



Celebrating MHLW's & PMDA's International Strategic Plan

***“Aligning International Regulatory Goals
Through Innovation and Collaboration”***

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Current Needs of Regulatory Stakeholders

Industry

- Improved ROI to sustain development of new products in pipeline
- Stable infrastructure to support commercial engagement and investment
- Transparent and consistent processes leading to more predictable outcomes
- Increased efficiency in regulatory transactions through convergence of requirements



Government/ Regulators

- Efficient and cost-effective regulatory policies
- Framework for quality decision-making
- Engagement of multi-stakeholders and effective communication
- Cross-cutting policies to maximise healthcare outcomes



Current Needs of Regulatory Stakeholders

Healthcare Professionals

- Confidence in regulatory processes
- Support advancing medical practices
- Clarity in information to make better informed decisions for patients



Common goal of faster access to affordable, high quality health products to patients



Patients

- Affordability of safe, high quality and efficacious health products
- Acknowledgment as significant contributor to regulatory decision-making
- Active participation in decision-making for their own health conditions





Industry's Perspective on Regulatory Gaps in Asia

Surveys and Focus Group meetings

- Part of **CoRE** project to understand regulatory needs in Asia from industry's and regulators' perspectives
- Two sessions conducted with **industry**
 - For **therapeutic products** (Jun 2014)
 - For **medical devices** (Oct 2014)
- **Discussions** focused on two topics
 - a. Regulatory training and development needs/gaps
 - b. Innovations in regulatory science, solutions and challenges



Industry's Perspective on Regulatory Gaps in Asia

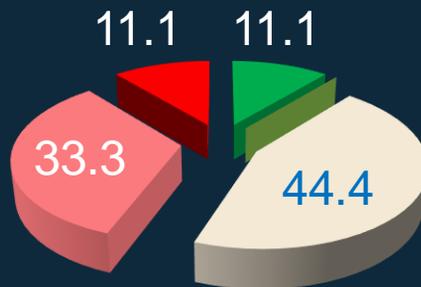
Therapeutic Products Companies

Competencies of national regulatory agencies can be improved



- Strongly agree
- Agree
- Neutral
- Disagree
- Strongly disagree

There are sufficient initiatives to converge regional regulatory requirements





Industry's Perspective on Regulatory Gaps in Asia

Therapeutic Products Companies

Gaps

- Scientific knowledge
- Knowledge of different cultures in Asia
- Soft skills and strategic planning
- Structure for continuous education in regulatory affairs

Innovation

- Reduction in time and cost, adaptive licencing
- Mutual recognition processes, shared reviews
- Policy changes

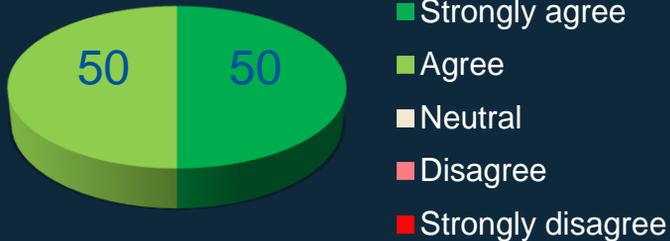
Challenges

- Different levels of receptiveness among regulators
 - Capabilities and capacities
 - Lack of transparency
 - Affordability of regulatory affairs education and training
- 

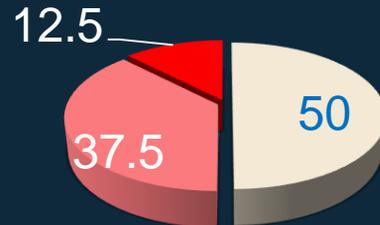
Industry's Perspective on Regulatory Gaps in Asia

Medical Device Companies

Competencies of national regulatory agencies can be improved



There are sufficient initiatives to converge the regional regulatory requirements





