

Regulatory Strategy Forum

1-2 March, Memphis TN
Inmotion Musculoskeletal Institute



Strategies for a Global Market

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Developing Regulatory Strategies for a Global Market

1. How do you globalize from the start of the strategic planning process?
2. What are the key attributes of your Global strategy
3. Where does this effect the current plan document?
4. Some International Regulatory Issues for your strategy



1. How do you globalize from the start of the strategic planning process?

4 Key Points to Successful Globalization of Your Plan

1. Address all the global requirements inside your strategic plan document:
 - A. **What is the registration strategy in each country where you want to market the product?**
 - ✓ Well researched regulatory plans, driven by regional staff, or distributor expertise.
 - *web sites are not accurate in International locations*
 - *Local staff live with their regulations everyday....empower them.*
 - B. **Determine the most rapid pathways to approval**
 - ✓ Afterwards determine the feasibility of the pathway
 - *Japan – Kuhatsu vs PC*
 - *Australia – CE Linked vs Conformity Assessment*
 - *Europe – Full QS vs Type Exam*
2. Assure there are resources for your plan
 - ✓ or adjust the execution pathway to meet current available resources.
 - *How quickly to submit, will extra funding reduce submission lag between countries*
 - *Sequential submissions globally vs parallel submissions*



1. How do you globalize from the start of the strategic planning process?

4 Key Points to Successful Globalization of Your Plan

3. Obtain buy-in to International strategies in parallel with buy-in for the domestic strategy
 - a. **Avoid TBD's, it is a clear rejection of a market**
 - b. **Buy-in must be at the HQ and the local offices**
 - c. **Include strategies for distribution markets.**
4. Make the International Reg strategy a 'hard stop' inside your development process
 - a. **Strategies must be determined early, in parallel with your US/EU strategies.**
 - b. **Don't permit the process to move forward without the global strategies complete**
 - c. **Include the requirements associated with the strategies. They need to be in the R&D plan early**



2. What are the key attributes of your Global Strategy?

Key Points to Consider in your framework

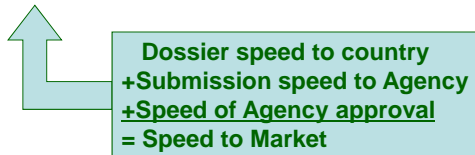
Primary Objective

Assure safety and efficacy
&
Gain approval in the USA



Secondary Objective

Fastest speed to market elsewhere in the world



2. What are the key attributes of your Global Strategy?

What should be included in a Global Strategic Plan?

- a) **Primary Approval Pathway in each country**
 - Country specific registration strategies
 - Country specific Country of Origin or Legal Manufacturer requirements
 - Strategy for Unregulated Markets
 - High risk 'upside strategies'
 - No TBD's
- b) **Technical Requirements which need to be addressed in development**
 - Applicable International Harmonized Standards (ISO, etc)
 - Applicable Japan Standards (JIS, PA)
 - Specific International standard compliance Requirements (Brazil, Korea)
 - Global definitions of 'clinical evidence'
- c) **Process to provide the data to the countries for submission**
 - Electronic vs hard copy and timelines for providing the documents
 - Pre and post country of origin approval
 - Country specific registration files vs standard file to distributors or local offices (clustering, strategy to avoid sequential submissions)
 - Strategy for rapid certifications (Export, CFG, CFS)
 - Strategy for rapid response to questions



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 - Strategy for rapid certifications (Export, CFG, CFS)
- d) **Process to develop the local registration file**
 - Created locally or centrally?
 - Requirements for HQ review of final file?
 - Impact of local language and local certifications
- e) **Strategy for site inspection requirements**
 - Identify the countries requiring inspections
 - Identify the type of site assessments (ISO standards vs local standards)



