

DEFENDING
YOUR
BUSINESS
AND
REPUTATION

PACIFIC LEGAL GROUP is an international law firm based in Bangkok which was established in 1992. Our combined staff of pharmacists, lawyers, clinical research associates, agricultural regulatory consultants and supporting registration personnel specialize in matters relating to the Food and Drug Administration and Ministry of Agriculture of Thailand.

For many years, we have prepared, submitted and followed up applications to the Food and Drug Administration of Thailand for registration of pharmaceutical, food, food supplement, medical device, dental, animal health, cosmetic, biotechnology, toxic substance and narcotic and psychotropic substance products.

PACIFIC LEGAL GROUP's registration pharmacists, lawyers and supporting registration personnel have substantial experience with the regulations and procedures of the Thai FDA, as well as the food and drug regulations and procedures of the countries in the Greater Mekong Region. (Myanmar, Vietnam, Laos and Cambodia).

The registration pharmacists and lawyers who compose **PACIFIC LEGAL GROUP's** staff are supported by a clerical staff experienced with the preparation of the documents required by the Thai FDA for registration of all types of products.

Among our clients are the leading companies in the pharmaceutical, healthcare, food, life science, medical device, dental, biotechnology, animal and agri-health and related industries.

We do not distribute products. We register products. Many of our clients use **PACIFIC LEGAL GROUP** to register their products because they do not want to be tied to a single distributor.



Our pharmacists, clinical research associates and lawyers also provide CRO services for clinical trial projects and manage consumer tests in Thailand and the Greater Mekong Region.

PACIFIC LEGAL GROUP provides quality clinical trials services and manages consumer tests on time and within budget.

Our agricultural regulatory consultants and pharmacists have extensive experience in registering plant protection products and animal health drug and feed products with the Thai FDA and MOA.

Our Thai international lawyers provide all of the supporting Thai general corporate, commercial and related legal services which our clients require.

Our pharmacists, lawyers, clinical research associates, agricultural regulatory consultants and supporting registration personnel have established good connections with the staff of the Thai FDA and its testing, science and medical research facilities as well as with the staff of the Thai MOA.

We deliver high quality services in a professional, timely, and economical manner in accordance with international law firm standards.

Confidentiality is of the utmost importance to **PACIFIC LEGAL GROUP**. We know that every phase of our clients' business is sensitive and we pledge to maintain strict secrecy and confidentiality on all assignments.



PACIFIC LEGAL GROUP can expedite the progress of product filings through the Thai FDA and MOA and is dedicated to the objects of obtaining Thai FDA and MOA registration licenses within the shortest possible time and with a minimum of problems.

Our registration pharmacists, lawyers, agriculture regulatory consultants and supporting registration personnel constitute the largest and most experienced team of Thai FDA and MOA product registration specialists in Thailand.

Some of the largest Thai and multinational companies use the services of **PACIFIC LEGAL GROUP** as an attractive and economical alternative for product registrations with the Thai FDA and MOA and for clinical trials and consumer tests. We are pleased to discuss our Thai FDA and MOA product registration and clinical trial and consumer test experience and to suggest cost effective ways in which we can work together.

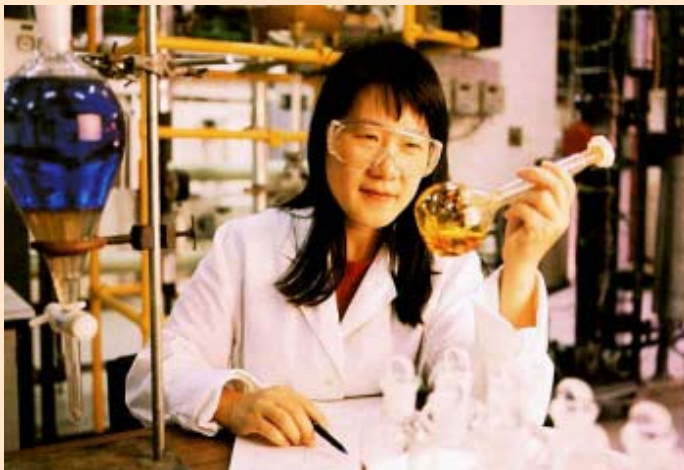
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Thai FDA Registration

