

# Regulatory Strategy Forum for Medical Devices

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Inmotion Musculoskeletal Institute

**Hot Topics**  
**Asia & Japan**  
**Latin America**  
**Middle East Africa**

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## Outline

- Trends of the past years
- Regulatory Direction: Japan
- Regulatory Direction: Asia
- Regulatory Direction: Latin America
- Regulatory Direction: Middle East Africa
- Most Critical Advocacy actions



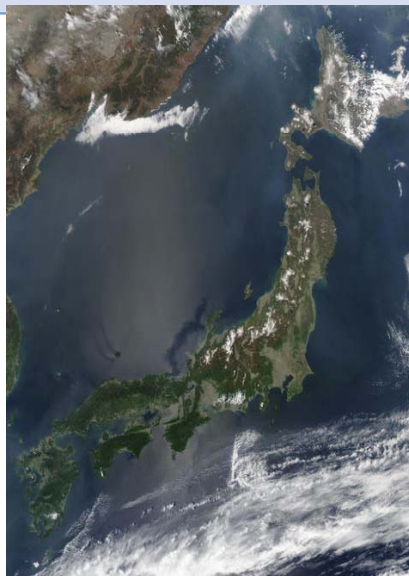
## Key Regulatory Changes OUS 2010 & 2011

- **2010**
  - [Canada](#) – fee's increase
  - [Australia](#) – Fee's increase
  - [Korea](#) – removal of CoO
  - [Brazil](#) – RDC 59
    - reduced file family size
  - [Mexico](#) – new post market submission burden
  - [India](#) – expanded regulated products
  - [Taiwan](#) – reduced QSD requirements
  - [China](#)- LM or CoO reg
  - [Japan](#) – new stability partial change regs
  - **Newly regulated:** Singapore, Sri Lanka, Pakistan, Bosnia
- **2011**
  - [Canada](#) – Change in Significant Change Definition
  - [China](#) – local clinical studies for DES, potential clinical studies for new technologies
  - [Australia](#) – Conformity Assessment for all Class III
  - [India](#) – expanded regulated products
  - [Brazil](#)- Hardware Service regulations
    - Post market reporting requirements
    - New RDC 59 requirements
  - [Mexico](#)- rapid approvals with Canada/US approvals
  - [Thailand](#)- new premarket requirements
  - [Japan](#)- Modular Submission pilot
  - **Newly regulated:** Saudi, Kuwait, Malaysia

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## Regulatory Direction: Japan

- PMDA continues to improve the medical devices review processes to make them
  - More predictable
    - More guidance
    - More 'Answers to Questions'
  - Great transparency
    - New consultation processes
    - Post submission meeting
  - Earlier submission opportunities
    - Changes to stability requirements
    - Additional Product Approval standards
    - Maturing of Japan offices of approved Notified Bodies.
  - Faster Reviewer times
    - Kuhatsu Process
    - Predicate devices
    - new Minor change Notification definitions
    - New partial Change definitions

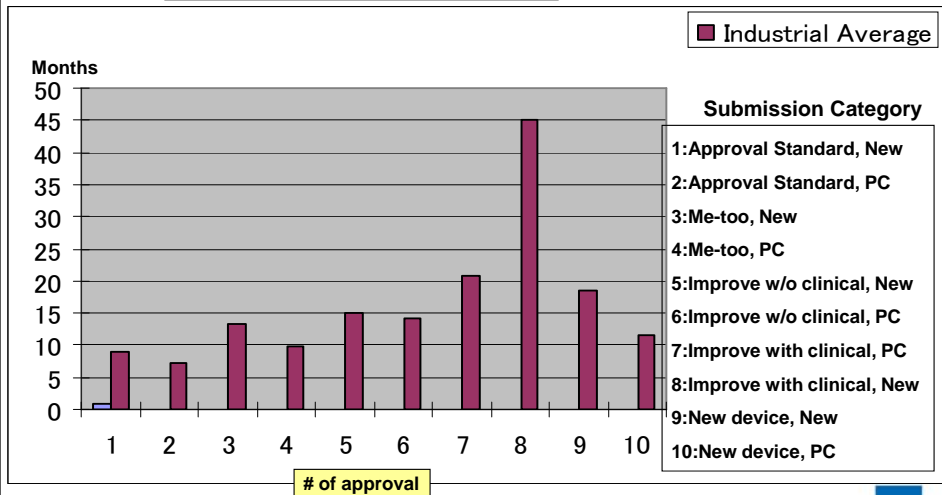


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## Time to Approval: 2009

Industry Average : 12.3 months

# of companies : 214



## Regulatory Direction: Japan

### Where will the Japan regulations go in 2011

1. Pilot for joint consultations - PMDA and FDA
  - 'semi pilot' of pre-submission consultations
2. Pilot for Modular Submissions
3. STED Comparison Proof of Concept (HBD, looking for participants)
4. 2011 target white paper on difference between FDA BIMO audits and PMDA Shomen Chosa (HBD)
5. Stability study requirements comparison??

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## Regulatory Direction: Asia

### China

- Fee's are still very low
- Acceptance of CoO or CoLM
- Combination product local clinical data
  - *Significant risk of expansion to all 'new technologies'*
- End of training and learning period

### Korea

- Adoption of CD DFU's for local language
- Removal of country of origin requirement
  - *Potential greater scrutiny on product specific clinical data*
- Fee's are still very low

### India

- Expansion of regulated devices beyond first 10 groups
- Low fee's
- Discussions on local clinical studies for combination products and new tech's

### Australia

- Expansion of devices requiring conformity assessment

### Newly regulated

- 2010: Singapore, India, Pakistan
- 2011: Malaysia



## Regulatory Direction: Latin America

### Brazil

- Protectionist statements from political leadership
  - *Protect/promote local manufacturers*
  - *25% tender price grace*
  - *Not enforce patent rules for devices*
- End of training and learning period
- What will happen to RDC 59??
- Technology driven reviewers

### Mexico

- Extended review times, and greater technical requirements in the submission documents
- Fast track process using Canada and/or US approvals
  - Similar to CR process

### Colombia

- Clearing all reviewers, and re-hiring

### Central America

- Loss of leadership in Costa Rica



## Regulatory Direction: Middle East

### Saudi Arabia

- Regs are in place
- Sound and logical
- Full compliance, high code of conduct will be expected
- Critical focus for RA departments

### Turkey

- Customs regulations essential join Turkey with the EU in the medical device regulations
- Critical new changes to listing software, connected to reimbursement
  - Review your company's status

### Newly Regulated/Discovered

- Morocco, Algeria, Bahrain, UAE, Kuwait



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## Critical Advocacy Actions

### RA Strategy

- Connect it to advocacy plan
  - Create listening posts
  - Build trust and credibility

- Training new reviewers
  - Japan
    - Request to Industry
  - FDA
    - Request to Industry
  - South East Asia
    - AHWP slow movement
    - GHTF re-structuring
  - Andes Region
    - Changing of the guard
- BRIC
  - Open to training in selected scenarios
  - Brazil, legal challenge to protectionist rules
  - China and expansion of the local clinical training
- Japan
  - HBD participation
  - STED Proof of Concept
- AdvaMed and EucoMed listening posts
  - China, Brazil, India, Mexico, Colombia, Russia etc

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## Questions??

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