STEM CELL CENTER

PROPOSAL FOR SETTING UP A REGENERATIVE MEDICINE AND STEM CELL TREATMENT CENTER

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Regenerative medicine one of the most advanced fields of medical research today. Many consider it to be a scientific-medical specialty because it incorporates research and self-repair protocols where adult stem cells, allogeneic compounds, and growth factors are applied to accelerate both the tissue regeneration and homeostasis restoration processes.

In the last ten years, we have come to understand how cells identify and respond to signals, interact with their environment, and self-organize within tissues to accelerate and enhance the healing process. This understanding has allowed medical researchers to manipulate these processes and replicate them in the clinic to repair damaged tissues, create new tissues, and continue to explore the organism's regenerative capacities.

It is becoming increasingly common to successfully use stem cells to improve the body's functions as well as to regenerate muscle, bone, heart tissue, and cartilage, among other things. There are now more than 5,000 clinical studies that show how regenerative medicine is a viable treatment option for complex diseases, where traditional medicine does not provide a satisfactory solution.

The Global Stem Cells Group is a leading regenerative medicine company. It endevours to provide the necessary infrastructure, scientific training, and support to doctors so they can apply technology based on autologous stem cells and allogeneic cell products derived from neonatal tissue.

This document contains technical and commercial information to develop high-end regenerative medicine centers for clinical application of adult stem cells. Among the primary project objectives will be the processing and storage of the different cell lines developed by the Global Stem Cells Group for a variety of patient populations. The centers will facilitate the use of autologous cell therapy, as well as the production, storage, and distribution of cellular products derived from neonatal tissue at the level of the clinic or the physician.

A COMPLETE SOLUTION

This project includes Hands-On training in cell processing and treatment protocols, equipment installation, cellular product storage procedures, supply inventories, and laboratory start-up.

Our goal is to provide a definitive "All in One Solution" that includes scientific and administrative training to enable the commercialization and success of the treatments with a single provider and at the lowest possible cost.

The Center will have a wide range of cell lineages and products available, as well as the patient treatment protocols and standard operating procedures (SOPs) used by our global clinical network.

Our **"Complete Solution"** includes the following:

- A feasibility study of laboratory requirements.
- Training and certification.
- Equipment, provisions, and the supply of cellular compounds.
- Installation and start-up.
- "Turnkey" Business Model including a complete Marketing Package.
- 24/7 Consultation Service with our Physicians faculty.

PROJECTIONS AND RETURN ON INVESTMENT

The regenerative medicine market is expected to reach $38 billion in 2024. Compared to just $13.3 billion in 2019, this equates to annual growth of 23.8%. Market growth is primarily driven by the increasing prevalence of chronic diseases and genetic disorders, increasing investments in regenerative medicine research, and the growing number of new regenerative medicine companies around the world.

There has been a tremendous upsurge in cellular research and new product development over the last decade. The increase of cellular applications and components in the regenerative medicine field and the growing awareness of personalized medicine have created a demand for the construction of new state-of-the-art treatment centers.

