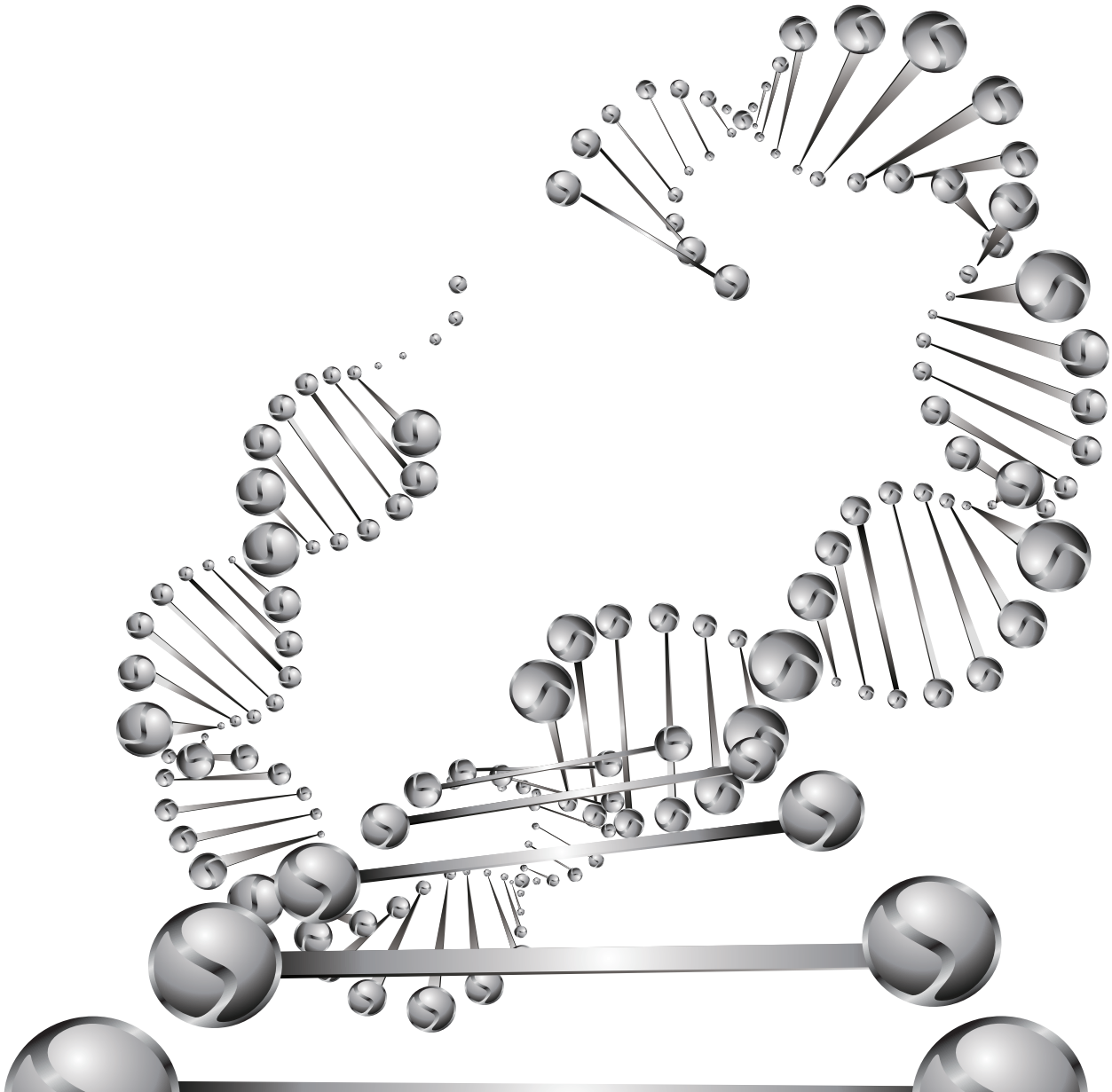
FIRM
Forum for Innovative
Regenerative Medicine

Forum for Innovative Regenerative Medicine



A message from the Chairperson

Our 12 years of activity since the Forum for Innovative Regenerative Medicine (FIRM) was established has contributed to the steady development of foundations for the regenerative medicine industry. I would like to express my appreciation to Dr. Ken-ichiro Hata, former Chairperson and Representative Director, who led FIRM from 2019. I supported him as Vice Chairperson and Representative Director during his tenure, and will continue to work toward the progress of the regenerative medicine industry in Japan.