PACIFIC LEGAL GROUP specializes in preparing, submitting and following up applications to the Thai FDA for the registration of the following products for import and sale in Thailand :

- PHARMACEUTICALS
- FOOD SUPPLEMENTS
- COSMETICS
- ANIMAL HEALTH
- TOXIC SUBSTANCES
- NARCOTIC AND PSYCHOTROPIC SUBSTANCES
- FOOD
- MEDICAL DEVICES
- DENTAL
- BIOTECHNOLOGY

PACIFIC LEGAL GROUP has an established performance record for these products. We can expedite the progress of product registration filings through the Thai FDA and speed up access to Thai markets.



Our pharmacists, lawyers and supporting registration personnel have established good connections with the staff of the Thai FDA as well as the testing, science and medical research facilities of the Thai FDA.

Our pharmacists, lawyers, and supporting registration personnel work smoothly and effectively to register our clients' products with the Thai FDA. Our group does so in the shortest possible time and with a minimum of problems.

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The pharmacists and lawyers on the staff of **PACIFIC LEGAL GROUP** have collective work experience of over 75 years with the registration of products with the Thai FDA.

Pre-filing Document Review

Prior to filing registration applications, **PACIFIC LEGAL GROUP** reviews documents and other materials received from the manufacturer, and provides advice regarding the category into which the product will be placed by the Thai FDA as well as what additional documents, if any, the Thai FDA will require.

Registration Times

Through our procedures to insure that all application files are complete, we make substantial efforts to reduce and eliminate time loss caused by Thai FDA requests for additional information.

PACIFIC LEGAL GROUP makes a firm commitment to its clients to register products with the Thai FDA in the shortest possible time.

Maintenance

PACIFIC LEGAL GROUP provides all the services required to maintain the on-going registration status of products after they have been registered.

Greater Mekong Region

PACIFIC LEGAL GROUP also prepares, submits, and follows up applications for registration of products with the food and drug regulatory authorities of the Greater Mekong Region countries (Myanmar, Vietnam, Laos and Cambodia).

Advertising

PACIFIC LEGAL GROUP prepares and submits applications to the Thai FDA for approval of product advertising.

Licenses

In addition to applications for product registration licenses, **PACIFIC LEGAL GROUP** also prepares, files and follows up applications for the additional licenses required by the Thai FDA, such as manufacturing licenses for local production and certificates of free sale for export, as well as licenses to import products into Thailand.

PACIFIC LEGAL GROUP also has experience with the Thai FDA procedures for transferring existing registration licenses.

Holding Licenses

For those companies which do not have an office in Thailand, **PACIFIC LEGAL GROUP** can hold the necessary Thai FDA import and product registration licenses. These services are always provided pursuant to a retainer agreement which requires **PACIFIC LEGAL GROUP** to transfer the licenses immediately upon request.

Thai law requires that Thai FDA import licenses and product registration licenses be held by Thai entities. Many companies which wish to do business in Thailand do not want to organize a Thai private limited company to hold their Thai FDA import and product registration licenses. They also do not want to entrust



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their Thai FDA import and product registration licenses to distributors in order to avoid being tied to a single distributor. For these reasons, **PACIFIC LEGAL GROUP** holds the Thai FDA import and product registration licenses for many of its clients.

SMP and Bioequivalence

The services which **PACIFIC LEGAL GROUP** provides includes SMP monitoring for new drug products.

PACIFIC LEGAL GROUP also provides bioequivalence studies for new generic drug products.

General FDA Matters

PACIFIC LEGAL GROUP provides consulting services on all general matters relating to the Thai FDA and the laws under which it operates.