	Price	Month 1		Month 2		Month 3		Month 4		Month 5	
Ordinary Income/Expense											
Income Regenerative Medicine											
Autologous Stem Cells Injections	1,750.00	3.00	5,250.00	3.00	5,250.00	4.00	7,000.00	4.00	7,000.00	4.00	7,000.00
IV Anti Aging Systemic Treatments	1,500.00	1.00	1,500.00	1.00	1,500.00	1.00	1,500.00	1.00	1,500.00	1.00	1,500.00
Allogeneic Stem Cells Injection	2,250.00	3.00	6,750.00	3.00	6,750.00	4.00	9,000.00	4.00	9,000.00	4.00	9,000.00
Platelet Rich Plasma	150.00	10.00	1,500.00	11.00	1,650.00	12.00	1,800.00	13.00	1,950.00	14.00	2,100.00
Total Income			***15,000.00***	0.00	***15,150.00***		***19,300.00***		***19,450.00***		***19,600.00***
Cost of Goods											
SVF Kits	295.00	2.00	590.00	2.00	590.00	2.00	590.00	3.00	885.00	3.00	885.00
Bone Marrow kits	400.00	1.00	400.00	1.00	400.00	1.00	400.00	1.00	400.00	1.00	400.00
Amnitic Fluid Vial	1,500.00	1.00	1,500.00	1.00	1,500.00	1.00	1,500.00	1.00	1,500.00	1.00	1,500.00
Exosomes Vial	525.00	2.00	1,050.00	2.00	1,050.00	2.00	1,050.00	3.00	1,575.00	3.00	1,575.00
Cord Blood Vial	950.00	1.00	950.00	1.00	950.00	1.00	950.00	1.00	950.00	1.00	950.00
PRP Kits	50.00	10.00	500.00	11.00	550.00	12.00	600.00	13.00	650.00	14.00	700.00
Total COGS			***4,490.00***		***5,040.00***		***5,090.00***		***5,960.00***		***6,010.00***
Gross Profit			***10,510.00***		***10,110.00***		***14,210.00***		***13,490.00***		***13,590.00***
Expense											
Employee Profesional Fees											
Electricity			100.00		100.00		100.00		100.00		100.00
Utilities - Other			150.00		150.00		150.00		150.00		150.00
Marketing			500.00		500.00		500.00		500.00		500.00
Total Utilities			750.00		750.00		750.00		750.00		750.00
Total Expense			750.00		750.00		750.00		750.00		750.00
Net Income			**9,760.00**		**9,360.00**		**13,460.00**		**12,740.00**		**12,840.00**

Month 6		Month 7		Month 8		Month 9		Month 10		Month 11		Month 12		First Year	
5.00	8,750.00	5.00	8,750.00	5.00	8,750.00	5.00	8,750.00	6.00	10,500.00	6.00	10,500.00	6.00	10,500.00	56.00	98,000.00
2.00	3,000.00	2.00	3,000.00	2.00	3,000.00	2.00	3,000.00	2.00	3,000.00	2.00	3,000.00	2.00	3,000.00	19.00	28,500.00
5.00	11,250.00	5.00	11,250.00	5.00	11,250.00	5.00	11,250.00	6.00	13,500.00	6.00	13,500.00	6.00	13,500.00	56.00	126,000.00
15.00	2,250.00	16.00	2,400.00	17.00	2,550.00	18.00	2,700.00	19.00	2,850.00	20.00	3,000.00	21.00	3,150.00	186.00	27,900.00
	25,250.00		***25,400.00***		***25,550.00***		***25,700.00***		***29,850.00***		***30,000.00***		***30,150.00***		***280,400.00***
3.00	885.00	3.00	885.00	3.00	885.00	4.00	1,180.00	4.00	1,180.00	4.00	1,180.00	4.00	1,180.00	37.00	10,950.00
2.00	800.00	2.00	800.00	2.00	800.00	2.00	800.00	2.00	800.00	2.00	800.00	2.00	800.00	19.00	7,618.00
2.00	3,000.00	2.00	3,000.00	2.00	3,000.00	2.00	3,000.00	2.00	3,000.00	2.00	3,000.00	2.00	3,000.00	19.00	28,518.00
3.00	1,575.00	3.00	1,575.00	3.00	1,575.00	4.00	2,100.00	4.00	2,100.00	4.00	2,100.00	4.00	2,100.00	37.00	19,460.00
2.00	1,900.00	2.00	1,900.00	2.00	1,900.00	2.00	1,900.00	2.00	1,900.00	2.00	1,900.00	2.00	1,900.00	19.00	18,068.00
15.00	750.00	16.00	800.00	17.00	850.00	18.00	900.00	19.00	950.00	20.00	1,000.00	21.00	1,050.00	186.00	
	8,910.00		***8,960.00***		***9,010.00***		***9,880.00***		***9,930.00***		***9,980.00***		***10,030.00***		***93,290.00***
	16,340.00		***16,440.00***		***16,540.00***		***15,820.00***		***19,920.00***		***20,020.00***		***20,120.00***		***187,110.00***
			750.00		750.00		750.00		750.00		750.00		750.00		4,500.00
	100.00		100.00		100.00		100.00		100.00		100.00		100.00		1,200.00
	150.00		150.00		150.00		150.00		150.00		150.00		150.00		1,800.00
	750.00		750.00		750.00		750.00		750.00		750.00		750.00		7,750.00
	1,000.00		1,750.00		1,750.00		1,750.00		1,750.00		1,750.00		1,750.00		15,250.00
	1,000.00		1,750.00		1,750.00		1,750.00		1,750.00		1,750.00		1,750.00		15,250.00
	15,340.00		**14,690.00**		**14,790.00**		**14,070.00**		**18,170.00**		**18,270.00**		**18,370.00**		**171,860.00**