The number of regenerative medicine products approved in Japan was four when I was appointed as Vice Chairperson five years ago, significantly increasing to 19 as of May 2023. The number of regenerative medicine products under research and development is also steadily increasing. Recently, the Japanese government's Basic Policies for Economic and Fiscal Management and Reform 2023 (also known as HONEBUTO) incorporated "Strengthening the Development of Innovative Pharmaceuticals, Medical Devices, and Regenerative Medicine Products" as part of the enhancement of drug discovery capabilities. Furthermore, the council of diet members promoting regenerative medicine has proposed that this year be the "First Year to Restart Promotion of Regenerative Medicine." Regenerative medicine is a growth field that is expected to form into a wide-ranging market, including the contract development and manufacturing organization (CDMO) business and peripheral industry business involved in manufacturing facilities, equipment, raw materials, components, testing, logistics, and other areas. It is urgently necessary for FIRM to strongly grasp the environmental changes that support the industrialization and growth of regenerative medicine in Japan, and to resolve the many issues that span the regenerative medicine field.

To date, as one of the exit strategies, we have made recommendations for the introduction of a new pricing method that appropriately evaluates the diverse values of regenerative medicine products, because the current drug pricing system is regarded as one of the causes of drug lag/loss in Japan. As a result, significant progress was made, in that FIRM's claims were partially reflected in the report of the meetings for "Study Group of Experts on Comprehensive Measures to Realize Rapid and Stable Supplies of Pharmaceuticals" held by the Ministry of Health, Labour and Welfare since last year. FIRM will continue to emphasize that flexible thinking and mechanisms that extend beyond existing frameworks are essential to enhance the industrialization of regenerative medicine. This applies not only to the drug pricing system, but also to other regulations and systems.

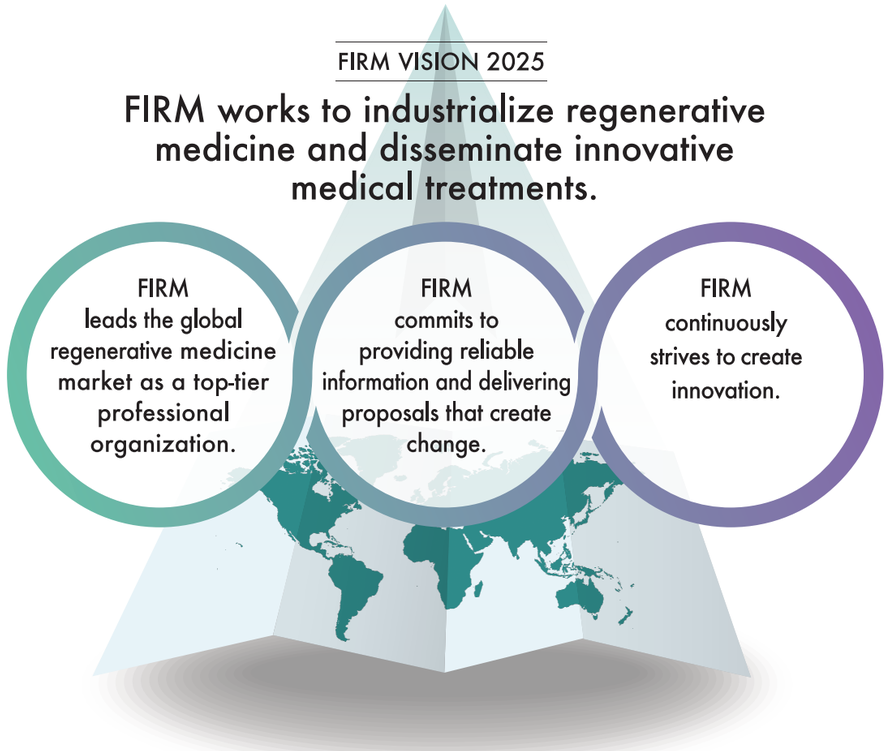
Representative Director, Chairperson
Yoshitsugu Shitaka

Support on entry remains one of our actions that must be addressed. Most regenerative medicine products originate from start-up companies and academia, and FIRM has been supporting them so far. In the future, we are confident that we will be able to achieve sustainable growth as an industry by contributing to strengthening the ecosystem for regenerative medicine from further upstream through collaboration with the government.

