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Regulatory requirements for stem cell therapy as per CDSCO in India comparison with Brazil

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ABSTRACT

Stem cells are fundamental units of every multicellular organism because they have the ability to differentiate into many kinds of mature cells. Stem cells have the characteristic of totipotency and also self-renewal. Adult stem cells possess multipotency with differential plasticity, which can be exploited for future generations of therapeutic options, though very early embryonic stem cells show totipotency. Fortunately, scientists did discover regulators in terms of pleuripotency, such as the oct-4 & Nanong protein. Stem cells occur in all of us, ranging from the initial stages of human development to the terminal stage of life. Stem cells are not specialized cells that become specialized cells, which comprise the various types of tissue in the human body. The ability of stem cells to regenerate and repair tissue is very promising. Stem cell therapy is a unique medical treatment that can use donor (allogeneic) or the body's own cells (autologous) to repair and regenerate damaged tissues. It has only been now that scientists have known stem cells well enough to consider the prospects of culturing them outside the body for extended periods.

Keyword: Stem cell, Clinical usage, Review, Regenerate.

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INTRODUCTION

Stem cells, because of their distinct proliferative, isolation, and tone-producing properties. They are a collection of immature cells that have the potential to create and repair every tissue or organ in the body. Through repairing damaged cells, stem cells provide reparative products that improve physical growth and aid in the recovery of organs. counting on the natural capacities of stem cells, experimenters have used their natural mechanisms for stem- cell- grounded remedy. The mechanisms of action through which stem cells can promote the rejuvenescence of towel are different, including

1. Inhibition of inflammation falls
2. Reduction of apoptosis
3. Promotion of angiogenesis, cell reclamation, and isolation

The cause of a complaint is a vital -consideration in opting the proper stem cell medium and in the rejuvenescence of towel/ organs using stem cells. It is expected that stem cell operations will improve the likelihood of creating treatments through cell restorative and complaint processes[1].

Types of stem cells:

Stem cells capacity to develop into multiple cell types sets them apart. To fully appreciate their potential in medical study and treatment, it is essential to understand their categories and subtypes:

Totipotent Stem Cells: These have the highest potency, capable of developing into any cell type in the body, including placental cells. The zygote, a fertilized egg, is a prime example of a totipotent cell.

Pluripotent Stem Cells:

With the exception of those needed for fetal development, pluripotent stem cells can differentiate into any form of cell.

Their subtypes include:

Embryonic Stem Cells (ESCs):

Derived from blastocysts, they can generate all body cell types ESC Research.

Induced Pluripotent Stem Cells (iPSCs):

Adult cells that have undergone genetic reprogramming and possess skills comparable to those of ESCs.

Multi-potent Stem Cells:

Limited to developing into a certain range of cells, typically within a specific lineage. Examples include: Mesenchymal stem cells, neural stem cells and hematopoietic stem cells.

Oligopotent Stem Cells:

These cells can differentiate into a few related cell types, such as lymphoid or myeloid stem cells that develop into specific blood cells

Unipotent stem Cells:

They can only differentiate into one type of cell, making them the most limiting in this regard. An example is muscle stem cells, which exclusively differentiate into muscle cells.

