Promoting Basic and Advanced Research and Technology in the Fields of the Health Sciences* and Enhancing their Infrastructure

Leading the Health Sciences to Contribute to the Health and Welfare of Humankind

Background of Establishment
The Japan Association for Advanced Research in Pharmaceuticals was founded in April 1985, following a recommendation from the Pharmaceutical industry Policy Forum, an advisory body to the Director General, Pharmaceutical Affairs Bureau, Ministry of Health and Welfare in October 1984 (This Ministry was reorganized into the Ministry of Health, Labour and Welfare (MHLW) on January 6, 2001). The association was reorganized in April 1986 as the Japan Health Sciences Foundation (JHSF), a non-profit foundation backed by the ministry and funded by 18 companies in such industrial sectors as pharmaceuticals, chemicals, food products, medical supplies and textile goods.

Objectives and Role
In recent years, dramatic strides have been made in biotechnology (genome science, bioinformatics, regenerative medicine, etc.). These advances have created an atmosphere of unprecedented hope for the health and welfare of humankind. JHSF now has an opportunity to make a real contribution to the health and welfare of humankind by promoting both advanced and basic sciences and technology in the fields of health care, pharmaceuticals, medical and welfare equipment and public health. In order to achieve these objectives, JHSF assembles top researchers from industry, academia and government and provides them with locations for joint research, functioning as a liaison between them or as a catalyst to progress their research.

Main Activities
JHSF is advancing research and survey project on various topics relating to drug discovery research based on advanced and basic sciences and technology in the fields of molecular biology, biotechnology, bioinformatics etc., public health, regulatory science and so forth. This project is conducted by scientists and R&D staff of member companies and fully supported by Japan Agency for Medical Research and Development (AMED) as a sponsored research.
In addition, in order to promote the active utilization of the results achieved by the research organizations under MHLW and their applications for the benefits of society, JHSF is deploying the TLO operations with the approval of the MHLW Minister. Furthermore, in order to promote scientific animal tests in compliance with the MHLW guidelines, JHSF has also launched Accreditation Project for Laboratory Animal Care and Use.

*Health sciences: In this context, the term is understood to include those scientific studies that have a direct connection with the health and welfare of humankind in such fields as health care, pharmaceuticals, medical and welfare equipment, and public health
Basic Policy

- JHSF is pushing forward with operations for promoting pharmaceutical and medical science and technology based on its social mission and role as a public corporation and through these operations is contributing to the health and welfare of humankind.
- JHSF focuses its activities on those subjects that are inappropriate as a government activity or that cannot be easily achieved in the private sector alone, and plays the leading role in cooperation and collaboration between industry, academia and government.
- The operations of JHSF are a strongly public character and the activities are funded by the government subsidy as well as by the budget provided from private sector. Furthermore, JHSF will also continue to promote the operations of its own projects.

**Membership system**

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<tr>
<th>Type</th>
<th>Supporting members</th>
<th>Maintenance members</th>
<th>Individual members</th>
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<td>Definition</td>
<td>Corporate body that approves the purpose for the establishment of JHSF and participates positively in its planning and administration.</td>
<td>Corporate body at the venture business level that approves the purpose for the establishment of JHSF and cooperates in its maintenance and promotion.</td>
<td>Individuals who approve the purpose for the establishment of JHSF.</td>
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**General Project**

JHSF conducts various activities relating to the topics selected by General Project Committee as General Project. This Committee is consisting of committee members from major supporting member companies. Under General Project Committee, following one committee and two working teams have been established and supporting JHSF's activities;

- Steering Committee is discussing and planning the topics Research and Survey Project should work on, etc.
- Promotion of Technology Transfer Working Team is organizing Bio-Interface, a seminar, in which biotech venture companies present their technologies and business plans to JHSF member companies.
- Biopharmaceutical’s Regulation Working Team is investigating and trying to establish new standards for biopharmaceutical's manufacturing.

In addition, General Project Committee is responsible for the selection of topics to be presented at JHSF workshop. The aim of this workshop is to bring enlightenment to member companies with regard to scientific and regulatory topics.

**Research and Survey Project**

This project involves investigation and survey for various themes relating to the promotion and reinforcement of drug discovery infrastructure in Japan. Scientists and R&D management staff of JHSF Supporting Member companies attend 3 groups, i.e. Medical Unmet Needs Survey Group, Drug Discovery Technology Survey Group, and Information Sharing and Training Group. Drug Discovery Technology Group is further divided into 3 working groups (WG); Overseas Survey WG, Domestic Technology Survey WG and Regulatory Science Survey WG. Members of these Groups and WGs conduct research and survey activities against wide-variety of issues surrounding drug discovery in Japan. All the activities of Research and Survey Project are being fully supported by MHLW as a sponsored research titled “Research on Development of New Drugs”.