Moreover, we established the Specific Processed Cells Committee in FIRM last year to discuss and resolve issues related to activities and CDMO business under the Act on Securing Safety of Regenerative Medicine. The regenerative medicine industry consists of not only the companies that conduct research and development of products under the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, but also the companies that conduct research and development under the Act on Securing Safety of Regenerative Medicine and the peripheral industries that support such companies. We expect that the three committees in FIRM, also including the Supporting Industries Committee and the Cell and Gene Therapy Products Committee, will continue to review relevant issues and formulate proposals for the progress of the regenerative medicine industry.

Finally, by building a team-led system, we aim to strengthen the operation base in FIRM as in FIRM VISION 2025 and to become a sustainable organization that supports mid- to long-term growth of regenerative medicine. Collaboration with other stakeholders is crucial for the future progress of the regenerative medicine industry, and FIRM would like to play a role in promoting various kinds of discussions as an elite group with strong expertise in regenerative medicine. Let us move forward together toward the progress of the regenerative medicine industry, by integrating the wisdom at FIRM, which comprises a wide range of industries.

FIRM'S VISION



Outline of FIRM

Name of company	Forum for Innovative Regenerative Medicine
Location	Nihonbashi Life Science Bldg. 6F, 2-3-11 Nihonbashi-Honcho, CHUO-KU TOKYO 103-0023, JAPAN Tel.+81-3-6262-1575 Fax.+81-3-6262-1576
Foundation	17th June, 2011
Member	Member companies 192 Corporate member/13 Individual members Number of member companies 152 Regular members/4 Special members/36 Supporting members/12 Individual members/ 1 Honorary members/

Representative Director, Chairperson	Yoshitsugu Shitaka (Astellas Pharma Inc.)	
Representative Director, Vice Chairperson	Ken-ichiro Hata (Japan Tissue Engineering Co., Ltd.)	
Vice Chairpersons	Shigeharu Nishiuchi (Hitachi, Ltd.) Tohru Hirose (Novartis Pharma K.K.)	
Directors	Mikitomo Yasutake (Asahi Kasei Corporation) Setsuko Hashimoto (CellSeed Inc.) Toshiki Sugimoto (Dai Nippon Printing Co., Ltd.) Tohru Takahashi (Daiichi Sankyo Co., Ltd.) Yutaka Yamaguchi (FUJIFILM Corporation) Yuji Sato (JCR Pharmaceuticals Co., Ltd.) Toshiyuki Kurata (Kyowa Kirin Co., Ltd.) Takashige Kondo (MEDINET Co., Ltd.)	Osamu Takahashi (PHC Corporation) Kazuya Omi (SRL, Inc.) Toru Kimura (Sumitomo Pharma Co., Ltd.) Mutsumi Sano (TAKARA BIO INC.) Keiji Iwashita (Takeda Pharmaceutical Company Limited) Takayuki Nakano (Teijin Limited) Kazuhisa Senshu (TERUMO CORPORATION)
Supervisory Board Members	Tadashi Sameshima (Cellth DeC) Hironao Yazaki (Ernst & Young ShinNihon LLC)	

(As of June 19, 2023)