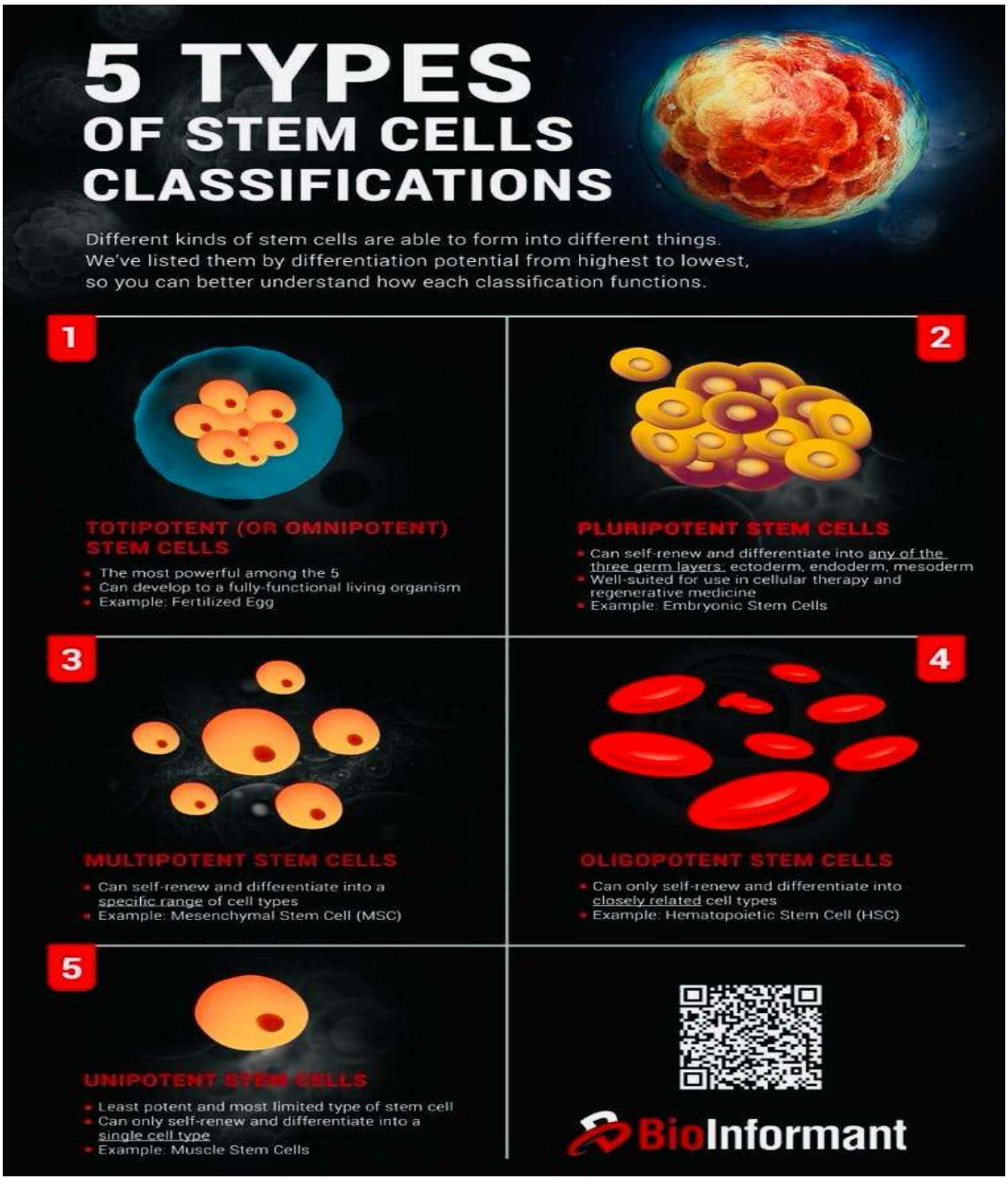

Figure 1: Classification of stem cells

Significance:

Researchers are studying stem cells to see if they can help to:

- Increase understanding of how diseases occur. The development of diseases and ailments may be better understood by researchers by seeing how stem cells develop into cells in bones, heart muscle, neurons, and other organs and tissue.
- Regenerative medicine involves creating new, healthy cells to replace diseased ones. Stem cells can be guided into becoming specific cells that can be used in people to regenerate and repair tissues that have been damaged or affected by disease.
- Individuals with leukemia, non-Hodgkin lymphoma, Hodgkin disease, and certain solid tumor malignancies may benefit from stem cell treatment. Individuals with immunodeficiencies, hereditary metabolic disorders, and aplastic anemia may also benefit from stem cell therapy.
- Stem cells are being studied to treat type 1 diabetes, Parkinson's disease, amyotrophic lateral sclerosis, heart failure, osteoarthritis and other conditions.
- t may be possible to cultivate stem cells into new tissue for use in regenerative medicine and transplantation. Researchers continue to advance the knowledge on stem cells and their applications in transplant and regenerative medicine.
- Test new drugs for safety and effectiveness. Before giving drugs in development to people, researchers can use some types of stem cells to test the drugs for safety and quality. This type of testing may help assess drugs in development for toxicity to the heart.

The efficiency of employing human stem cells that have been turned into tissue-specific cells to evaluate novel medications is one of the emerging research topics. For the testing of new drugs to be accurate, the cells must be programmed to acquire properties of the type of cells targeted by the drug. Techniques to program cells into specific cells are under study.