Translation

PACIFIC LEGAL GROUP's staff can translate, into English or Thai, all documents such as product labels and package inserts. Arrangements can be made through our office for translation into other languages.

PACIFIC LEGAL GROUP provides all of the services which are required for the management of clinical trials and consumer tests in Thailand and the Greater Mekong Region. We are dedicated to operating at international good clinical practice standards.

Clinical Trial Management

PACIFIC LEGAL GROUP's pharmacists, clinical research associates and supporting personnel provide services which cover all aspects of international clinical trials projects from preparing, filing and following up Investigational New Drug (IND) applications to product registration to SMP monitoring. Our services include preparation of clinical studies; study monitoring; and site and data management.

We maintain effective communications with sponsors and make certain that all study data is collected in accordance with ICH-GCP guidelines.

Consumer Tests

PACIFIC LEGAL GROUP's pharmacists and lawyers also provide all of the services which are required for consumer tests of cosmetic and other products in Thailand and the Greater Mekong Region.

We conduct subject recruitment and select investigators and study sites. We monitor tests and data management.



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Regulatory Affairs for Clinical Trials and Consumer Tests

The pharmacists and lawyers on **PACIFIC LEGAL GROUP**'s staff also orchestrate and manage all of the various steps in the regulatory process for clinical trials and consumer tests to facilitate interactions and negotiations with the Thai FDA, ERC's and other regulatory authorities.

PACIFIC LEGAL GROUP's pharmacists and lawyers have substantial experience with and in-depth knowledge of all of the regulations and procedures of the Thai FDA, ERC's and the Ministry of Public Health which are applicable to clinical trials and consumer tests. We have good contacts with regulatory authorities throughout the region.

PACIFIC LEGAL GROUP is committed to providing high quality services to our clinical trial and consumer test clients on time and within budget.

PACIFIC LEGAL GROUP's staff includes pharmacists who specialize in the registration of animal health products. These pharmacists register animal health drug products with the Thai FDA and animal health feed products with the Livestock Development Department and Fisheries Department of the Thai Ministry of Agriculture.

For the convenience of our clients, our animal health registration personnel provide specialized services for the following types of animal health products.

- ***Livestock Specialties*** Our pharmacists register drugs and biological products with the Thai FDA and livestock feed products with the Livestock Development Department.
- ***Companion Animal Products*** Our pharmacists register drug and hazardous substances for companion animals with the Thai FDA and companion animal feed products with the Livestock Development Department.
- ***Pharmaceutical Raw Materials (Active/Inactive)*** Our pharmacists register pharmaceutical raw materials for animal health drug products with the Thai FDA and for animal health feed products with the Livestock Development Department.
- ***Aquaculture products*** Our pharmacists register hazardous substance products and aquaculture feed products with the Fisheries Department.



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Licenses

In addition to applications for product registration licenses, **PACIFIC LEGAL GROUP** also prepares, files and follows up applications for the additional licenses required by the Thai FDA and MOA such as manufacturing licenses for local production and certificates of free sale for export as well as licenses to import animal health products into Thailand.

Customs

Our pharmacists also provide services for animal health drug and feed products at the Thai Customs Department.

Established Performance Record

PACIFIC LEGAL GROUP has an established performance record in registering animal health drug and feed products with the Thai FDA and the Livestock Development and Fisheries Department in the shortest possible time and with a minimum of problems.

Plant Protection Products

The staff of **PACIFIC LEGAL GROUP** includes agricultural regulatory consultants who register plant protection products with the Department of Agriculture of the Thai Ministry of Agriculture and the comparable regulatory authorities in the Greater Mekong Region. These agricultural regulatory consultants also maintain the registration status of these products after they have been registered with the Department of Agriculture.



If You Have Already Registered A Company In Thailand

Thai law requires that Department of Agriculture registration certificates must be held by Thai companies.