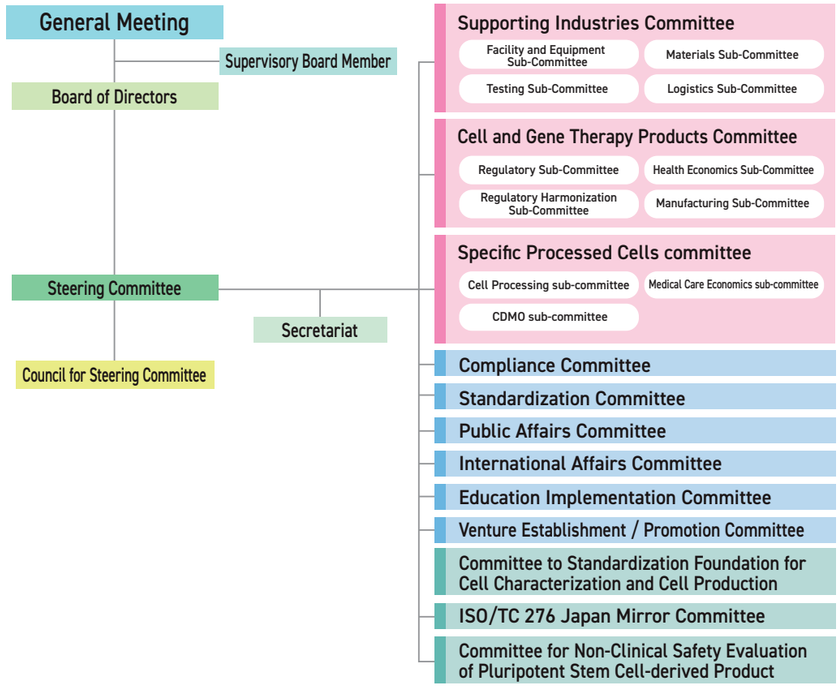
Introduction of FIRM

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

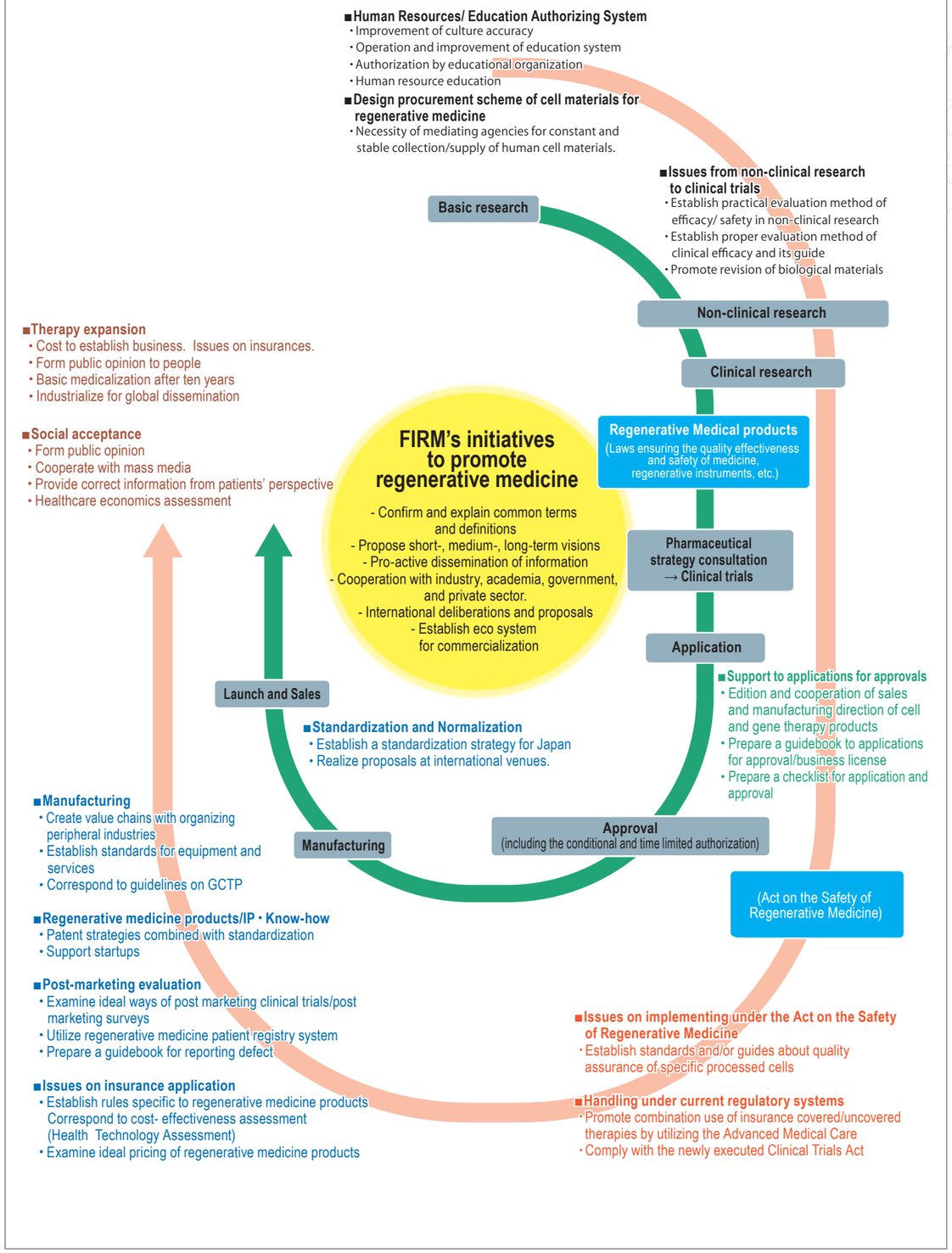
1. Provide solutions or advices of commercialization strategies on regenerative medicine
2. Promote mutual exchange and cooperation between the people involved in regenerative medicine both in and out of Japan
3. Conduct surveys and Statistical analyses for regenerative medicine
4. Host and organize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

