

REGULATORY. COMPLIANCE. KNOWLEDGE.



MAE
CONSULTING GROUP, LLC

Going Global: Commercializing Your Life Sciences Innovation Around the World

**MAE Consulting Group LLC
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Topics

- Regulatory and Marketing Strategies
- Launch Strategies
- Risks and Trade-Offs
- Market Application Requirements
 - EU, China and Japan
- Time and Money
- Trade Compliance Need-To-Know

Regulatory Strategy

- Must be aligned with marketing and business strategy
- Best to understand market strategy early in the product lifecycle
 - Develop 3-5 year plan
 - Regulatory strategy should be based on marketing/business strategy
 - Registration process can take 1-3 years in some countries so time to market is crucial
 - Think parallel, not serial

Initial Launch Strategy

- In order to develop a viable business and regulatory strategy, you must understand your target market, the amount of internal and external resources required, and the amount of reimbursement available
- From a timeline perspective, there can be a several month difference in launching new medical devices into the U.S as compared with the EU
 - The FDA requires evidence of both safety and efficacy of a device
 - European CE Marking only requires proof of safety and that the device performs in a manner consistent with the manufacturer's intended use

Common Regulatory Strategy Options

- Seek Clearance/Approval in the U.S. First
 - Seeking FDA clearance gives medical device companies the advantage of being able to launch their products to the largest medical device consumer market in the world
 - Additionally, medical device companies can expect more consistent reimbursement and better intellectual property protection
- Seek Clearance/Approval Overseas First (Typically EU)
 - Initial feedback on your product from a clinical use perspective
 - Potentially generate revenue sooner (depending on reimbursement and target country within the EU)
- Start Clearance/Approval Process in Parallel
 - Typically this is US and CE Marking
 - Ideal strategy in terms of reducing regulatory risks due to costly delays in the launch of a device, but requires the most resources

Risks and Tradeoffs

- For start-up medical device companies, funding is limited
 - Companies must determine the tradeoffs of their regulatory strategy in order to minimize risks
 - For example, although the CE Marking timeline can be faster and the process is predictable, there is no guarantee that the device will be widely accepted by physicians or reimbursable by each government in each European country
 - Additional clinical evaluations and registration might be required in some EU countries to show the efficacy of the device from a marketing perspective

Risks and Tradeoffs

- The FDA regulatory process is longer and has a higher burden for safety and efficacy, however;
 - Once a device has received FDA clearance, companies can start marketing their product in the entire U.S.
 - Reimbursement in the U.S., such as Medicare, is more consistent since there is only a single government
 - Some foreign regulatory agencies require a device be registered in the country where the legal manufacturer resides as part of their registration process and final approval
 - Goes back to the company's business and marketing strategy

Assembly of Documentation

Country Req	EU (CE Marking) MDD 93/42/EEC	China CFDA	Japan PAL MHLW/PMDA
Documentation	General Information	Application form	Application Form
	EC Declaration of Conformity	Legal Qualification certification for medical device manufacturing enterprise	General Requirements
	Device Classification and Rule Number	CFG/CFS	STED
	Name and Address of AR	Copy of Clearance/Approval Letter in the country of origin	<ul style="list-style-type: none"> • Declaration of Conformity • Device Description • Essential Principles Checklist • Risk Analysis • Design Information • Manufacturing Information • Product Verification • Product Validation • Labeling • Clinical Studies • Software V&V • Technical Standards
	Product Description	Product technical specifications	
	Product Specifications	Product instruction for use	
	Product Verification	Product Safety Testing Type (Recognized by SFDA)	
	Product Validation	Clinical report	
		Product Quality Guarantee certifying that the quality of the product is exactly the same as the product marketed in the country of origin	
		Letter of Authorization for In-Country Agent	
		Letter of Authorization for designated Distributor	
		Letter of Authorization for registration	
		Letter of Authorization for standard	
		Statement of quality responsibility	
	Truth and accuracy statement		
	Obtain CCC Mark, if required		

Assembly of Documentation

Country Req	EU (CE Marking) MDD 93/42/EEC	China CFDA	Japan PAL MHLW/PMDA
Notarization & Legalization	No	Yes	Yes
Classifications	I, IIa, IIb, III	I, II, III	I, II, III, IV
Product License Valid Period	Rolling recertification every 3 years	4 Years (soon 5 years)	5 years
Prerequisites	ISO 13485	ISO 13485 and In-country Registration	ISO 13485 and In-country Registration
In-Country Representation	Authorized Representative	Legal Agent and After-Sales Agent	Market Authorization Holder (D-MAH)

National Differences

- Due diligence in terms of in-country contacts
 - In-country agents – most countries require submissions through a person or company that resides in the country
 - Distributors – some companies use distributors to register products and distribute product post approval
 - Due Diligence Audits – virtual or on-site; perform extensive due diligence to find the best medical distributor
- Due diligence in terms of additional testing/documentation
 - NRTLs – If your product requires product safety testing then you should work with your NRTL from the beginning (design stage)
 - Work with the NRTL to test for base standard, national differences and CB Scheme

Time & Money

CE Marking EU	Device Class	Cost	Total Time (avg days)	
	Class I (m/s)	\$3,000.00	Typically 1-3 days assessment time plus pre-review, device dependent. Typical cost per day \$1050-\$2000.	
	Class IIa	\$4,250.00		
	Class IIb	\$5,500.00		
	Class III	\$7,500.00		
13485	Typical cost is \$6000 for the certification by NB. Preparation costs is not included and is dependent on individual company readiness			
China SFDA	Device Class	Registration Cost	Testing Cost	Total Time (avg months)
	Class I	None	None	12
	Class II		\$8,000	10-18
	Class III		\$5,000-\$15,000	18-36
	Clinical Trials	\$200,000 (Class II and III)		
Translation fees not included				

Time & Money

	Requirement	Cost	Total Time (avg months)
Japan MHLW/PMDA	Foreign Manufacturer Accreditation	\$1,420	1-2
	Quality System Audit Costs for Foreign Manufacturing Sites	\$813 - \$8,950	1-2
	Final PMDA Review & Certification Costs MHLW, Review and Conference Assessment Fees	\$4,272 - \$90,778	3 - 16
<p>For Ninsho (Class II Specified Controlled) use of Registered Certification Body (e.g. Notified Body) separate fee Clinical Study Fees and time not included; typical for Shonin (Class II - IV) applications Translation fees not included</p>			

Trade Compliance Regulations

- Import/Export Regulations
 - HTS -Harmonized Tariff Schedule
 - EAR – Department of Commerce Bureau of Industry and Security (BIS)
 - OFAC – Office of Foreign Assets Control
 - Import/Export Trade Management
- Some companies use a broker to maintain import compliance and Freight Forwarders for export compliance but the company is ultimately responsible for all import and export activities



Thank You

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