First of all I would like to introduce myself, I’m Kenichiro Hata. I have recently been designated the Chairman during the 2019 General Meeting and at this year’s second conference of Board of Directors, and I would just like to say a few words.

What regenerative medicine provides us with.

“Regenerative medicine” is medicine that positively utilizes physical cells to help tissues and organs restore their natural functions which have been lost, whether it be through dysfunction or malfunction. Our country, in spite of having previously been producing numerous excellent results in pure research, used to be regarded as one which still has many challenges which it needs to overcome before generating practical application. In 2012, Dr. Yamanaka of Kyoto University and his colleagues were awarded the Nobel Prize in Physiology or Medicine for their research in iPS cells, which displayed their high-level research results in this particular field to not only people in Japan but people abroad. This has made not only researchers but also the general population more aware of regenerative medicine.

As of June 2019, our country has approved the manufacturing and sales of seven regenerative-medicine-related products. These products primarily utilize living cells, which in turn makes them totally unique and different from other conventional drugs and medical devices, whilst advocating new treatment methods to patients. Whilst it has also become clear that those regenerative-medicine-related products are now having to overcome new challenges which concern the establishment of a business model, including provision methods and treatment costs. It is imperative that we appropriately solve these problems in order to industrialize regenerative medicine in the future.

What the Forum for Innovative Regenerative Medicine (FIRM) offers to regenerative medicine.

FIRM started in 2011, as a gathering place for corporations aiming to industrialize regenerative medicine with 14 initial corporations. Currently, it boasts over 250 corporations. The diversity of member corporations characterizes FIRM. In other words, it consists of not only corporations who are manufacturing and selling regenerative-medicine-related products, but also those that are handling machinery, devices and a variety of materials necessary for cell culture, and even those corporations who are engaging in the business of industrializing regenerative medicine in the future. As I mentioned before, the challenges which we now face regarding the practical application of regenerative medicine, lies not only in the mere manufacturing of the products but also in how to establish the industrial network centering around regenerative medicine and to bring forth a new medical culture. In an attempt to save patients who are suffering from intractable diseases, whilst at the same time trying to establish a new medical industry, we intend to create new values by integrating the experience accumulated by diverse corporations. FIRM should be, we earnestly hope, a place where member corporations can amass their technologies for the purpose of corporealizing regenerative medicine.

To bring forth a new “joy” through regenerative medicine. That is my desire.
Towards Commercialization of Regenerative Medicine

Objective

Regenerative medicine and cellular medicine promise new concepts of medical technology that cannot be provided by existing medicine and medical instruments. It is the intention of FIRM to provide the medical industry and patients who cannot find satisfaction with existing medical treatment with alternative medical technology. We will also work with the industry, government and universities to turn Japan into a world leader in regenerative medicine, to ensure that research results are quickly commercialized and aggressively pursue comprehensive measures to overhaul our social structure.

Activities

1. Provide solutions or advices of commercialization strategies on regenerative medicine
2. Promote mutual exchange and cooperation between the people involved in regenerative medicine both in and out of Japan
3. Conduct surveys and Statistical analyses for regenerative medicine
4. Host and organize research workshops and hold open lectures on regenerative medicine
5. Conduct additional and related projects on regenerative medicine

Organization (April 1, 2020)
Overview of FIRM History

2011
June
Established “The Forum for Innovative Regenerative Medicine (FIRM)” with 14 companies

2015
March
Opened the FIRM subsidiary office in Kansai area

2016
May
Entered into MOU with Centre for Commercialization of Regenerative Medicine (CCRM) in Canada for accelerating Regenerative Medicine

July
Hosted the 1st “Regenerative Medicine Crossroad in Tokyo”

October
Entered into MOU with The Council for Advanced Regenerative Medicine (CARM) in Korea for accelerating Regenerative Medicine in both countries

Introduced the environments surrounding Regenerative Medicine in Japan at the workshop in Cell & Gene Meeting on the MESA 2016

Hosted the 2nd “Regenerative Medicine Crossroad in Tokyo”

Cosponsored “Regenerative Medicine Japan” session in BioJapan 2016 with Japan Bioindustry Association (JBA) and conducted four sponsored seminars

November
Cosponsored the “2016 World Alliance Forum in San Francisco”

Entered into MOU with China Medical Biotech Association (CMBA) in China

Hosted the 1st “Regenerative medicine venture supporting seminar”

December
Received approval of ISO New Work Item Proposal on design process to establish specification of cell transportation

2017
February
Hosted the 3rd “Regenerative Medicine Crossroad in Tokyo”

Hosted the 2nd “Regenerative medicine venture supporting seminar”

August
Entered into MOU with Association of Biotechnology Led Enterprises (ABLE) in India

October
Entered into MOU with AusBiotech in Australia

Cosponsored “Australia - Japan Regenerative Medicine Round Table”

Entered into MOU with Cell and Gene Therapy Catapult (CGT Catapult) in UK

Entered into MOU with International Society for Cell & Gene Therapy (ISCT)

2018
February
Entered into MOU with Israel Stem Cell Society (ISCS) in Israel

April
Hosted “The 1st Asia Partnership Conference of Regenerative Medicine Associations (APACRM)”

Entered into MOU with Biotechnology and Pharmaceutical Industries Promotion Office (BPIPO) in Taiwan

September
Hosted the 8th “Regenerative Medicine Crossroad in Tokyo”

Hosted the 6th “Regenerative medicine venture supporting seminar”