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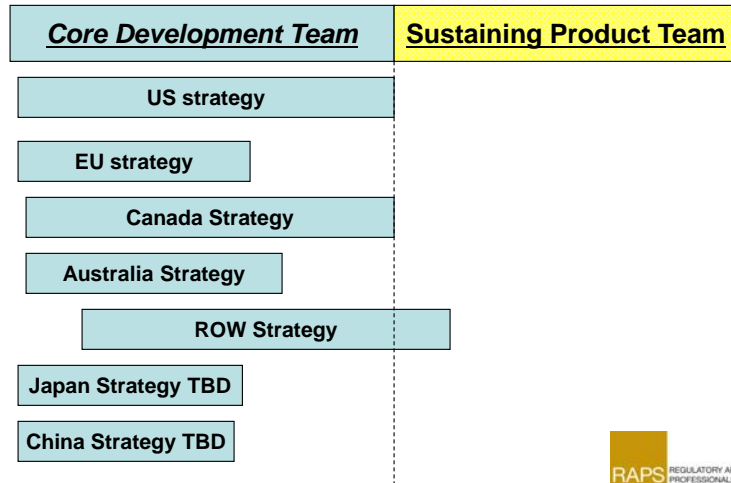
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- b) **Technical Requirements which need to be addressed in development**
- c) **Process to provide the data to the countries for submission**
- d) **Process to develop the local registration file**
- e) **Strategy for site inspection requirements**
- f) **Language requirements and remediation plans**
 - Languages on labels and inserts
- g) **Agency meetings, strategy and timelines**
 - Identify where pre-submission meetings will be required, allocate the resources (SME's)
- h) **Resource allocation and process for responding to Agency questions**
 - Speed to respond = speed to market
 - Allocate the resources (SME's)



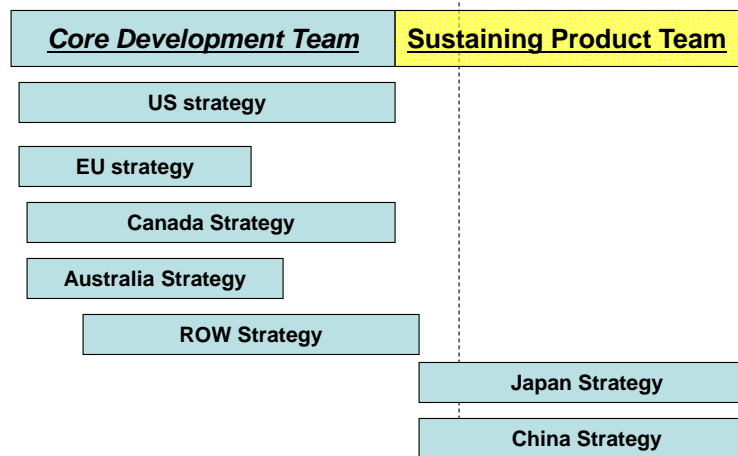
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Resource allocations for responding to agency meetings and questions



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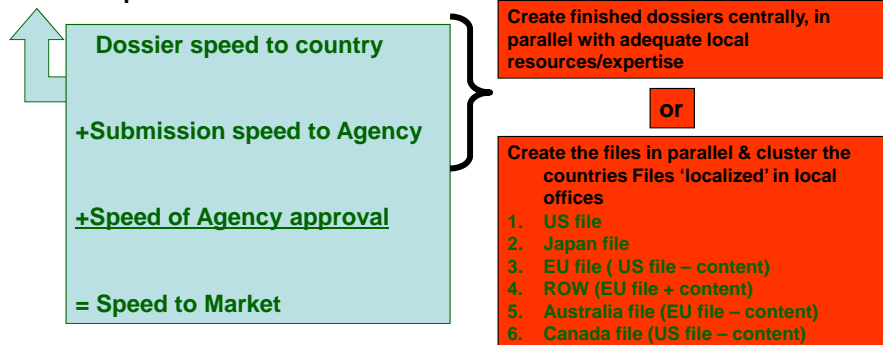
Key Points to Consider in your framework