Key information regarding CDSCO:

CDSCO, headquartered in New Delhi, operates 9 zonal offices, 7 sub-zonal offices, 18 port offices, 7 central laboratories, and 6 small labs throughout India.

It is run by the Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India.

CDSCO is in charge of licensing medications, conducting clinical trials, establishing drug standards, monitoring the quality of imported drugs, and working with state drug regulators. It grants permits for specialist pharmaceuticals such as blood products, IV fluids, vaccinations, and sera in collaboration with state authorities.

CDSCO is divided into eight divisions: BA/BE, New Drugs, Medical Devices and Diagnostics, DCC-DTAB, Import and Registration, Biologicals, Cosmetics, and Clinical Trials.

The Drug Controller General of India (DCGI) is responsible for regulating pharmaceuticals and medical devices under CDSCO, with advice from the Drug Technical Advisory Board (DTAB) and Drug Consultative Committee (DCC).

- To conduct business with CDSCO in India, manufacturers must choose an Authorized Indian Representative.
- CDSCO ensures the safety, efficacy, and quality of pharmaceuticals and medical devices in India by overseeing and enforcing the pharmaceuticals and Cosmetics Act[2].

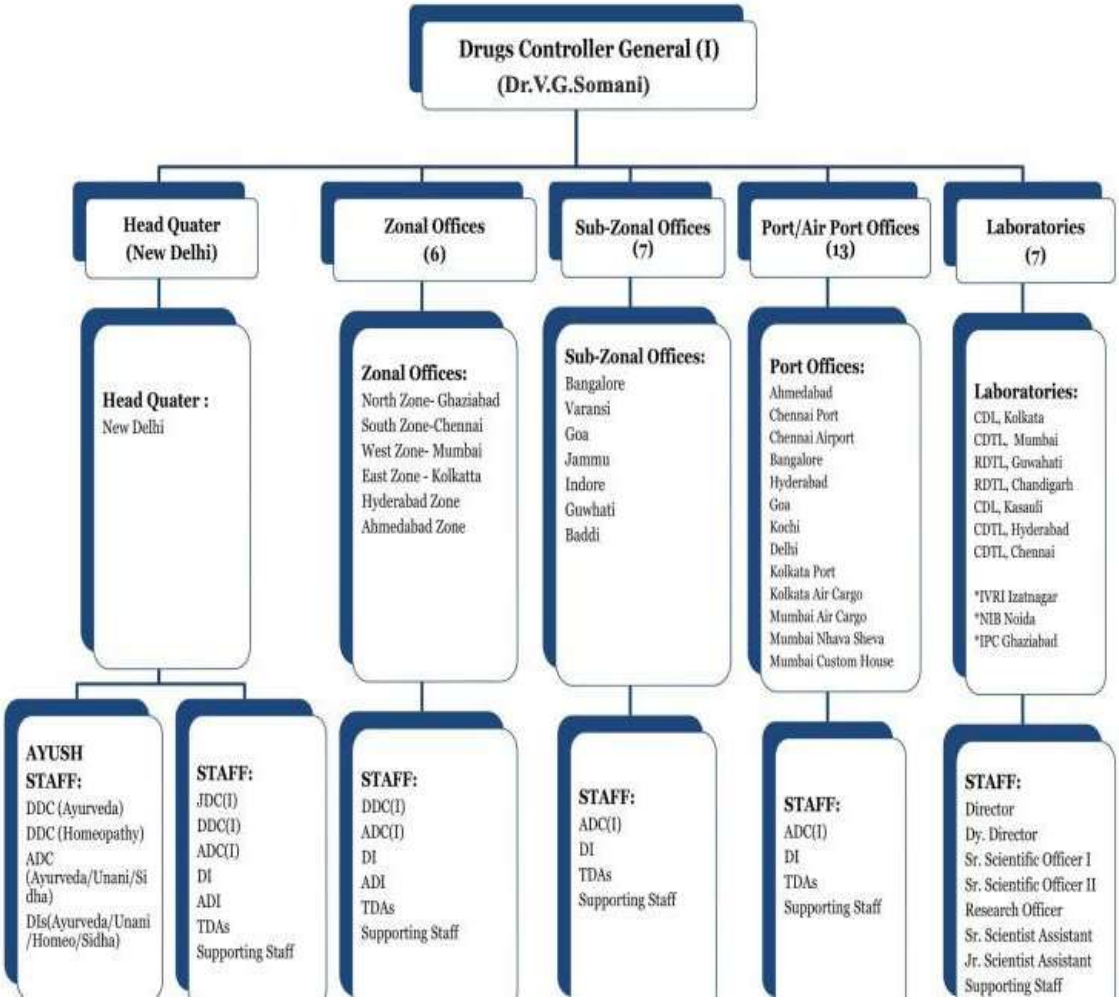

Figure 2: Organization of CDSCO in India

Key information regarding ANVISA in Brazil

The Brazilian Health Surveillance Agency, commonly known as ANVISA, abbreviated from Portuguese "Agencia Nacional de Vigilancia Sanitaria," is the food and drug regulatory agency in Brazil. ANVISA was created in 1999 and is linked to the Ministry of Health. It is characterized by its administrative independence, financial autonomy, and the stability of its directors. In the federal public regulatory structure, the agency is connected to the Ministry of Health. ANVISA's primary