CELLULAR PRODUCTS SOURCES

From a clinical point of view, the objective of implementing a treatment center is to use biological products – fresh or stored – as tools for regenerative medicine to replace and/or repair cells and tissues that have been damaged by natural aging, pathology, or trauma.

Among the most common sources of Mesenchymal Stem Cells (MSCs), from the youngest to the oldest, is the blood within the umbilical cord, the adipose tissue, and bone marrow. These sources have a high potential for self-renewal, are highly adaptive, and have a broad tissue distribution. Furthermore, these stem cell types are not only adept at forming cartilage tissues, but are also used in the treatment of neurological, respiratory, and metabolic disorders as well as a wide range of chronic and autoimmune diseases.

The main lineages and cellular products in the Global Stem Cells Group's Cellular Therapy Treatment Center project are outlined below:

Kits for obtaining the cells derived from Adipose Tissue.

A heterogeneous mixture of cells is obtained and isolated through enzymatic dissociation and density separation, a technique designed to extract the cells in the reservoir of the surrounding floating adipocytes. These stromal vascular cells are a potentially valuable resource to resolve numerous issues in the regenerative medicine field. Within this complex set of cells are the stem cells derived from the adipose tissue (ADSC) and mesenchymal stem cells (MSC's), which are surprisingly similar to the above. Both cells can be differentiated into a variety of cell types (such as bone, cartilage, and muscle cells, endothelial cells, and neurons).

Kits for obtaining cells derived from bone marrow

A wide range of therapeutic applications can be performed using stem cells as progenitor cells that are aspirated mainly from the bone marrow and then injected directly into the tissues to improve the regeneration process. Mesenchymal stem cells obtained from bone marrow have chondrogenic, osteogenic, and radiogenic potential.

After differentiation to mesenchymal progenitor cells, these cells support: bone formation through osteogenesis; adipose tissue through adipogenesis; cartilage formation through chondrogenesis; muscle formation through myogenesis; tendon/ligament formation through teno/ligamentogenesis; and the formation of cells similar to neurons through neurogenesis.

Kit for Platelet Rich Plasma (PRP) isolation

Cellgenic PRP is rich in cytokines and growth factors and is commonly used as part of a combination or as a booster treatment for the stem cells described above. Platelets make up 1% of the total blood volume. PRP also contains a high level of growth factors and cytokines that facilitate the regeneration process and support immune functions. Although PRP does not contain stem cells, it promotes regeneration and is ideal at curing tears and reducing inflammation. PRP has excellent results in treating meniscal tears and rotator cuff tears.

Exosomes (extracellular vesicles)

The isolation of signaling vesicles filled with growth factors and proteins among other compounds emitted by stem cells are used for treatments rather than the stem cells themselves, which is a next-generation therapy. This process makes sense since other cells react to these signals and change their behavior accordingly. There is enormous therapeutic potential for extracellular vesicles, especially exosomes. Cellgenic Flow Exosomes contain approximately 300 billion exosomes per milliliter. Exosomes are nanoparticles that contain proteins and RNA. They can be transferred to other cells and can support tissue repair and homeostasis.