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Secondary Objective

Fastest speed to market elsewhere in the world



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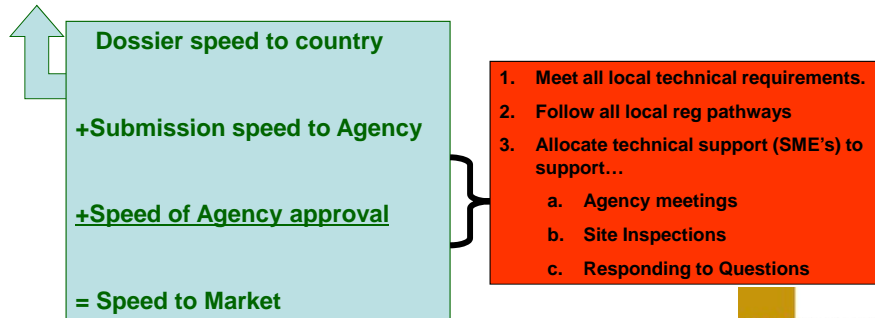
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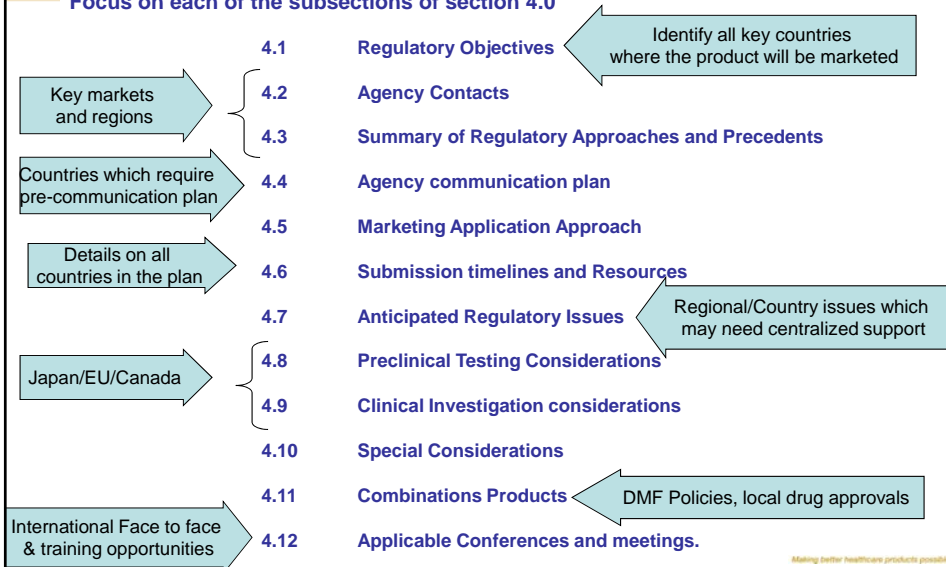
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3. Where does this effect the current plan document?

Should be incorporated into each applicable section of the plan, not as a addendum.
Focus on each of the subsections of section 4.0



4. Some International Regulatory Issues for your strategy

Country	Multiple Submission Pathways	Classification process	Local Technical Standards?	Local QMS Requirements?	Country of Origin required?	Legalization of documents required?
EU	yes		ISO/EN	Yes	No	No
Japan	yes		JIS and Product Approval Standards	Yes	No	No
Canada	No		no	Yes	No	No
Australia	Yes		no	No	No	No
China	No		yes	Yes	Yes	Yes
Brazil	No		yes	Yes	Yes	Yes
S. Korea	No		no	No	No	No

In Summary

....to make your strategy a global strategy...

1. Design your strategy as a Global strategy
 - ✓ Assure there are resources/processes to support rapid global launch
 - ✓ Obtain buy-in to International strategies in parallel with buy-in for the domestic strategy
 - ✓ Make your International Regulatory strategies requirement a 'hard stop' inside your development process
2. What should be included in a Global Strategic Plan?
 - ✓ Primary Approval Pathway in each country
 - ✓ Technical Requirements which need to be addressed in development
 - ✓ Process to provide rapid data to the countries for submission
 - ✓ Process to develop the local registration file
 - ✓ Strategy for site inspection requirements
 - ✓ Language requirements and remediation plans
 - ✓ Agency meetings, strategy and timelines
 - ✓ Resource allocation and process for responding to Agency questions

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