goal is to protect and promote public health, by exercising health surveillance over products and services, including processes, ingredients, and technologies that pose any health risks.

ANVISA's vision is to achieve legitimation in society as an integral part of the Brazilian Unified Health System, via a nimble, modern, transparent, and domestic and international benchmark in health surveillance and regulation. ANVISA's mission is "to protect and promote public health and to intervene in the risks caused by the production and use of products regulated by health surveillance. This mission must be carried out in coordination with states, municipalities and the Federal District, according to the Brazilian Unified Health System principles, to improve the quality of life of the population."

ANVISA was accepted as a new regulatory member of the International Council on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). As part of the objective to extend its global outreach, ICH, in November 2016, welcomed ANVISA from Brazil and the Ministry of Food and Drug Safety (MFDS) from South Korea as the first new regulatory Members, together with the Biotechnology Innovation Organization (BIO) as a new industry association Member. There are now 13 members and 22 observers.

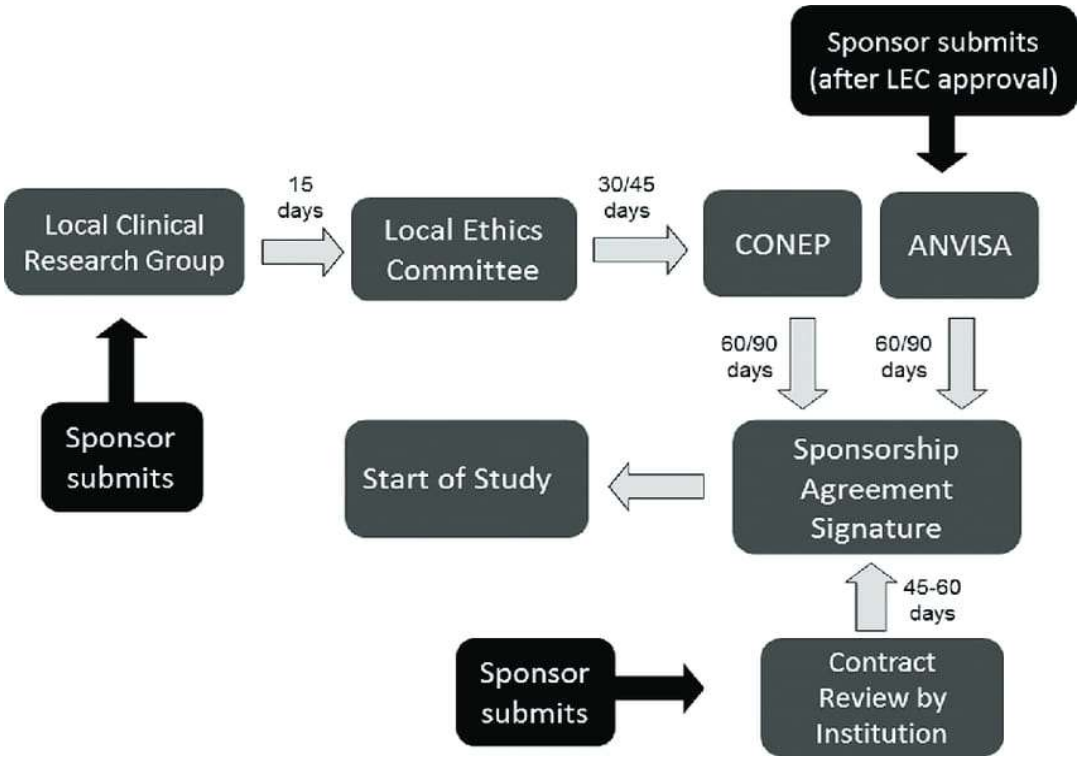

Figure.3: Organization of ANVISA in Brazil

Overview of stem cell market in India

India Stem Cell Market Overview:

The India stem cell market size reached USD 0.49 Million in 2024. Looking forward, IMARC Group expects the market to reach USD 1.32 Million by 2033, exhibiting a growth rate (CAGR) of 11.50% during 2025-2033. The market is broadening with improving regenerative medicine, increasing biotech research investment, higher occurrences of chronic disease, and wider awareness of stem cell banking. Government support to biotechnology, need for targeted medicine, and partnerships between private companies and research institutions are further driving the growth of the market[6].

Report Attribute -Key Statistics

Base Year:2024

Forecast Years:2025-2033

Historical Years:2019-2024

Market Size in 2024: USD 0.49 Million

Market Forecast in 2033: USD 1.32 Million

Market Growth Rate (2025-2033):11.50%

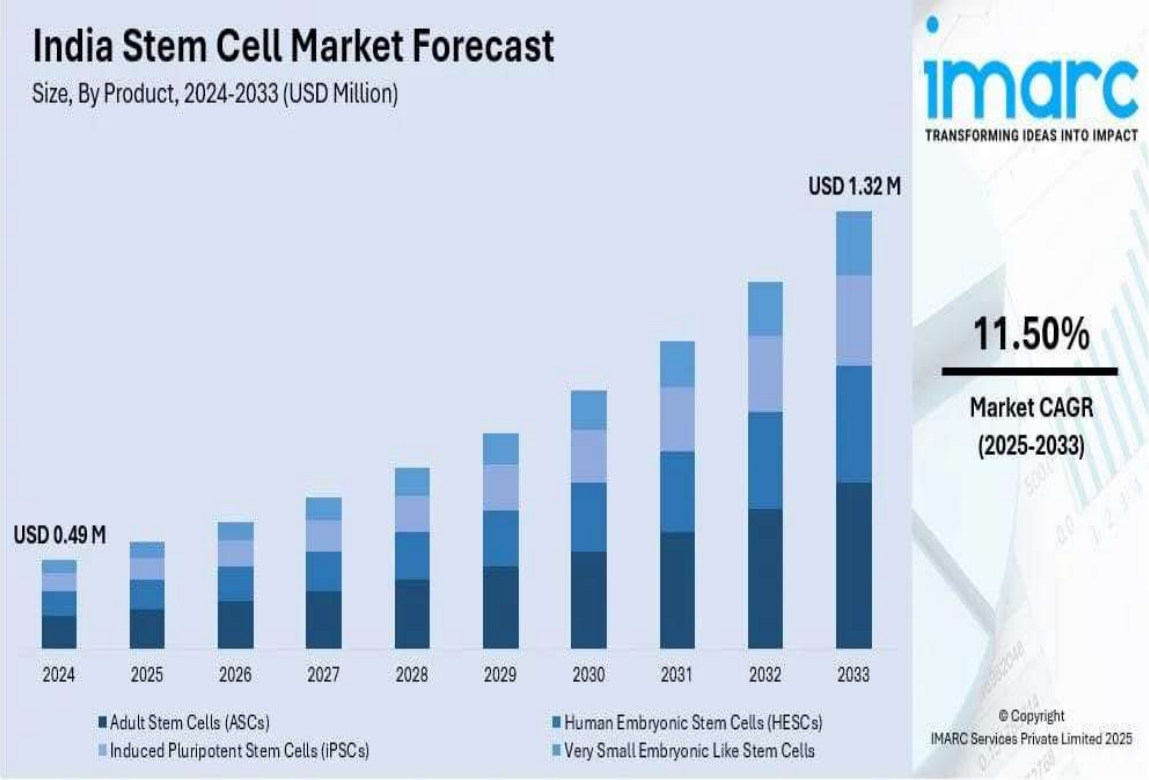

Figure 4: Stem cell market in India

Overview of stem cell in Brazil

Brazil stem cells market highlights

The Brazil stem cells market generated a revenue of USD 390.2 million in 2024 and is expected to reach USD 742.6 million by 2030.

The Brazil market is expected to grow at a CAGR of 11.3% from 2025 to 2030.