**Flow-chart, Research & Survey project**

- **JHSF**
- **Medical Unmet Needs**
- **Drug Discovery Technology Survey**
- **Information Sharing & Training**
- **Recommendations** (reflecting the know-how and ideas of front-line scientists of pharma-and bi-industry)
- **Regulatory Agency**
  - Medical Organizations
  - Universities
  - Research Institutes
  - Pharma & Related Companies

**Member Companies**

**Challenges of Pharma & Bio-industry**
- drug needs
- drug targets
- regulatory trends
- leading-edge technologies
- R&D strategy

**Theme proposal**

**Participation** (as research collaborator)

**Reinforcement of private-public partnership and promotion of the creation of Japan-origin new drugs and new therapeutic technologies**
In May 2003, JHSF established the Health Science Technology Transfer Center (HSTTC) as a TLO approved by the Ministry of Health, Labour and Welfare (MHLW), based upon support from MHLW. HSTTC oversees the following operations aimed at the effective utilization return to society of the research results from the national research institutions under MHLW.

(1) Regarding inventions by researchers at national research institutions under MHLW that are to be inherited by the national government, JHSF takes over from the national government the right of application of patents and enforces establishment of various rights and the maintenance and administration of the patents and other rights.

(2) Marketing and licensing for private sectors including the registered members of HSTTC, based on applicable patent rights, etc.

(3) JHSF collects the fees produced by licensing and permission of patents and other rights and returns a part of these to the national government.

(4) JHSF holds education and training on patents for researchers in national research institutions.

(5) JHSF performs other related operations required by the HSTTC, holds lectures and provides information on technology transfer.

National research institutions under MHLW that are the targets of this project

- National Institute of Health Sciences (NIHS)
- National Institute of Public Health (NIPH)
- National Institute of Infectious Diseases (NIID)
- National Rehabilitation Center for Persons with Disabilities (NRCD)
- National Cancer Center (NCC)
- National Cerebral and Cardiovascular Center (NCVC)
- National Center of Neurology and Psychiatry (NCNP)
- National Center for Global Health and Medicine (NCGM)
- National Center for Child Health and Development (NCCHD)
- National Center for Geriatrics and Gerontology (NCGG)
- National Institutes of Biomedical Innovation, Health and Nutrition (NIBIOHN)
- National Hospital Organization (NHO)
- National Institute of Occupational Safety and Health, Japan (JNIOSH)
Hitherto, animal testing institutions in Japan have managed themselves independently according to management guidelines issued under amendments to the Japanese law for the prevention of cruelty to animals. Recently, however, there has been a call for the establishment of an external system to evaluate the independent management system. Accordingly, the Center for the Accreditation of Laboratory Animal Care and Use was established as an external organization with the purpose of assessing and verifying compliance to the “Basic Guidelines for Proper Conduct of Animal Testing and Related Activities in the Research Institutions under the Jurisdiction of the MHLW”, (hereinafter referred to as the “Basic Guidelines”). The objective of the center is to promote the optimum enforcement of scientific animal testing.

Outline of assessment:
Assessments are conducted by the center in “document surveys”, based on documents in a form specified by the center and submitted by applicants, and in “field surveys”, based on visits to the organization that is conducting the animal testing. The results of the surveys are examined by the Evaluation Subcommittee for compliance to the Basic Guidelines. When the results of the assessments are approved, a certificate is issued by the Administration Committee, which is the top decision-making body of the center.
Organization chart

History

1986  April 1, Establishment of JHSF.
      Start of General Project and Governmental/Private-sector Joint Research Project.
1990  First Publication of the JHSF bulletin “Human Science”.
1991  Operations commemorating the 5th anniversary of JHSF.
1995  Operations commemorating the 10th anniversary of JHSF.
      Start of the Research Resources Supply Project.
1997  Start of the Promotion Projects on Health Sciences Research.
1998  Start of the JHSF website.
2002  Start of the Publishing Project.
2003  Start of the TLO Project Approved by the Ministry of Health, Labour and Welfare.
2004  Start of the JHSF mail magazine “HS eMagazine”.
2008  Start of the Accreditation Project for Laboratory Animal Care and Use.
2013  Registration as a Public-Interest Incorporated Foundation.

October 2017
8 min. on foot from Akihabara and 8 min. from Kanda Station of the JR Line.
5 min. on foot from Akihabara and 5 min. from Kodenmacho Station of the Hibiya Line.
3 min. on foot from Iwamotocho Station of the Shinjuku Line.