2024

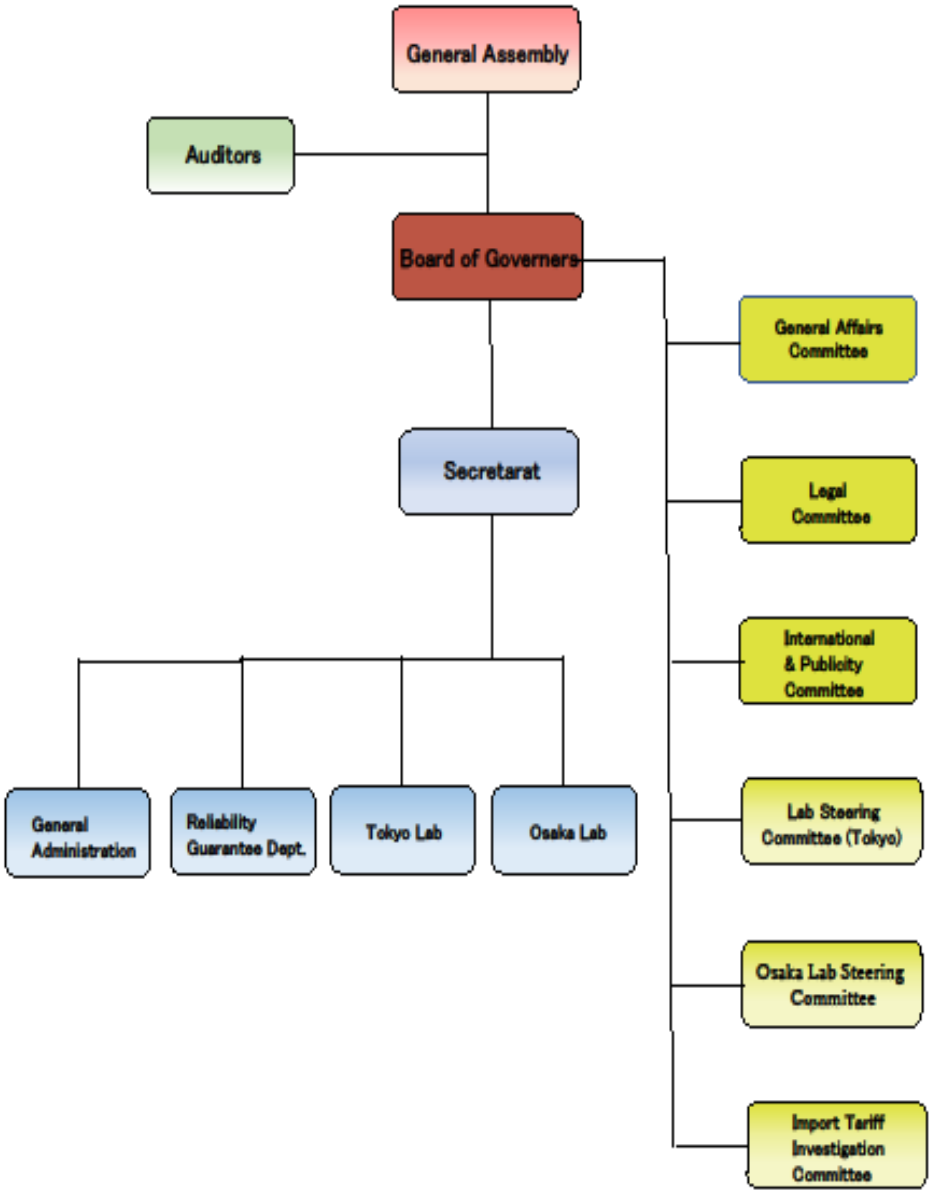
GUIDE

FOR

JPTA

www.japta.or.jp

Organization Chart



Greetings

Ichiro Fujikawa
JPTA Chairperson

The Japan Pharmaceutical Traders' Association (JPTA) was established in June 1963 as an incorporated public-interest association under the jurisdiction of the Ministry of Health and Welfare (reorganized later as the Ministry of Health, Labour and Welfare).

The mission of the Association has been to fulfill its public obligation by operating laboratories which were jointly established by its member companies, pursuant to the then prevailing Pharmaceutical Affairs Law requiring importers of drug substances (Active Pharmaceutical Ingredients) to conduct quality tests by themselves.
In 2012, some legal changes have been made to the Public-Interest Corporation Law and the Association became a "general" incorporated public- interest organization. Thanks to generous support, we celebrated our 50th anniversary in 2013.
In April 2005, the drastically revised Pharmaceutical Affairs Law (PAL) was enforced. With this revision, foreign drug manufacturers became included in the framework of the Japanese regulatory system, reflecting globalization of the pharmaceutical business.
In November 2014, PAL was further revised in the part of medical devices reflecting their own business development and now it is called as "Yakki Ho" (the Pharmaceuticals and Medical Devices Law).
In spite of such changes, the unchanged mission of the Association is to serve as a portal for information exchange with those countries, their local manufacturers and related industries where APIs are produced. Also, the important mission that remains unchanged is to maintain an excellent monitoring system at the border for controlling the quality of imported APIs.

