell therapy
- Tissue engineering

- Substantially manipulated
- Non-homologous use

- Homologous use
- Minimum manipulated (no substantial)
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**CONVENCIONAL THERAPY**

**Blood products or classical cell and tissue transplants** - Specific regulations (authorized and licensed banks, GMP, standardized production, donor selection criteria, laboratory tests, etc)

**Cell Therapy convencional**

Clinical Trials – Approval by the Ethical Committees
Therapeutic use – Acknowledgement by the Medical or Dental Federal Councils
GMP Cells – specific regulations – Resolution Anvisa
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National Cell Therapy Network

- Created in 2008
- 8 Cell Technology Centers

**Financial Support:** Ministry of Health and Ministry of Science and Technology of Brazil

Promotion of national scientific research
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LEGAL FRAMEWORK

- Standard for the approval of clinical trials
- Standard for the marketing authorization
- Standard for the Good Cell Practices

“regulatory model of biologics products”
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ANVISA in Cooperation with the Committee for Advanced Therapies-CAT

1- Developed in **clinical trials** from phase I/II to III authorized and monitoring by Anvisa

2- Assessed by Anvisa for obtaining **marketing** authorization
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Advanced Therapy Products

ANVISA

3- Manufacture according to GMP, certified by Anvisa when intended to be administered to humans.

4- Post marketing requirement- BIOPHARMACOVIGILANCE (follow-up of efficacy/adverse reactions, risk management, traceability)

5- Establishment licensing/authorized by local regulatory authority
Thank you for your attention!
Gracias!
Obrigado!

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