In 2024, the product that generated the highest income in terms of segment was adult stem cells. The most profitable product category with the quickest increase during the predicted period is induced pluripotent stem cells.

Stem cells market data book summary

Market revenue in 2024-USD 390.2 million

Market revenue in 2030-USD 742.6 million

Growth rate-11.3% (CAGR from 2024 to 2030)

Largest segment -Adult stem cells

Fastest growing segment Induced Pluripotent Stem Cells

Historical data :2018 - 2023

Base year:2024

Forecast period:2025 - 2030

Quantitative units -Revenue in USD million

Market segmentation Adult Stem Cells, Human Embryonic Stem Cells, Induced Pluripotent Stem Cells, Very Small Embryonic Like Stem Cells

Key market players worldwide-Thermo Fisher Scientific Inc, STEMCELL Technologies, CellGenix, PromoCell GmbH, Takara Bio Inc, Lonza Group Ltd, ATCC, Bio-Techne Corp[7]

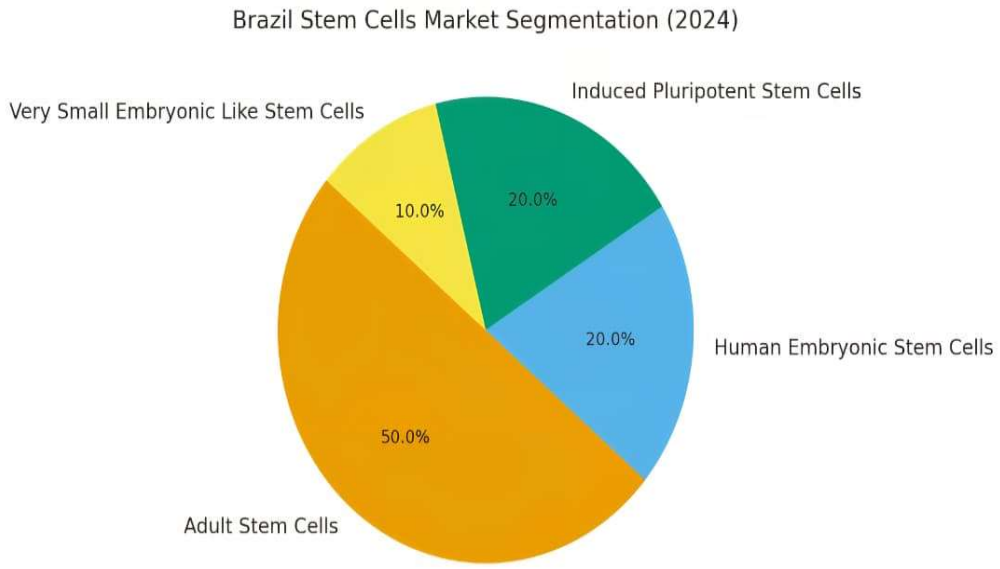

Figure 5: Stem cell market in Brazil

Key Differences:

1. Governance: India follows a central + state dual structure, Brazil has a single autonomous agency.
2. Leadership: India – DCGI; Brazil – Board of Directors.
3. Scope: ANVISA regulates food & tobacco in addition to drugs/devices, while CDSCO mainly covers drugs, cosmetics, devices.
4. Imports: India requires import licenses & registrations. Brazil requires local representation.
5. Global Role: ANVISA is part of ICH & ICMRA; CDSCO is aligning but not yet a full ICH member.

Case studies in stem cell therapy

1. Spinal Cord Injury

- Case: A 21-year-old man with a complete spinal cord injury at the thoracic level underwent autologous bone marrow-derived stem cell transplantation.
- Treatment: Mesenchymal stem cells (MSCs) were injected intrathecally.
- Outcome: After 6 months, partial sensory recovery and improved bladder control were observed[5].

2. Type 1 Diabetes Mellitus

- Case: A 27-year-old female with uncontrolled Type 1 diabetes.
- Treatment: Pancreatic islet-like clusters derived from stem cells were transplanted.
- Outcome: Significant reduction in insulin requirements and improved HbA1c levels[6].

3. Leukemia

- Case: A 10-year-old boy diagnosed with acute lymphoblastic leukemia.
- Treatment: Hematopoietic stem cell transplantation (HSCT) from a matched sibling donor.
- Outcome: Complete remission achieved, disease-free survival beyond 5 years.