We will step up the collection of information from overseas and provide the information on the Japanese pharmaceutical regulations to overseas in order to control the quality of APIs and to ensure stable supplies. We will strengthen the broad range of such activities.
As a member of the pharmaceutical industry contributing to the national healthcare and medical treatments, we will keep working hard to support a stable supply of safe, high-quality and affordable drugs for the future.

Outline of JPTA

1 Objectives

JPTA will contribute to the improvement of the national healthcare by supporting adequate provision of medicines through fervent efforts of stable import and supply of safe and good quality APIs, etc.

2 Membership

JPTA consists of traders of medicines, APIs, their related products, cosmetic materials, additives for food, etc. who agree to the objectives of the Association and are accepted as regular or associate members.

3 Operation of Quality Assay Labs

JPTA operates quality assay laboratories in Tokyo and Osaka, which meet GMP standards. The members and associate members can conduct quality assays of imported APIs by requesting these labs as “external testing institutes”.

Requests from non-members are also accepted based on the agreement. It is also possible to use our labs as MHLW’s registered assay labs.

4 Dissemination of Japanese Pharmaceutical Regulation and Contribution to International Harmonization

JPTA also hold seminars and conferences for member companies and their customers on Japanese pharmaceutical regulations. Especially, we also present our services to foreign API manufacturers in their countries so that smooth business can be achieved by providing Japanese pharmaceutical regulatory information.

5 Admission (Procedures, Perks)

We welcome your entrance to our association!

You may contact our secretariat for consultation

Admission Requirements: Traders of pharmaceutical and related products,

Japanese branch or agent of foreign pharmaceutical companies, recognized and accepted by the Board of Governors of the Association.

Admission Procedures: You are requested to submit an Admission Application.

Class of Members, Perks, Fees

1) Regular Member

(those who fulfil the requirements and are accepted by the Board of Governors)

[Perks]

- Association's laboratories can be designated as external contract laboratories.
- Members' page on website is accessible for regulatory information (including some English translations) and reports from Association's committees.
- Participation is possible to seminars and overseas events given by the association.

[Fees]

- Admission Fee: 500,000yen
- Monthly Fee: 40,000 yen

2) Associate Member

(Those who do not fulfill the requirements for Regular Members but engaged in pharmaceutical related business and those bodies organized by them and are accepted by the Board of Governors)

[Perks]

- Members' page on website is accessible for regulatory information (including some English translations) and reports from Association's committees.
- Participation is possible to seminars and overseas events given by the association.

[Fees]

- Admission Fee: 100,000 yen
- Monthly Fee: 15,000 yen

Members' Main Businesses

1 As a Trader

Most of the Association members are traders importing and promoting sales for APIs and relevant products regulated by PMD Act and licensed as medicines manufacturers (to be legally responsible for packaging, labeling and storage), for controlling the quality and delivering the products appropriately.

① Search for Overseas Manufacturers

In addition to above requirements, PMD Act requires accreditation of foreign manufacturers, MF registration, GMP compliance investigation, etc.
As a supporter for MAH/MAA, member traders are searching API manufacturers capable of coping with the regulatory requirements and able to make stable supply, etc.

② Import Procedure Management

On importing APIs and relevant products, member companies conduct various activities other than what is stipulated by PMD Act, such as negotiation with foreign API manufacturers, custom clearance, exchanging of various agreements and contracts, management of regulatory documentations. Additional jobs such as patent and supplier investigation, delivery, temporary financing for imported goods, etc. are also meticulously executed.

2 In-Country Caretaker

Many of the member companies serve as in-country caretakers for MF registration* by foreign manufacturers. The number of items handled in this manner by member companies accounts for more than half of the total registrations in Japan.

Note: Master File (MF) registration and In-Country Caretaker

Pursuant to the Pharmaceuticals and Medical Devices Law, when a substance is manufactured by a foreign manufacturer, it is possible to register a Master File including information on the manufacturing method, etc. with the Pharmaceuticals and Medical Devices Agency (PMDA). Since the procedure of MF registration is conducted in Japanese, it is mandatory that MF registration procedures shall be handled by a resident of Japan (an "**in-country caretaker**").

3 Agent for Accreditation Application of Foreign Manufacturers

Accreditation of foreign manufacturers can be applied for not only by foreign manufacturers themselves but also by a Japanese marketer (MAH/MAA) as their agent for inspection application. In case MAH/MAA cannot fulfill the responsibility of an application agent, the regulation allows a capable person/company to surrogate the application responsibility. Many of our members undertake this responsibility.