CellGenic Pure derived from Umbilical Cord

CellGenic Pure derived from Umbilical Cord Blood contain nucleated living cells that exert an anti-inflammatory and immunomodulatory effect, which helps to optimize the cellular environment. The paracrine signals include a growth factor that secretes living nucleated cells that stimulate tissue to undergo mitosis and regenerate. Live nucleated cells can secrete growth factors over long periods, unlike amniotic products or placental derivatives that have very few nucleated living cells, if any. They only function during the half-life of the growth factor (from a few hours to a few days).

Amniotic Fluid

Cellgenic AF connective tissue allograft. It is derived from human placental tissue that is free of chorion and amniotic fluid, then cryopreserved to maintain the viability of intercellular messengers. This compound modulates cellular reconstruction in place of scar tissue formation, including growth factors, fibronectin, laminin, hyaluronic acid, proteoglycans, and other proteins. The anti-inflammatory and antifibrotic proteins of placental compounds reduce inflammation, fibrous tissue growth, and the possible formation of scar tissue, because they reduce TGF-B, suppress proinflammatory cytokines, and inhibit MMPs and the creation of fibroblasts.

TRAINING AND CERTIFICATION

Global Stem Cells Group has played a leading and visionary role in training medical scientists to translate laboratory research into clinical practice. This certification program offers a cohesive curriculum designed to provide precise instruction in the basic concepts of cellular behavior, laboratory processes, and their practical application at the clinic or physician level.

The program provides physicians with detailed instructions and hands-on practice for collecting all tissue samples, using laboratory equipment, processing and isolation protocols for obtaining autologous cellular product, and how administering treatment to the patient. Having this information at hand is vital to succeed in managing effective cellular products, allowing one to know every step of the process and control its quality.

The **Practical Experience** includes the following topics:

1. Operative Pre-Post Instructions.
2. Practical experience of fat tissue collection.
3. Practical experience in SVF insulation, washing, digestion, and centrifugation.
4. Photo-activation techniques and cellular counting.
5. Defrosting and freezing techniques for cellular products.
6. Dosing and handling liquid nitrogen freezers.
7. Puncture, extraction, and filtering techniques.
8. Equipment operation and practical experience under supervision.

LABORATORY EQUIPMENT

Our company uses several platforms and technologies to achieve project objectives in the short and long term. To operate a successful stem cell processing center, we need to install the essential laboratory equipment for the harvesting, isolation, and reintegration of autologous stem cells as well as equipment for the cryopreservation of allogeneic cellular products. Some customers may require specialized culture equipment such as Co2 incubators, as well as characterization and analysis equipment. Below is a list of some of the equipment needed to establish a basic cell therapy laboratory.

Laboratory Equipment

1. Class IIA2 Bio-security Cabinet

Designed to process tissue samples in a small and clean environment. The portable mini 18 "laminar flow cabin is classified as an ISO class 5 cabin because it uses a 2-stage filtration process and reaches 99.97% filtering efficiency in particles of 0.3 or greater.

2. Stem Cell PhotoActivation Device

Studies have proven when exposed to a specific wavelength of LED light, stem cells and platelet-rich plasma gets activated. This directly results in higher growth factors and cytokine levels in Platelet-Rich Plasma. This light can also enhance the proliferation and osteogenic differentiation of Mesenchymal Stem Cells.

3. Incubator-Shaker

This device is a compact size Shaker incubator, although it has a powerful agitator and a large workspace for various holding platforms. Its small footprint permits the stable shaking and precise temperature control of 37 degrees to simulate the ideal temperature so that cells do not lose their viability.

4. Laboratory centrifuge

Features a variable rotor for 15-50 mL tubes for the cell colony cultivation, tissue isolation, and blood separation. The use of a tilting rotor favors the separation of particles by density gradient, which increases the concentrations of the cellular products.

5. Conventional Refrigerator

A Frost-Free Freezer to store enzymatic and acellular components such as exosomes, as well as growth mediums.