4. Heart Failure

- Case: A 58-year-old male with ischemic cardiomyopathy (low ejection fraction).
- Treatment: Intracoronary infusion of autologous bone marrow stem cells[7].

Outcome: Increase in ejection fraction from 25% to 40% within 6 months, improved exercise tolerance.

Challenges in stem cells therapy:

1. Scientific & Technical Challenges

- Cell Source and Quality: Obtaining safe, pure, and consistent stem cells (embryonic, adult, or induced pluripotent) is difficult.

- Differentiation Control: Ensuring stem cells develop into the right type of tissue (e.g., neurons, cardiac cells) without errors.
- Integration: Newly introduced cells must connect properly with existing tissues, nerves, and blood supply.
- Immune Rejection: Even stem cells can be attacked by the patient's immune system, especially if not derived from the patient's own body.
- Tumor Formation (Teratomas): Stem cells can grow uncontrollably, leading to tumors if not properly regulated.

2. Ethical & Social Challenges

- Embryonic Stem Cell Controversy: Using human embryos raises ethical and religious debates.
- Consent & Exploitation: Risk of misuse in obtaining cells or exploiting vulnerable patients.
- Unproven Clinics: Many unregulated clinics worldwide offer unsafe stem cell treatments, leading to false hope and risks.

3. Clinical & Medical Challenges

- Safety & Long-Term Effects: Limited data on how transplanted stem cells behave over years.
- Standardization: Lack of uniform protocols for preparation, dosage, and administration.
- Patient Variability: Age, disease stage, and genetic background affect treatment outcomes.
- Regulatory & Financial Challenges
- Strict Regulations: Approval from authorities (FDA, EMA, etc.) is lengthy and complex.
- High Costs: Therapy is expensive due to lab work, safety testing, and clinical trials.

Accessibility: Treatments may remain available only to wealthy patients or in developed nations[8].

Future perspective of stem cell therapy

It is very promising, as it is one of the most rapidly advancing fields in modern medicine. Here's a structured overview for you:

1. Regenerative Medicine & Tissue Repair

Stem cells will be widely used to regenerate damaged tissues and organs (heart, liver, pancreas, spinal cord, cartilage, skin).

Bioengineered organs using stem cells may reduce the need for organ transplantation.

2. Neurological Disorders

Ongoing trials show potential in Parkinson's disease, Alzheimer's, multiple sclerosis, and spinal cord injuries.

Induced pluripotent stem cells (iPSCs) can be used to create personalized neurons for repairing nerve damage.

3. Diabetes Treatment

Stem-cell–derived beta cells are being developed to replace damaged insulin-producing cells, offering a possible cure for Type 1 diabetes.

4. Cancer Therapy

Stem cells can be used for targeted drug delivery and in immune modulation to improve cancer treatments.

Stem-cell–derived CAR-T therapies are under investigation to enhance immunotherapy.

5. Anti-aging & Cosmetic Applications

Stem cells are being studied for skin rejuvenation, hair regrowth, and anti-aging therapies.

This field is expected to grow rapidly due to consumer demand.

6. Challenges & Ethical Considerations

tumorigenicity (risk of cancer from uncontrolled growth).

Immune rejection in allogeneic therapies.

Ethical debates about embryonic stem cells.

High costs and accessibility issues.

7. Future Outlook (Next 10–20 Years)

Stem cell therapy could shift from being experimental to mainstream medical treatment.

Integration with gene editing (CRISPR), 3D bioprinting, and nanotechnology will create advanced solutions.

Widespread availability is expected in cardiology, neurology, orthopedics, and endocrinology.

Potential to extend human life expectancy and improve quality of life[9].

Comparison of Regulatory Requirements: India vs. Brazil

Table 1: **This above table provides a high-level overview of the similarities and differences in a regulatory requirement for stem cell therapy in India with Brazil[10].**

Serial No.	Aspect	India	Brazil
01	Regulatory Authority	Indian Council of Medical Research (ICMR) and Central Drugs Standard Control Organization (CDSCO)	National Health Surveillance Agency (ANVISA)
02	Governing Guidelines	National Guidelines for Stem Cell Research (2023 update)	ANVISA Resolution (RDC No. 214/2018) for Advanced Therapy Products
03	Classification	Stem cell-based interventions are considered as New Drugs under Drugs &	Classified as Advanced Therapy Medicinal Products (ATMPs),