Note: Accreditation of foreign manufacturers

Pursuant to the Pharmaceuticals and Medical Devices Law, a foreign manufacturer intending to manufacture and export drugs to Japan is required to be accredited by the Ministry of Health, Labour and Welfare, by proving that its manufacturing capability is equivalent to that of Japanese manufacturers. The required inspection is done by PMDA.

Committee Activities

In addition to the foregoing activities, we offer various information, support and cooperation through the following committee activities in line with the objectives of the Association so that each member may achieve its business goals;

1. General Affairs Committee

The committee carries out discussions and planning about meetings (General Assembly, the Board of Governors, and the Executive Governors Board), officers and membership necessary to efficiently operate the Association activities, as well as its rules, organization, personnel affairs, assets, accounting and other matters.

2. Legal Committee

The committee investigates and researches matters and consults with the relevant authorities and other organizations as necessary, and then promptly notifies its members of the findings. It also holds seminars in order to enhance knowledge of the PMD Act and related regulations and to ensure compliance therewith.

3. International and Publicity Committee

The committee promotes international cooperation with foreign corporate associations. It also participates in international exhibitions as well as holds seminars to introduce Japan's pharmaceutical regulatory systems to foreign manufacturers. It plans seminars and workshops together with related Committees. It publishes the Association's activities and information about the government and the industry to its members via the Association's website and its journals.

4. Laboratory Steering Committee (Tokyo and Osaka)

Aiming to improve the precision and speed of testing to meet the needs of member companies and correspond to the improved level of science, the committees formulate measures to expand and upgrade testing facilities. In addition, the committees are proposing to secure that the laboratories located in Tokyo and Osaka install GMP-compliant facilities, to maintain qualification as "testing institutes for registration by the Minister of Health, Labour and Welfare" and as "external testing institutes of pharmaceuticals".

5. Import Tariff Investigation Committee

The committee conducts investigations and studies aiming to abolish or reduce tariffs on APIs and intermediates imported by member companies and contributes to the promotion of trade through negotiation with the relevant authorities.

All Out Activities of JAPTA

1. CPHI Japan Seminars

Since 2010 every April, JPTA has given regulatory seminars and panel discussions inviting speakers from MHLW and PMDA, and also speakers from CCCMHPIE (China) and APIC, EU, etc. The theme has been on international procurement of APIs and exchange of opinions about stable API supply drawing public attention to points at issue.

2. CPHI China and CPHI Korea Seminars

On the occasion of CPHI China in cooperation with CCCMHPIE, and CPHI Korea with KPTA, JPTA has given presentations on the Japanese regulatory affairs inviting and having PMDA officers explain the Japanese pharmaceutical regulatory systems.

3. Participation and Dispatch of PMDA officers

JPTA members participate and ask PMDA to send speakers to the Active Pharmaceutical Ingredients Committee (APIC)'s annual conference to exchange information on APIs and regulatory systems.

4. Preparation of English Translations for Regulatory Notices

It is imperative to give an early notice to foreign manufacturers if there is any change of the Japanese regulatory systems. Thus, JPTA is translating such regulatory notices on APIs into English and distribute them among the members so that they could

communicate with their suppliers and customers. In addition, copies of all related notices in Japanese on medicines are sent to the member companies.

5. Publication of JPTA Journal

The first issue was out in April 2016 and are published annually since then. The information covers news of the Association, special issues on new regulations, topics of CPHI and APIC, ICH Q series, and various information on management, etc. We believe the quality of the information is exclusive comparing to other sources because of its nature.

Operation and Use of Our Laboratories

1. Contracts of Assays for Imported APIs and relevant products

The Association's labs (Tokyo and Osaka) carry out quality assays of the APIs and relevant products imported by the members according to the compendia by their stipulated instruments and test standards and methods.
Request of assays from non-members can also be accepted after due consultation.

2. Registered External Testing Institutes

It is possible to use our labs as a MHLW's registered external testing institute by pharmacies, pharmacy drug manufacturers, cosmetic manufacturers, etc. for their applications for various licenses and for required official tests.
Please contact our secretariats for consultation.

Outline of the available laboratories and assay services are as follows:

① Japan Pharmaceutical Traders' Association Laboratory 3-23-4 Ukima, Kita-ku, Tokyo 115-0051 Japan Registration No.12	②Japan Pharmaceutical Traders' Association Osaka Laboratory 2-5-7 Honmachi, Chuo-ku, Osaka-shi, Osaka-fu, 541-0053 Japan Registration No.92

Both are registered as of March 2004, and re-registered in March 2022.