Organization



(As of July 1, 2023)

Towards Commercialization of Regenerative Medicine



Supporting Industries Committee

Promote efforts to develop and revitalize the regenerative medicine peripheral industry value chain.

Core members' meeting

1. Identify and organize issues in the manufacturing value chain, and consider solutions to those issues through discussions with the FIRM's Committees.
2. Hold meetings to exchange opinions with the Ministry of Economy, Trade and Industry, the Ministry of Health, Labour and Welfare, PMDA, the Japanese Society for Regenerative Medicine and other parties to communicate issues and requests of companies in peripheral industries.
3. Provide opportunities to promote member companies and products through exhibitions, FIRM events, websites, etc.

Facility and Equipment Sub-Committee

1. Identify and resolve issues related to facilities (CPCs) and equipment with FIRM's Committee.
2. Organize workshops and tours of facilities owned by each company.
3. Exchange opinions and information with the JSRM, academia, the METI and other regulatory authorities.

Materials Sub-Committee

1. Discuss materials-related issues, prepare a user guide and Q&A collection, and examine the FIRM mark.
2. Activities of the Review Group for Standard for Biological Ingredients, and updating the list of products obtained confirmation of eligibility for materials for regenerative medicine, etc.

Logistics Sub-Committee

1. Identify logistics-related issues and consider solutions.
2. Organize facility tours and workshops.
3. Activities for dissemination and implementation improvement of the "Inquiry List of Companies that Can Provide Logistics Services and Articles for Regenerative Medicine."

Testing Sub-Committee

1. Compile the collection of FIRM cases of test and inspection methods/equipment, and disseminate the case collection to Type 3 Area (dental, cosmetic, plastic surgery, etc.).
2. Hold workshops on "how to expand overseas."
3. Consider preparing an inquiry list.

Cross Sub-Committee Working Groups

Event Planning WG
Market Research Planning WG
Standardization Study WG
Study Session Planning WG

Cell and Gene Therapy Products Committee

Sort out regulatory and other issues related to regenerative medicine products' development, manufacture, sales, etc., clarify priority issues, and conduct activities.

Core members' meeting

Compile issues faced by regenerative medicine companies into concrete proposals and recommendations, and negotiate with regulatory authorities for new establishments or improvements.

1. Proposal for a scheme to provide out-of-specification (OOS) products
2. Proposal for medical technology and technology fees considering ensuring patient access
3. Consider the introduction of facility standards following FACT, etc.
4. Improved operation of the Regenerative Medicine Registry
5. Study of issues in conditional and time-limited approval systems

Regulatory Sub-Committee

Consider issues related to the regulatory system and draft proposals and recommendations. In addition, promote industrialization by providing the guidance and tools for the current regulations and systems.