In addition to the above, FIRM has made a number of proposals and public comments, hosted roundtable discussions and seminars with government offices and affiliates, and through these activities, FIRM is strengthening the cooperation between Regenerative Medicine organizations both in and out of Japan.
Committees Working on Industry Challenges

Supporting Industries Committee
- The Supporting Industries Committee discusses how the peripheral industries that support regenerative medicine should be structured from the viewpoints of both suppliers and users, and then, in close cooperation with other committees of FIRM, it creates an appropriate value chain that supports the peripheral industries.
- The committee has established specialized Working Groups (WG) for six fields to drive the creation of each element of the value chain, including “Cell Processing Facilities,” “Cell Processing Systems,” “Plastic Ware, Consumables, and Materials,” “Reagents and Culture Media,” “Logistics,” and “Test and Measurement Equipment.” From these WG, four (4) of FIRM’s original standards, the guides for “Logistics,” “Automated Cell Culture System,” “Plastic Ware,” and the case study of “Cell Processing Facilities,” have already been published and three (3) more standards will be published by the end of 2018 (available only in Japanese).
- The committee works on developing and offering draft proposals of international standards originating from FIRM’s standards in collaboration with the “Standardization Committee” and other committees.

Standardization Committee
- The Standardization Committee leads the development of standards in the field of regenerative medicine in the following ways:
  - Firstly, we identify the need and gaps for standardization both at the domestic level and at the international level by investigating and analyzing the current status of, and challenges ahead for, the industrialization of regenerative medicine with particular focus on establishing a value chain that will support regenerative medicine from the industrial sector.
  - Secondly, we crystallize these needs and gaps into concrete standardization items through collaborations inside and outside of FIRM, e.g., partners from academic and government sectors inside and outside of Japan.
  - Finally, we develop standards on these items through collaborations with our worldwide partners in standardization organizations such as ISO (International Organization for Standardization).

Regulatory Committee
- The Regulatory Committee conducts studies on regulatory systems for regenerative medicine, which should be in line with the realities at the medical frontline, and makes proposals to promote the commercialization of regenerative medicine.
- The committee provides tangible tools such as guidebooks for member companies and relevant parties to develop a proper understanding of the latest regulatory systems in order to facilitate the commercialization of regenerative medicine.
- The committee has established specialized Working Groups (WG) such as a “WG for RMP* Approval and Licensing Procedures Guidelines,” a “WG for the RMP Guidebook Adverse,” a “WG for Making Proposals to the Regulatory System,” etc. to take actions proactively and efficiently in order to achieve the above mentioned goals.

Medical Economics Committee
- The Medical Economics Committee proposes solutions for the challenges in the industrialization of regenerative medicine and cell therapies, focusing on the economic aspects.
- The committee considers and proposes “the most appropriate way to reimburse regenerative medicine products for the developers and manufacturers under the Pharmaceutical and Medical Device Act.”
- The committee considers and proposes the best options for patients in order to expand patients’ access to regenerative medicine and cell therapies conducted under the Act for Ensure Safety in Regenerative Medicine.

RMIT (Regenerative Medicine Industrialization Tactical Committee)
The RMIT Committee plays a key role as a point of contact for accelerated industrialization of regenerative medicine and gene/cell therapy in Japan.
The RMIT Committee responds to various inquiries and requests from domestic and international companies, venture enterprises, and academia relating to the development and commercialization of regenerative medical products and gene/cell therapy in Japan, and gives their best effort to help them resolve their bottlenecks and inadequacies.
The RMIT Committee is committed to providing tactical and practical aid to allow leading-edge medical care technologies to swiftly reach ailing patients.

ISO/TC276 Japan Mirror Committee

ISO/TC 276 (International Organization for Standardization Technical Committee 276) Biotechnology covers standardization in the field of biotechnology processes including analytical methods and bioprocessing, in both of which are major challenges in industrializing regenerative medicine.
FIRM organizes Japan Mirror Committee for ISO/TC 276 and Committee to Standardize Foundation for Cell Characterization and Cell Production. Experts from academia, government, and industry are actively participating in these committees. FIRM members are core experts who lead discussions in ISO/TC 276 international conferences. The contributions by the FIRM members at these conferences are highly respected that they organize arguments and provide comprehensive and appropriate advice.
FIRM members, with government/academia experts of Japan Mirror Committee for ISO/TC 276, discuss the essentials to promote industrialization of regenerative medicine through standards. It leads to ISO NP (New Work Item Proposal) from Japan as well as valuable inputs to standard proposals from outside Japan.
ISO/TC 276 is expected to be the centerpiece for the process of regenerative medicine. More than 100 experts from worldwide gathered at the ISO/TC 276 Plenary and Working group meetings held in Beijing this June. FIRM will sponsor, organize and operate its next meetings in 2019 to be held in Nihonbashi, Tokyo, Japan.

CoNCEPT (Committee for Non-Clinical Safety Evaluation of Pluripotent Stem Cell-derived Product)/MEASURE (Multisite Evaluation Study on Analytical Methods for Non-Clinical Safety Assessment of Human-Derived Regenerative Medical Products)
The FIRM-CoNCEPT supports MEASURE, which is an AMED-granted Study led by Dr. Yoji Sato at National Institute of Health Sciences, to achieve its goal.
The mission of CoNCEPT/MEASURE is to provide regulatory science-based globally acceptable consensus for safety evaluation policy in the R&D of pluripotent stem cell-derived products. Especially, validated methods for tumorigenicity evaluation, which are in alignment with regulatory direction and international standard, will be developed through multi-institutional joint research.