Types of tests available

We can perform many general tests and assays of Japanese Pharmacopeia, Japanese Pharmaceutical Codex, Japanese Standards of Quasi-drug Ingredients, Japanese Pharmaceutical Excipients, Japan's specifications and standards for food additives, etc.

Some examples of frequently performed tests are shown below:

• Physical and chemical tests (mechanical and chemical analysis)

Liquid chromatography	Gas chromatography
Thin-layer chromatography	Nuclear magnetic resonance spectroscopy
Infrared spectrophotometry	Atomic absorption spectrophotometry
Ultraviolet-visible spectrophotometry	Optical rotation determination
Water determination (Karl Fischer method)	Ammonium limit test
Heavy metals limit test	Arsenic limit test
Nitrogen determination	Refractive index determination
Melting point determination	Qualitative tests
Chloride limit test	Sulfate limit test

• Biological/microbiological/biochemical tests

Bacterial endotoxins test　　Microbial assay for antibiotics

Microbiological examination of non-sterile products

General Incorporated Association

JAPAN PHARMACEUTICAL TRADERS' ASSOCIATION

Membership List

As of January 1, 2024

ACE TRADING CO., LTD.
Alfresa Pharma Corporation
AR BROWN CO., LTD.
Arysta Health & Nutrition Science Corporation
Ashland Japan Ltd.
Aurobindo Pharma Japan K.K.
BASF Japan Ltd.
Biobridge K.K.
C.B.C Co.,Ltd.
Chemix Inc.
Chori Co., Ltd.
Chukan Butsu Ltd.
COSTECH Pharma Inc.
Daesang Japan Inc.
DKSH Japan K.K.
DFE Pharma K.K.
ESTCHEM CO., LTD.
EUROAPI JAPAN G.K.
Evonic Japan Co., Ltd.
Forsitech inc.
Fuji Chemicals Ltd.
Fujikawa & Co., Ltd.
High Chem Company Limited
HIGUCHI INC.
Hovione Limited
Ichimaru Co., Ltd.
Inagaki Yakuhin Co., Ltd.
Indena Japan Co., Ltd.
Itochu Chemical Frontier Co., Ltd.
Iwase Cosfa Co., Ltd.
Japan Sopharchim Co., Ltd.
KADERA YAKUHIN LTD.
KANEDA CO., LTD.
Kanematsu Chemicals Corporation
Kawazu Sangyo Co., Ltd.
Kenko Corporation
Kimura Sangyo Co., Ltd.
KISCO LTD.
Koa Shoji Co., Ltd.
Kongo Yakuhin Co., Ltd.
KONISHIYASU CO., LTD
Koyo Mercantile Co., Ltd.
KYOWA PHARMA CHEMICAL CO., LTD.
Marubeni Chemix Corporation
Maruzen Chemicals Co., Ltd.
Matsumoto Trading Co., Ltd.
MDL CHEMIPHARM CO.,LTD
Meggle Japan Co., Ltd.
Meiwa Corporation
Merck Ltd.
MIK PHARM CO., LTD.
Miki & Co., Ltd.
Mitsubishi Chemical Corporation
Mitsui & Co., Ltd.
Miwa Company Ltd
Miyako Kagaku Co., Ltd.
Miyuki Yakugyo Co., Ltd.
MP GOKYO FOOD & CHEMICAL Co.,Ltd.
MUROMACHI CHEMICALS INC.
Nabelin Co.,Ltd
NAGASE & CO., LTD.
Namiki Shoji Co., Ltd.
Nichibai Trading Co., Ltd.
Nippon Axellia Co., Ltd.
Nippon Bulk Yakuhin Co., Ltd.
NIPPON SOLVAY K.K.
PQE Japan
PRODUCTS ESZE CORP.
Pyxchemi K.K.
RETTENMAIER JAPAN CO., Ltd.
Riverson & Co., Ltd.
Riverstone & CO., Ltd.
Roquette Japan K.K.
S. Kato & CO.
SANCT Corporation
Seiko Trading Co., Ltd.
Shigematsu & Co., Ltd.
Shima Trading Co., Ltd.
Shin Nippon Yakugyo Co., Ltd.
Shiono Chemical Co., Ltd.
Sogo Trading Co., Ltd.
SPERA NEXUS, Inc.
Summit Pharmaceuticals International Corporation
Symrise K.K.
Tohri & Company Ltd.
TOSCO CO., LTD.
Usino Company Limited
Watahan Trading Co., Ltd.
Watanabe Chemical Co., Ltd.
Yamaguchi Yakuhin Shokai Ltd.
Yamakawa & Co., Ltd.
YUKI GOSEI KOGYO CO., LTD.

(92 member companies)

GUIDE FOR THE JAPAN PHARMACEUTICAL TRADERS' ASSOCIATION

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