If you have already registered a company in Thailand, you can own the Department of Agriculture registration certificate.

If you use a distributor to register your products, the distributor will customarily require that the product be registered in its name. The result will be that you will then be tied to a single distributor.

When **PACIFIC LEGAL GROUP** registers your products, the registration certificates will be in the name of your Thai company. You will then be able to conduct your business through any distributor you choose in Thailand.

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If You Do Not Have A Company In Thailand

If you do not have a company in Thailand, **PACIFIC LEGAL GROUP** can be your representative to register your products with the Department of Agriculture. **PACIFIC LEGAL GROUP** can hold the Department of Agriculture registration certificate in its name as your representative under an agreement which would permit you to transfer the registration certificate at any time.

PACIFIC LEGAL GROUP's lawyers can also provide all of the services at the Thai Ministry of Commerce which are required to organize a company for you in Thailand to hold your Department of Agriculture registration certificates.

We can assist you in finding a distributor for your products.

Registration Time Periods

- If the plant protection product has been previously registered by any company in Thailand, the registration time period at the Department of Agriculture will be 2 to 4 weeks.
- If the plant protection product has not been previously registered in Thailand but has a standard Thai label in the Department of Agriculture form, the registration time period at the Department of Agriculture will be 6 to 10 months.
- FAO Phase Registration Procedures will be followed for new products.
- Phase I registration time period - 6 to 8 months.
- Registration field trials - 1 to 2 crop seasons.
- Phase II or III registration time periods - 8 to 12 months.

Field Trials

The agricultural regulatory consultants on the staff of **PACIFIC LEGAL GROUP** provide all of the services for organizing and managing the field trials which are required by the Department of Agriculture for the registration of plant protection products.

Advisory Services

PACIFIC LEGAL GROUP's plant protection specialists also provide advisory services for the plant protection business with emphasis on market research, project management and marketing.

Expedite Registration

PACIFIC LEGAL GROUP can expedite the progress of plant protection registration filings through the Department of Agriculture and speed up access to Thai markets.



PACIFIC LEGAL GROUP provides all of the support services required by multinational dental product manufacturers and suppliers which want to conduct business operations in Thailand and the Greater Mekong Region. We can represent you in the Thai market more effectively and at a lower cost than if you used your own sales staff.



Create New Dental Business

PACIFIC LEGAL GROUP offers dental product manufacturers and suppliers a reliable and complete resource for the creation of new business in Thailand and the Greater Mekong Region.

As agents for multi-national manufacturers and suppliers of dental products, **PACIFIC LEGAL GROUP** can create a new dental business for you in Thailand by finding potential distributors, by helping you to develop new business and by providing market support.

Match-Making

PACIFIC LEGAL GROUP can provide valuable match making services by introducing you to the contacts that can help develop your business in Thailand.

We can identify alliances between multi-national manufacturers or suppliers and distributors of dental products in Thailand and the Greater Mekong region.

As a “match-maker”, **PACIFIC LEGAL GROUP** can find the best distributors for dental products. We search for sources of supply for distributors. We help negotiate the best contract terms for our clients.

Registration of Dental Products

PACIFIC LEGAL GROUP's pharmacists, lawyers and supporting registration personnel have many years' experience registering dental products with the Thai FDA. **PACIFIC LEGAL GROUP** can expedite the progress of product filings and make certain that you obtain Thai FDA registration licenses for your dental products within the shortest possible time.

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As an international law firm based in Bangkok, **PACIFIC LEGAL GROUP** can provide all of the supporting general corporate, commercial and related legal services which its clients require in Thailand including :

- Organization of limited and public companies
- Formation of partnerships and joint ventures
- Intellectual property rights (trademarks, patents and copyrights)
- Taxation
- Obtaining Government licenses
- Banking and Finance
- Securities
- Applications to Thailand's Board of Investment
- Counsel on Alien Business Operation Act matters and business under the Thai - U.S. Treaty of Amity and Economic Relations
- Review and drafting of all types of contracts and agreements
- Effecting mergers, acquisitions and reorganizations
- Real Estate and Construction
- Environmental
- Project Finance
- Health Care
- Product Liability

PACIFIC LEGAL GROUP's lawyers specialize in providing the legal services required by the firm's Thai FDA and MOA product registration clients. These services frequently include intellectual property matters as well as organization of private limited companies due to Thai laws that require that Thai FDA and MOA import and product registration licenses be held by Thai entities.

