2 777 Flow Chart of Assignment

(1) Confirmation of Product Category

The applicant vendor provides product information and a complete list of ingredients.

(2) Case Evaluation

AMSI submits a price quotation or commission contract for the product under application.

(3) Commission Formalized

The applicant signs and returns the price quotation or signs the commission contract to establish cooperation relationship.

(4) Document Preparation

The applicant provides a single domestic contact and a foreign contact for AMSI, and provides documents for review by AMSI. After AMSI receives the first payment installment or the complete payment, it will provide the applicant with a complete set of recommendations.

(5) Formal Application

After document preparation has met the submission criteria and payments have been cleared, the application may be formally submitted after the applicant provides the government-required fees.

(Supplementary Documents or Responses to Reviewer Concerns)

Provide further documents as required by Ministry of Health and Welfare.

(6) Permit Issued

After the case is approved, the applicant works with AMSI to prepare suitable documents and certificate fees required by the government, before picking up the permit.

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ASIA MEDICAL AFFAIRS SOLUTIONS INC.

http://www.amsi.com.tw/

Asia Medical Affairs Solutions Inc. was established in 2002. For over decades, as one of the few medical and pharmaceutical consultation companies with multiple specializations, we have assisted innumerable products in their successful entry into the greater Asian market. We have successfully completed inspection and registration of products in more than 20 countries. We sincerely look forward to leveraging these experiences to provide you with inspection, registration, and professional consultation services for pharmaceuticals, medical devices, cosmetics, and foods in various countries.

For many years, confidentiality has been the most important principle strictly followed by Asia Medical Affairs Solutions. In doing so, Asia Medical Affairs Solutions has received extremely high acclaim and many accolades from the industry. With good faith, we sincerely ask you to allow us to help you in resolving various regulatory matters and obtaining permits to sell products on the market, thereby enabling you to cast products into the market without lingering worries. In this way, good products may be released into the world at the right times.

Asia Medical Affairs Solutions deserves your trust for the following five reasons:

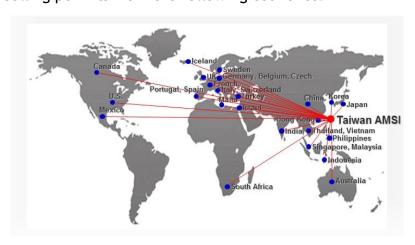
- 1. Our compliance with the principle of absolute confidentiality.
- 2. Our drive to focus on the importance of products.
- 3. Our practical experience dealing with products in many countries.
- 4. Our ability to integrate numerous fields.
- 5. Our precise, accurate, and efficient registration services.



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Our Experience

For over over decades, domestic and foreign industry leaders and well-known brands have favored and relied upon Asia Medical Affairs Solutions, with product registration categories spanning pharmaceuticals, medical devices, cosmetics, and foods. With gratitude, we have completed these tasks without letting our clients down. In turn, major foreign manufacturers have praised us or even directly appointed our company to provide assistance. In the past, we have successfully completed inspection and registration of products to obtain selling permits from the following countries:



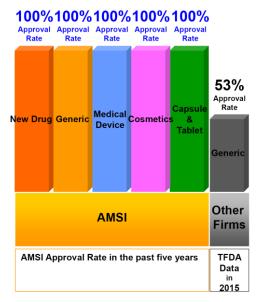
Asia:	- Turkey	- Belgium	- Latvia
- Taiwan	- Iran	- Sweden	- Liechtenstein
- China	America:	- Switzerland	- Lithuania
- Hong Kong	- U.S.A.	- Czech Republic	- Netherlands
- Singapore	- Canada	- Iceland	- Norway
- Japan	- Mexico	- Malta	- Poland
- Korea	- Argentina	- Austria	- Romania
- Australia	- Brazil	- Croatia	- Slovakia
- India	Europe:	- Cyprus	- Slovenia
- Indonesia	- U.K.	- Denmark	- Ukraine
- Malaysia	- France	- Estonia	Africa:
- Philippines	- Germany	- Finland	- South Africa
- Thailand	- Italy	- Greece	Oceania:
- Vietnam	- Portugal	- Hungary	- Australia
- Israel	- Spain	- Ireland	- New Zealand

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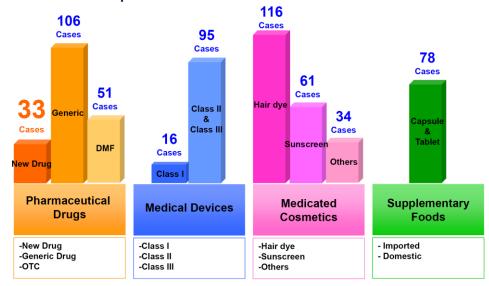
Optimal Consultation Quality

Asia Medical Affairs Solutions is made up of the most professional team of consultants, enabling us to provide the highest quality service after integrating various expert opinions. We seek to maximize efficiency for our clients' products under the existing system, so that they can enjoy stable development without crossing legal boundaries. We hope to provide each client with solid and timely professional services, as well as precise, flexible, and practical recommendations.