6. Automatic Cell Counter

The automatic stem cell counter gives you accurate results of the live and dead cell counts in just seven seconds. The cell counter's accuracy is second to none.

7. Ultra-Low Temperature Freezer or Tank with Liquid Nitrogen

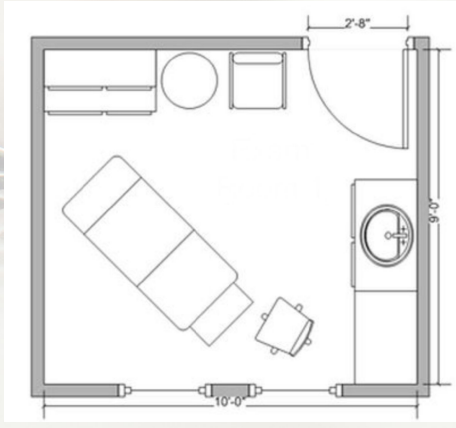
Suitable for storage in the liquid or vapor phase. The temperature in the upper part of the racks is -82 ° C during the vapor phase.

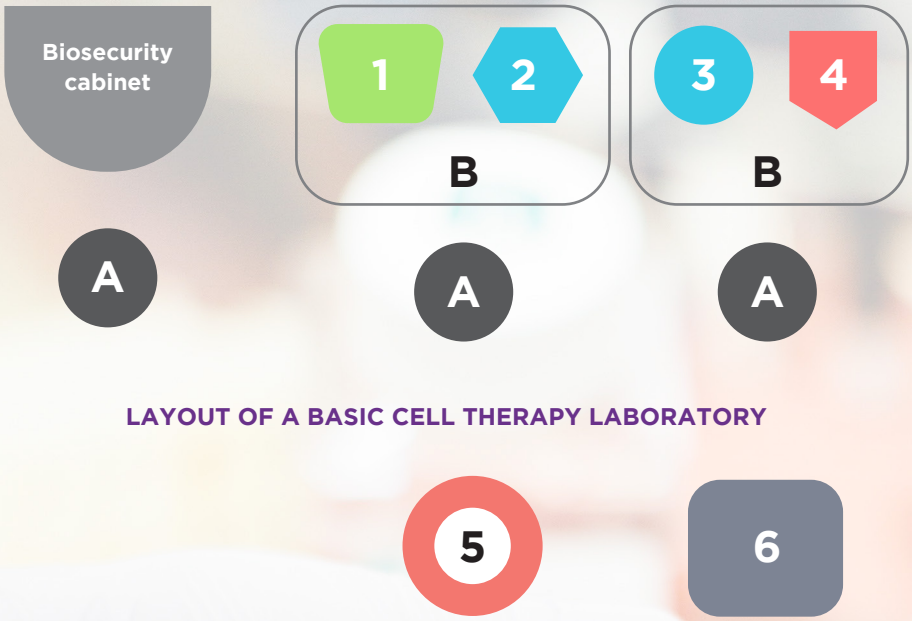
CONSTRUCTION REQUIREMENTS

The Global Stem Cells Group has created a template explicitly designed to support the assemblage of these regenerative medicine centers that includes their laboratory equipment layout design to enable the collection and processing of cellular products. This infrastructure provides the flexibility to offer a multitude of services for projects that vary in volume and sample size, while still maintaining efficient and effective processing timeframes and costs.

Standard Procedures Room for tissue **extraction and cell therapy administration**

Sterility is one of the most critical elements to consider when setting up a laboratory to process adipose tissue, bone marrow, or allogeneic cellular components. We recommend a secluded room with a laminar flow cabinet or a biosafety cabinet, which is an essential element if you do not have an operating room. Below you can see the ideal layout for a cell therapy unit within a clinic.