PACIFIC LEGAL GROUP's lawyers are also experienced in advising international clients on all aspects of Thai immigration matters, such as visas and work permits (and renewals).



Fees

PACIFIC LEGAL GROUP's fee arrangements for all of the services which it provides are flexible and cost effective. We keep costs as low as possible. The amounts of our fees depend upon the complexity of the projects and are subject to discounts for assignments which involve multiple product registrations. The amount and structure of all fees are discussed and agreed upon with our clients before we commence work on any project.

PACIFIC LEGAL GROUP also provides Thai FDA and Thai Ministry of Agriculture product registration services on a fixed fee retainer basis for companies which desire to outsource all or a substantial amount of their regulatory work. The monthly retainer payments under these Retainer Agreements are usually lower than the amounts required to employ in-house registration pharmacists.

PACIFIC LEGAL GROUP is committed to bringing in its clinical trial and consumer test projects within budget.

All of PACIFIC LEGAL GROUP's fees for providing legal services to its clients are either based on hourly time charges or fixed fees.

We would be pleased to discuss our experience with Thai FDA and Thai MOA product registrations as well as with clinical trials and consumer tests and to suggest cost-effective ways in which we can work together.

Registration Times

The registration time periods for products registered with the Thai FDA and Thai Ministry of Agriculture depend upon the complexity of the product being registered. They do not include time spent responding to Thai FDA or Thai MOA requests for additional data.

In order to assure the prompt registration of all products, it is essential that a complete application be filed with the Thai FDA or the Thai MOA. PACIFIC LEGAL GROUP reviews all the



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product files received from clients in order to determine if these files are complete according to Thai FDA or Thai MOA standards. We make substantial efforts to reduce and eliminate time loss caused by Thai FDA or Thai MOA requests for additional information.

PACIFIC LEGAL GROUP makes a firm commitment to its clients to register products with the Thai FDA and the Thai MOA in the shortest possible period of time.

Reports

It is **PACIFIC LEGAL GROUP**'s policy to provide continuous reporting to its clients of all of its work on a weekly and monthly basis. Additional meetings are also held as frequently as our clients require.

PACIFIC LEGAL GROUP was established in 1992 by its founder and Managing Director, Paul G. Russell. Mr. Russell, a graduate of Harvard University Law School and a member of the New York Bar, has over 25 years' experience as a partner of leading law firms in the United States.

For the past twelve years Mr. Russell has worked in Thailand as counsel to foreign companies with products requiring Thai FDA and Thai MOA registration.

The staff of **PACIFIC LEGAL GROUP** is composed of pharmacists, lawyers, clinical research associates, agricultural regulatory consultants and supporting regulatory specialists with extensive experience with the Thai FDA and the Thai Ministry of Agriculture. The staff has been specially organized to provide support services to professionals in the fields of health care, pharmaceutical, clinical research, food, life science, medical device, dental, biotechnology, animal and agri-health and other related industries. **PACIFIC LEGAL GROUP**'s registration staff has extensive experience with completing all necessary forms required for Thai FDA and Thai MOA registration.

Over the years, the pharmacists, lawyers, clinical research associates, and agricultural regulatory consultants working for **PACIFIC LEGAL GROUP** have established excellent relations with the key decision makers of the Thai FDA and its supporting testing, science and medical research facilities as well as with the officials of the Thai MOA. They constitute the leading team of FDA and MOA registration specialists in Thailand.