■ Approval Rate



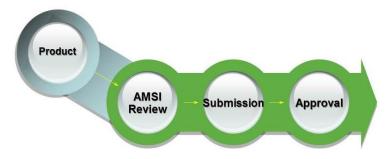
Submission Experiences



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Various Fields

Asia Medical Affairs Solutions knows that clients feel lost and troubled when there are an unknown number of regulatory obstacles standing in their way before new products can be released. In Taiwan, we are a truly rare interdisciplinary and professional medical and pharmaceutical team of consultants. Together we possess an advanced ability to help determine the optimal attributes of a product, so that the client can cover all bases in making the best choices in its applications. The client can then rest easy and devote efforts to promoting the product on the market.



■ Main Services

Medicinal Products		Medical Devices	
New Drug	New Chemical Entity (NCE)	New Medical	Class I Medical Device
Application (NDA)	New Administration Route	Device	Class II Medical Device
	New Indication		Class III Medical Device
	New Combination		
	New Dosage Form		
	New Dose		
	New Strength		
	Orphan Drug		
	Bridging Study Evaluation (BSE)		
Generic Drug	Generic Drug (Generic Product)	In vitro	Class I Medical Device
	Over The Counter Drug (OTC	Diagnostic	Class II Medical Device
	Drug)	Devices (IVD)	Class III Medical Device
	Controlled Drug		Re-registration/Change/Variation
	Bioavailability (BA)		License Renewal
	Bioequivalence (BE)		Transference
	Dissolution		

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	D			
	Re-registration/Change/Variation			
	Transference			
	License Renewal			
Manufacturing	PIC/S GMP	General and	Class I Medical Device	
Plant	Plant Master File (PMF)	New	Class II Medical Device	
	Good distribution Practice (GDP)	Medical	Class III Medical Device	
	GMP Inspection	Devices	Re-registration/Change/Variation	
	Transfer and Authorization		License Renewal	
	Renewal		License Transfer	
			Quality System Documentation	
			QSD Registration	
Drug Substance	API DMF Registration	GxP	QSR · ISO13485:2016 · TWN	
(API)		GMP	QMS;	
		GDP	US EUA, US 510(k), MDR CE,	
			TFDA Registrations	
			Taiwan GMP	
			Taiwan GDP	
Local Agent	In-Country Caretaker	Others	Purchasing Agent for	
	Marketing Authorization Holder		Qualified Working Standards	
			(i.e., in-house or secondary	
			standard)	
Cosmetics		Food/Supplements		
New Medicated	Registration of New Medicated	Food and	Health Food	
Cosmetics	Cosmetics	Supplement	Imported Food in Tablet or	
			Capsule Form (Dietary	
			Supplement)	
			Food Additive	
			Genetically Modified Food	
			Special Dietary Food	
			Vitamin Supplement	
			Ready-to-Eat Soy Bean Food	
			Re-registration/Change/Variation	
			License Transfer	
			License Renewal	

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General	Registration of General Medicated	Others	Formula Reviewing
Medicated	Cosmetics		Package Reviewing
Cosmetics	Re-registration		Consultation
	Change/Variation		
	License Transfer		
	License Renewal		
Test/Assay	Test/Assay for Registration of	Environmental Agent	
	Medicated Cosmetics		
Others	Advertisement	Environmental	Registration of Environmental
	Formula Reviewing	Agent	Agent
	Package Reviewing		
	Consultation		
Veterinary Drugs		Others	Consultation
Veterinary Drugs	Registration of Veterinary Drugs	Local Agent	
	Re-registration	License	In-Country Caretaker
	Change/Variation	Management	Marketing Authorization Holder
	Transference	License	Purchasing Agent for
	License Renewal	Holder	Qualified Working Standards
Others	Consultation	Responsible	(i.e., in-house or secondary
		People	standard)