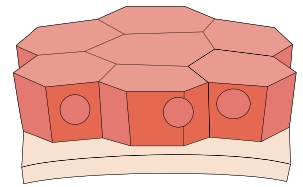


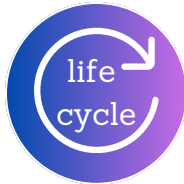
# Innovations in Regenerative Medicine Products



**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/)  
<https://www.cirm.ca.gov/>

[FDA-Approved Cellular and Gene Therapy Products](https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products)

<https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products>

[OTP Learn](https://www.fda.gov/vaccines-blood-biologics/news-events-biologics/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

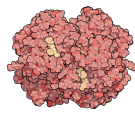
**Gene Therapy:** applied to the body through in-vivo, or to the modified cells via ex-vivo and returned to patient's body

**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



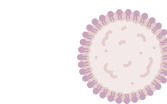
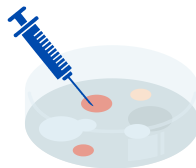
DNA RNA



Protein



Lentivirus



Lipid Nanoparticle

**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



**Adult Blood Stem Cells**



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

