Innovations in Regenerative Medicine Products

Regenerative products (therapies) involve the use of stem cells, engineered biomaterials, gene editing, and other technologies to repair or replace damaged cells, tissues, or organs.

FDA’s Role in Regulation

- Regulate products over their entire lifecycle
- Provide oversight of clinical trials
- Advance development by providing guidance documents and engaging stakeholders throughout the development of innovative products that meet patients' needs

Office of Therapeutic Products (OTP)

Part of the U.S. Food and Drug Administration (FDA) Center for Biologics Evaluation and Research (CBER) who regulate Regenerative Medicine Products

Resources

California Institute for Regenerative Medicine
https://www.cirm.ca.gov/

FDA-Approved Cellular and Gene Therapy Products

OTP Learn
https://www.fda.gov/vaccines-blood-biologics/news-events-biologics/otp-learn
Types of Regenerative Medicine Products

Gene Therapy

**DEFINITION:** Involves the use of genetic material (DNA or RNA) to treat or prevent a disease

**Gene Editing:** process of editing pieces of DNA through genetic material

**Gene Therapy:** applied to the body through in-vivo, or to the modified cells via ex-vivo and returned to patient’s body

**Vectors:** a means of delivering the therapy into the cell (viral vs. non-viral vectors)

- **Ex-Vivo** Extracted cells are modified and reintroduced to the patient’s body
- **In-Vivo** Modifications are inserted directly into the patient’s body through viral or non-viral delivery vehicles

Stem Cell Therapy

**DEFINITION:** A cell which has the ability to divide and create an identical copy, known as self-renewal, and can divide to form cells that mature into cells that make up every type of tissue and organ in the body

**Types of Stem Cells:** Adult, fetal, perinatal, embryonic, induced pluripotent stem cells