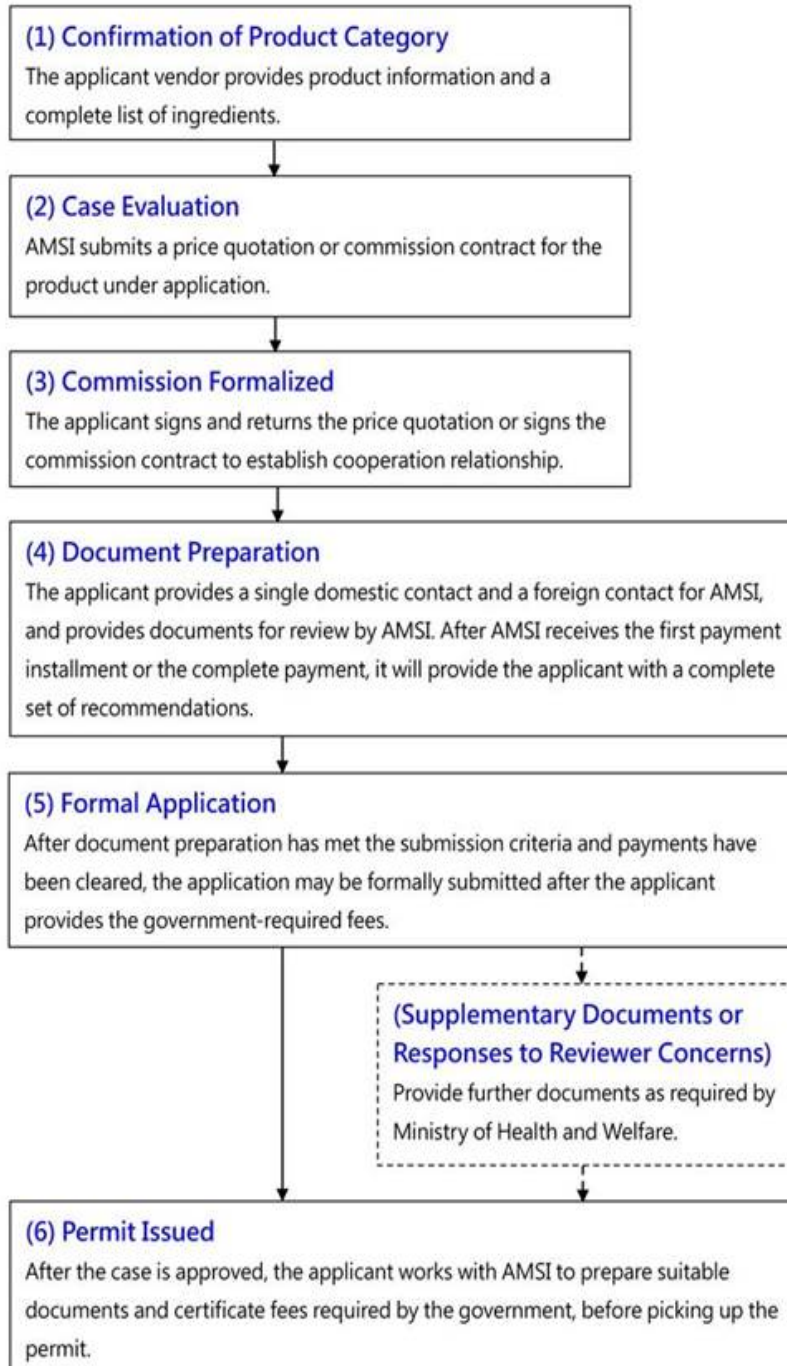


AMSI Flow Chart of Assignment



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.

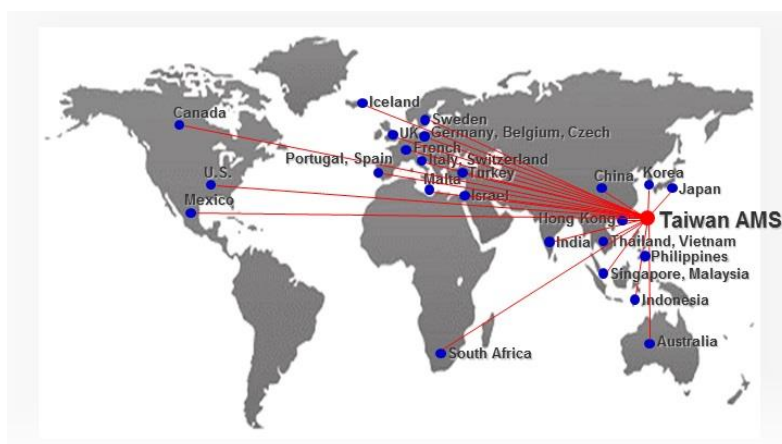
Asia Medical Affairs Solutions deserves your trust for the following five reasons:

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.**



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:

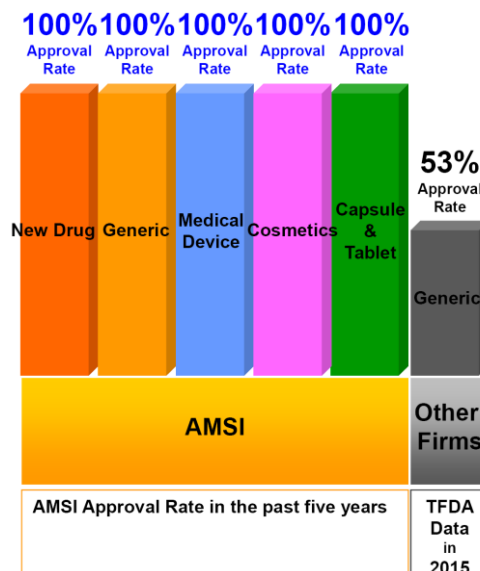


- | | | | |
|---------------|-----------------|------------------|-----------------|
| Asia: | - Turkey | - Belgium | - Latvia |
| - Taiwan | - Iran | - Sweden | - Liechtenstein |
| - China | America: | - Switzerland | - Lithuania |
| - Hong Kong | - U.S.A. | - Czech Republic | - Netherlands |
| - Singapore | - 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 |

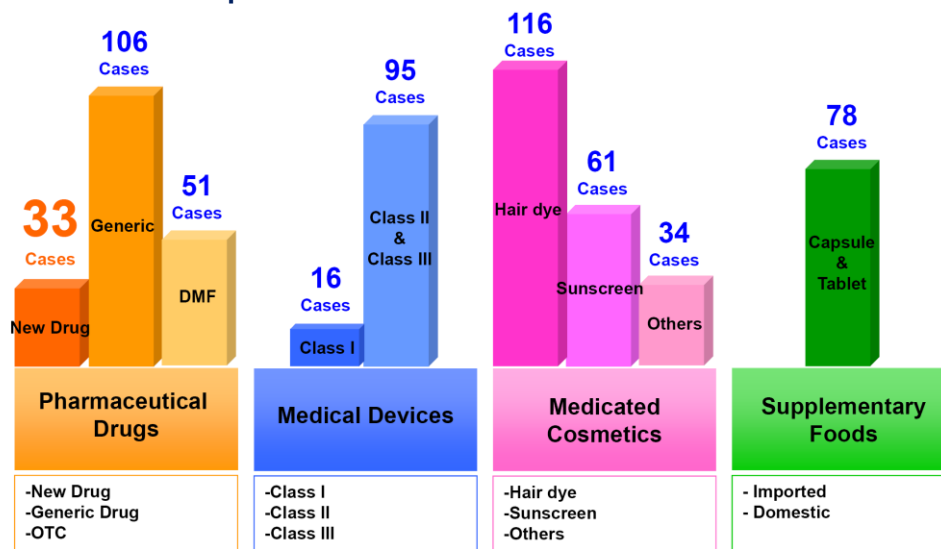
Optimal Consultation Quality

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

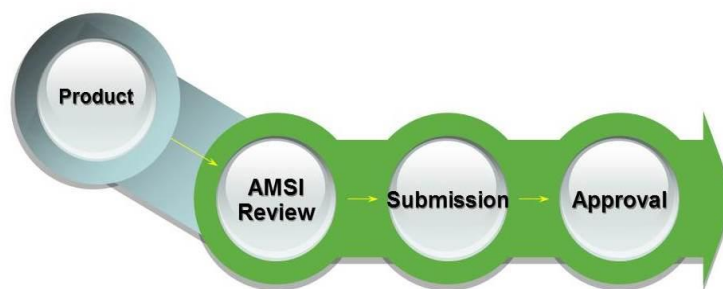


■ Submission Experiences



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

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

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