

About IHOKEN

Outline of IHOKEN

The Japan Pharmaceutical Industry Legal Affairs Association (“IHOKEN”), established on April 6, 1981, is the only organization that researches legal affairs surrounding pharmaceutical companies and pharmaceutical-related companies. Its research extends from the various legal areas relating to pharmaceutical companies and companies that produce medical devices, regenerative medical products, and other pharmaceutical-related products, to compliance, intellectual property, pharmaceutical regulations, clinical development, medical issues, and more, and it currently has 363 registered individual members from 106 member companies.

The primary objective of IHOKEN is “to contribute to the improvement of national health and welfare by promoting development in the pharmaceutical industry through conducting research, gathering and exchanging information, and coordinating and cooperating with relevant authorities and organizations to serve the needs of pharmaceutical companies and pharmaceutical-related companies, under the shared awareness of the association’s policy that foster the development of “Legal Minds” of our members. IHOKEN also believes that one of its key purposes is for its individual members to make efforts to enhance their capabilities as professionals in legal affairs, compliance, intellectual property, pharmaceutical regulations, and related areas through mutual education on a wide range of topics relating to daily industry affairs.

Annual membership fees from the member companies are the main source of revenue for the administration of IHOKEN, which ensures its financial independence. At the same time, IHOKEN coordinates with the Federation of Pharmaceutical Manufacturers’ Associations of Japan (FPMAJ), the Japan Pharmaceutical Manufacturers Association (JPMA), and other industry organizations to jointly pursue the sound development of the pharmaceutical industry, its member companies, and other pharmaceutical companies one example of which is IHOKEN’s cooperation with JPMA for the establishment of “the JPMA Compliance Program Guideline.”

Administration of IHOKEN

IHOKEN’s operations are planned and managed by the Board of Directors (which consists of elected directors and auditors), six committees, and one special committee, with clerical support from the Secretariat, in accordance with matters decided by the General Assembly, IHOKEN’s main decision-making organ. IHOKEN has its headquarters in Tokyo, but also has a Kansai branch to assist activities in the Kansai area particularly Osaka which is a center for pharmaceutical companies.

Directors and Auditors

Chairman	Hisahito Osuka	Alnylam Japan K.K.
Vice Chairman	Mitsutaka Okano	Daiichi Sankyo Co., Ltd
Vice Chairman	Yukihiko Okamura	Otsuka Medical Devices Co., Ltd.
Vice Chairman	Yoshitaka Saito	TAIYO Pharma Co., Ltd.
Vice Chairman	Satoshi Sawada	FUJIFILM Toyama Chemical Co., Ltd.
Chief Director	Kazuhide Ikeda	Shionogi Pharma Co., Ltd.
Director	Takaaki Ishii	Sumitomo Pharma Co., Ltd.
Director	Kinichi Enomoto	Pfizer Japan Inc.
Director	Hideki Katayama	Otsuka Pharmaceutical Factory, Inc.
Director	Yasushi Shimokawa	The Research Foundation for Microbial Diseases of Osaka University
Director	Masakazu Nishiyachi	Chugai Pharmaceutical Co., Ltd.
Director	Keigo Baba	Maruho Co., Ltd.
Auditor	Tetsuri Kobayashi	Mochida Pharmaceutical Co., Ltd.
Auditor	Takeshi Yamada	CSL Behring K.K.

Counselor

Yasunori Shibata	Former vice chairman of IHOKEN, Former secretary general of IHOKEN, resigned from SANWA KAGAKU KENKYUSHO CO., LTD.
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Research Groups, Monthly Meetings, Seminars in Practical Legal Affairs, and Journal “LEGAL MIND”

Registered members’ research activities are mainly coordinated through research groups. With the formation of the “Medical Affairs and Clinical Development Research Group” in April 2018, IHOKEN currently has 11 standing research groups in total nine groups in Tokyo, two groups in Osaka, the Compliance Research Group based in Tokyo and Kansai, and a Special Research Group for revising the “Database of Pharmaceutical Contract Formats”. Each registered member belongs to at least one of these research groups, and exchanges knowledge and information and fosters its legal mind through research activities and communication with other members in the research group. Monthly meetings are held (i) to provide an opportunity for each research group to present its results and (ii) to hear special lectures delivered by experts from the industry, government, and academia. In 2017, IHOKEN invited potential members to monthly meetings including the “IP Advance Month” to promote joining IHOKEN. As part of its efforts toward professional education in legal affairs,

compliance, intellectual property, pharmaceutical regulations, and other areas, IHOKEN provides “Seminars in Practical Legal Affairs” nine times a year and gives opportunities for registered members and other employees of the member companies to hear expert lectures. The journal “LEGALMIND” also plays an important role in IHOKEN’s activities. The journal publishes transcripts of the special lectures delivered at monthly meetings, reports of research groups, and other content, and is highly regarded internally and externally. The March 2018 issue of “LEGALMIND” was the 395th monthly issue including its predecessor publication, the “IHOKEN NEWSLETTER.” Thirty-seven special issues of “LEGALMIND” have also been published from time to time, including “Guideline for Compensation of Subjects’ Health Injury in Clinical Studies” (2015). Commemorative books have been issued every five years since IHOKEN’s establishment, the most recent of which was “History of the 40 Years of IHOKEN” (2022).

About “IHOKEN GUIDE”

Every July, IHOKEN publishes the “IHOKEN GUIDE” in print and online, containing a summary of IHOKEN, a description of its activities, and other information. Readers who are considering joining IHOKEN are encouraged to refer to the “IHOKEN GUIDE.”