LAYOUT OF A BASIC CELL THERAPY LABORATORY

MARKETING CONSULTANCY

As a project participant and a member of our global network of clinics, you will be provided with a commercial approach program with practical tools and ideas to promote your regenerative medicine practices. Topics include:

- Guides on how to do a successful Patient consultation
- Training in telephone correspondence and handling objections
- Patient flow management and process control
- Frequently Asked Questions (FAQS)
- Digital presence (website, landing pages, social media)
- Monitoring strategies (follow-ups)
- How to use paid ads (Adwords) and social media marketing (Facebook ads) to attract new patients
- Email marketing
- Video Production
- How to use content marketing to attract the target audience
- Promoting a regenerative medicine clinic in the digital era
- Influencer marketing

STEMCELL CENTER

CERTIFICATIONS AND FINISHED PROJECTS


CERTIFICATE OF PATENT

REGISTRATION NUMBER

10-0960695

TITLE OF THE INVENTION

PATENTEE

INVENTOR

THIS IS TO CERTIFY THAT THE PATENT IS REGISTERED ON THE REGISTER OF THE KOREAN INTELLECTUAL PROPERTY OFFICE.

COMMISSIONER, THE KOREAN INTELLECTUAL PROPERTY OFFICE


CERTIFICATE OF PATENT

REGISTRATION NUMBER

10-0810063

TITLE OF THE INVENTION

PATENTEE

INVENTOR

THIS IS TO CERTIFY THAT THE PATENT IS REGISTERED ON THE REGISTER OF THE KOREAN INTELLECTUAL PROPERTY OFFICE.

COMMISSIONER, THE KOREAN INTELLECTUAL PROPERTY OFFICE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EC DECLARATION OF CONFORMITY

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EC DECLARATION OF CONFORMITY

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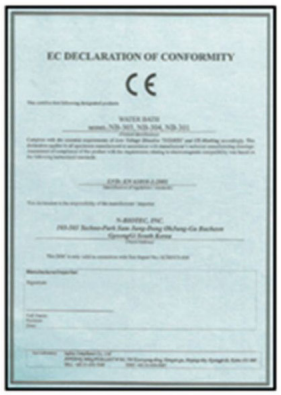
DESKTOP LARGE SHAKING INCUBATOR

N-BIOTEK INC.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의료기기 제조품목 신고증


KFDA

의료기기 제조품목 신고증


Intertek

AUTHORIZATION TO MARK


SGS

CERTIFICATE OF LVD COMPLIANCE

CE


SGS

CERTIFICATE OF EMC COMPLIANCE

CE


EC DECLARATION OF CONFORMITY

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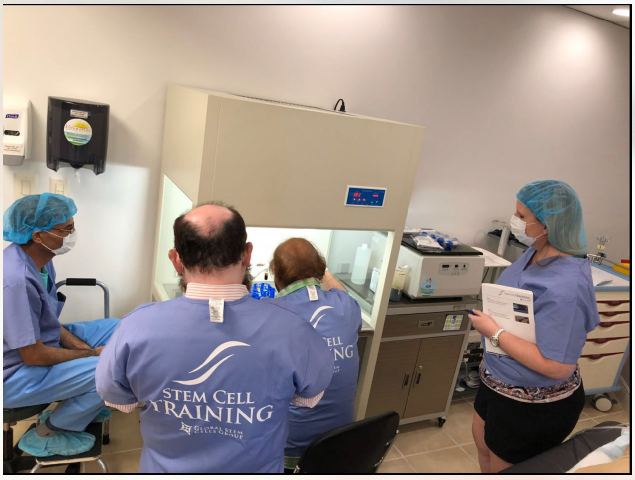
STEM CELL CENTER MEDLEY, FL



STEM CELL CENTER MIAMI, FL

STEM CELL CENTER CANCUN, MX

STEM CELL CENTER SAN JUAN, PR

STEM CELL CENTER BOGOTA, COL

STEM CELL CENTER GUADALAJARA, MX

STEM CELL CENTER BRUSELAS, BEL

STEM CELL CENTER BUENOS AIRES, ARG

STEM CELL CENTER LIMA, PERU

Stem Cell Center

Enabling physicians to make the benefits of stem cell medicine a reality for patients around the world.

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