Health Economics Sub-Committee

Clarify issues in the current NHI price calculation and the revision rules, and aim to establish a unique price calculation rule based on the features and characteristics of regenerative medicine products.

Manufacturing Sub-Committee

Consider issues related to manufacturing and drafts proposals and recommendations. Work closely with peripheral industries and the Supporting Industries Committee.

Regulatory Harmonization Sub-Committee

In cooperation with the International Affairs Committee, focus on the activities of APACRM, and promote activities such as exchanging opinions in cooperation with overseas organizations.

Specific Processed Cells Committee

Provide support for regenerative medicine (RM) related to research using specific cell processed products (SCPP), and patient treatments as the medical practices to promote RM under the Act on the Safety of Regenerative Medicine ("ASRM") and related regulations.
The committee will commit to achieve the right direction of SCPP manufacturers (notification, accredited or licensed facility), problem-solving support for medical institutions that provide RM, and sharing information to patients.
We take actions for policy guidance of ASRM, through discussions within FIRM and with related organizations (Japanese Society for Regenerative Medicine, disease-specific societies, Ministry of Health, Labour and Welfare, Ministry of Economy, Trade and Industry, PMDA, etc.).

Core members' meeting

Discuss and steer the future direction of whole committee and three sub-Committees' activities.

Cell Processing Sub-Committee

Realize the homogenization in manufacturing among 3 types of SCPP facility operators by standardizing the quality of manufacturing including overall operation, in addition to dealing with hardware and software associated with manufacturing involved with RM under ASRM.

Medical Care Economics Sub-Committee

Regarding RM under ASRM, we will realize mixed use of RM that is not covered by Public Health Insurance (exemption from the ban on mixed medical treatment) and that is covered such an insurance, and commercialization of private insurance to improve patient access.

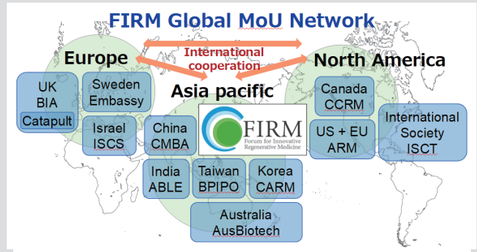
Contract Development and Manufacturing Organization Sub-Committee

Find out specific characters and identify challenges related to manufacturing of RM under Pharmaceutical and Medical Devices Act (PMD Act) and ASRM. In addition, we will contribute to competitive advantages in Japanese CDMOs and accelerating RM industrialization through discussions within FIRM and with related organizations.

A study session on ASRM

International Affairs Committee

Support the international collaboration and expansion of member companies, accelerate product innovation, and actively contributing to the advancement of industrialization within the regenerative medicine sector. Additionally, we aspire to collaborate with governmental bodies to harmonize regulations across Asian countries and regions, with the goal of creating an Asian market on par with those in Europe and North America.



We have established a worldwide collaborative network through the signing of MoUs with international industry associations and related academic societies dedicated to advancing the regenerative medicine sector. Beyond symposium co-sponsorship, we will leverage ongoing Asian insights from the Asian Partnership Conference of Regenerative Medicine (APACRM), an initiative catalyzed by FIRM, to enhance mutual understanding in Europe and the United States.

APACRM serves as a means to facilitate more specific discussions on critical regulatory science matters within the field of regenerative medicine, with the goal of achieving regulatory harmonization in Asia.

APACRM
Asia Partnership Conference of Regenerative Medicine

A scene at APACRM

Main committees

Compliance Committee

FIRM members must be aware of their social mission to “contribute to a healthy future for people through the spread of regenerative medicine,” and must live up to society's trust by maintaining high ethical standards and conducting business with integrity as a life-related industry. The Compliance Committee contribute to the promotion of the industrialization of regenerative medicine products through activities to raise awareness and educate members to comply with laws, regulations and FIRM rules and voluntary standards, and to foster a high level of compliance awareness among members.