		Cosmetics Act	includes cell and gene therapies
04	Approval Requirement	All clinical use requires DCGI approval + ethics committee clearance	Clinical use requires ANVISA approval + CONEP (National Research Ethics Commission)
05	Permitted Uses	Only hematopoietic stem cell transplantation (HSCT) is an established therapy. Others considered experimental.	HSCT is approved; other stem cell therapies are restricted to clinical trials
06	Clinical Trials	Mandatory registration in CTR-I (Clinical Trials Registry – India)	Trials must be registered in REBEC (Brazilian Clinical Trials Registry)
07	Commercial Use	Prohibited without DCGI approval; unproven therapies are banned	Commercial use only after ANVISA approval; clinics offering unapproved therapies face penalties
08	Research Oversight	Institutional Committee for Stem Cell Research (IC-SCR) at each institution	CONEP oversees ethical approval; ANVISA regulates technical standards
09	Patient Safety & Ethics	Strict informed consent, no direct-to-patient marketing, no unapproved therapies allowed	Strong emphasis on ethical consent, restrictions on advertising unapproved therapies
10	Enforcement	Violations may result in trial suspension, fines, or cancellation of license	ANVISA imposes fines, closure of clinics, and legal actions against non-compliance

Summary of comparison:

India → Very cautious, restricts use mainly to hematopoietic stem cell transplants, everything else is considered experimental and must go through DCGI + ICMR guidelines. Brazil → Uses a European-style ATMP regulatory framework, allows research but tightly regulates clinical/commercial use through ANVISA**.**

CONCLUSION

The regulation of stem cell therapy remains one of the most critical and evolving aspects of translational medicine. Due to their unique ability to self-renew, differentiate, and exert therapeutic effects, stem cells hold immense promise but also pose significant ethical, safety, and efficacy concerns. Regulatory frameworks worldwide such as those from the U.S. FDA, European Medicines Agency (EMA), World Health Organization (WHO), and national authorities like CDSCO and ICMR in India—have established stringent requirements to govern every stage of stem cell research and clinical application. These include donor consent, ethical approval, characterization of stem cell lines, compliance with Good Manufacturing Practices (GMP), rigorous preclinical testing, phased clinical trials, and post-marketing surveillance. Despite these guidelines, challenges persist due to variability in international standards, the emergence of unproven therapies, and the fast pace of scientific advancement. Therefore, continuous regulatory refinement is essential to strike a balance between fostering innovation and ensuring patient safety.

Greater emphasis on global harmonization, transparent ethical practices, and evidence-based approval processes will strengthen public trust and accelerate the safe clinical translation of stem cell therapies. Ultimately, well-defined regulatory pathways are indispensable not only for safeguarding health but also for realizing the full therapeutic potential of stem cells in modern medicine[12].

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REFERENCES:

1. Mohammad Mousaei Ghasroldasht, Jin Seok and Ayman Al-Hendy, Hang-Soo Park, Farzana Begum Liakath Ali. Stem Cell Therapy: From Idea to Clinical Practice. International journal of molecular science. Int. J. Mol. Sci. 2022, 23:1-21
2. Central Drugs Standard Control Organization (Import & Registration Division) Guidance Document. Document No. IMP/REG/200711. Central Drugs Standard Control Organization. About CDSCO. Available from CDSCO Official Website: https://cdsco.gov.in
3. India stem cell market trend. Available from: URL: https://www.imarcgroup.com/india-stem-cell-market.
4. Brazil market trend. Available from: URL:https://share.google/images/NX6MPAZ1fNGdl9vzP
5. Case study of stem cell therapy in spinal cord injury. Available from: URL:https://share.google/w0PXyQ7l1TvBjZxCh
6. Case study of stem cell therapy in diabetes. Available from: https://share.google/mtLmo5DvXC88nsWdX
7. Case study of stem cell therapy in heart injury. Available from: https://share.google/RAJ8bCdghINhEdpe0
8. Major challenges of stem cell therapy. Available from: URL:https://share.google/jU43fHSVjTwEyUHdE

9. Challenges of stem cell therapy. Available from: URL:https://chatgpt.com/share/68c2f2f7-dd80-8004-87d7-11f73ca2ae33
10. Comparison of Regulatory requirements for stem cell therapy India versus Brazil: URL:https://chatgpt.com/share/68c2f24f-af3c-8004-9c1b-b46bc998b327