Standardization Committee

The committee is contributing to the industrialization of regenerative medicine by studying issues to develop a set of standards that can be utilized by many stakeholders involved in the regenerative medicine value chain, and studying measures to promote the spread of the developed standards.
In particular, as a measure to promote the spread of the standards, the committee is taking the lead in establishing and operating a certification system (commonly known as the FIRM mark) for products and services in peripheral industries beyond the framework of the committee.

Public Affairs Committee

In order to realize the policies proposed by FIRM, the committee promote information dissemination to gain the understanding and sympathy of stakeholders regarding activities related to policy themes, and promote public relations activities to foster public understanding of FIRM's contribution to society through regenerative medicine and other products, and of FIRM's efforts toward industrialization.

FIRM's characters: Firmin & Keroron

Education Implementation Committee

The committee aims to understand the current status of human resources and human resource development needed for the development of regenerative medicine-cell therapy and gene therapy and to realize human resource development that will lead to the promotion of industrialization in this field. This activity is in cooperation with academia, the Japanese Society for Regenerative Medicine, and other related organizations.

Venture Establishment / Promotion Committee

Through industry-government-academia collaboration to establish an incubation system, the committee works to support creation and fostering of start-up venture companies, which will serve as engines for the industrialization of regenerative medicine.
As main activities, the committee will hold events unique to FIRM to support entrepreneurship in academia and promote growth of startup companies, and develop a foundation for disseminating information that will contribute to supporting creation and fostering of startup companies.


Venture Establishment Support Forum
(by Venture Establishment / Promotion Committee)


A FIRM's seminar at Regenerative Medicine Japan
(by Public Affairs Committee)

Committee to Standardize Foundation for Cell Characterization and Cell Production / ISO/TC 276 Japan Mirror Committee

The ISO/TC 276 Japan Mirror Committee are the national deliberative body of ISO/TC 276 (International Organization for Standardization Technical Committee 276) and carry out standard development in the field of “biotechnology.”
The Committee to Standardize Foundation for Cell Characterization and Cell Production will carry out the abovementioned projects entrusted by the Ministry of Economy, Trade, and Industry for standardization activities in the field of regenerative medicine.
Both committees are composed of industry, academia, and government members, primarily FIRM members.


ISO/TC 276 7th Plenary Meeting and Joint WG Meeting (Nihonbashi, Tokyo)


ISO/TC 276 Joint WG Meeting (Toronto, Canada)

ISO/TC 276 has Germany as its secretariat and consists of the following working groups. FIRM, as a domestic deliberative body, is responsible for domestic activities in each working group and operates Working Group 4, contributing to international standardization in the field of regenerative medicine.

WG	title	Secretariat
1	Terminology	Germany
2	Biobanks and bioresources	France
3	Analytical methods	United States of America
4	Bioprocessing	Japan
5	Data processing and integration	Germany

Committee for Non-Clinical Safety Evaluation of Pluripotent Stem Cell-derived Product

Deliberate and achieve consensus on safety evaluation methods that are consistent with international regulatory policies, which is important in the research and development of pluripotent stem cell-derived regenerative medicine products.
Disseminate the results of tumorigenicity test methods and cellular pharmacokinetics tests obtained through multi-site studies both domestically and internationally.

Through the international consortium activities of HESI CT-TRACS (Health and Environmental Science Institute, Cell Therapy TRAcking, Circulation, & Safety committee), we will conduct performance evaluation of the test method for tumorigenic hazard detection in cell processed products at multiple joint public-private institutions to clarify the reproducibility and usefulness of the test method and to form consensus and achieve international standardization of test methods for risk assessment specific to cell processed products. In addition, we will domestically and internationally disseminate technical improvements in the tumorigenicity-related test method and pharmacokinetics assessment test method, which have been compared and verified at multiple institutions and foster consensus toward the international standardization of these test methods. Furthermore, we will continue to develop and establish assessment test methods with further improved simplicity, versatility, sensitivity, etc., with the aim of achieving international technological superiority.


February 4-5, 2020, IABS, Tokyo, Japan

FIRM's members

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The United States Pharmacopeia
Toshiba Corporation
Trust Express Co., Ltd.
TWOCELLS Company, LIMITED

Individual Members
Total 12 persons

Honorary Member
Total 1 persons

(As of June 19, 2023)

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