Industry's Perspective on Regulatory Gaps in Asia

Medical Device Companies

Gaps

- Framework for competencies
- Lack of recognition for experienced and qualified regulatory affairs personnel
- Lack of support from management
- Lack of regulatory affairs education at undergraduate level

Innovation

- Policy changes
- Regular training
- Mutual recognition processes

Challenges

- Compliance risks from outsourcing
- Balancing between regulating and control



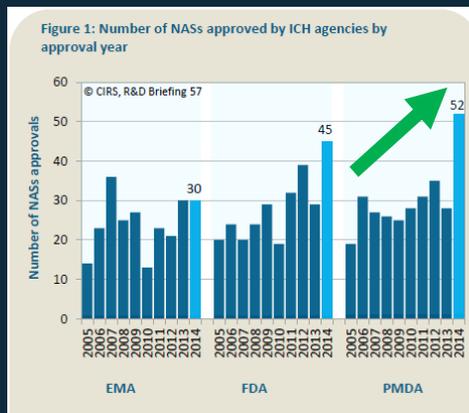
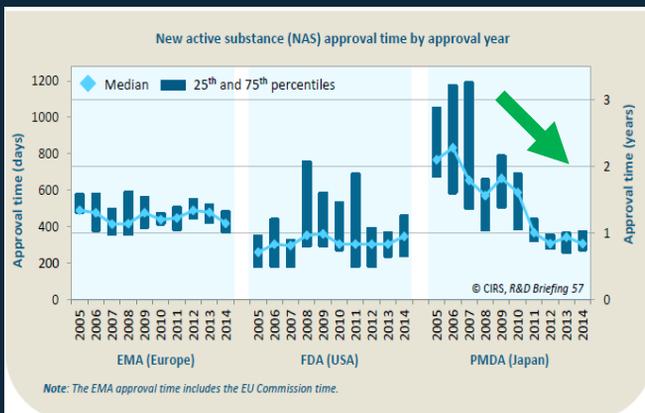


Regulatory System Challenges

- Lack of convergence of regulatory processes and requirements despite harmonised guidelines
 - Lack of regulatory talent pool to support regulatory processes and strategy development
 - Lack of infrastructure to bridge regulatory processes to rapidly advancing healthcare sciences
 - Lack of platforms to exchange ideas, promote representation and foster closer collaborations across regulatory stakeholders
 - Lack of regulatory education and training
- 

Innovation in Regulatory Processes

- PMDA's review of regulatory processes and requirements has led to significant decrease in approval times, facilitating faster access to new medicinal products



Source: Centre for Innovation in Regulatory Science. R&D Briefing 57, July 2015.

Innovation in Regulatory Processes - ICH

 <p>FDA Fast Track</p>	<p>A process designed to facilitate the development and expedite the review of drugs to treat serious conditions or unmet medical need</p>	<ul style="list-style-type: none"> • More frequent meetings with FDA to discuss drug development plan • More frequent communication on clinical trials
 <p>FDA Breakthrough Therapy</p>	<p>A process designed to expedite the development and review of drugs that demonstrate substantial improvement compared to available therapy</p>	 <p>EMA Conditional Approval</p>
 <p>FDA Accelerated Approval</p>	<p>Regulation allowing drugs for serious conditions that filled an unmet medical need to be approved based on a surrogate endpoint</p>	 <p>EMA Exceptional Circumstances</p>
 <p>FDA Priority Review</p>	<p>A process that directs resources to the evaluation of drugs that represent improvements in safety or effectiveness compared with standard applications</p>	 <p>EMA Accelerated Assessment</p>
<p>Regulation allowing drugs fulfilling unmet medical need for severe, life-threatening or rare diseases to be approved with limited clinical safety or efficacy data, provided a positive benefit-risk balance</p>	<ul style="list-style-type: none"> • Conditional approval is granted before all data are available (valid for one year, on a renewable basis; once pending studies are provided, it can become a "normal" marketing authorisation) 	
<p>Regulation allowing drugs fulfilling unmet medical need for severe, life-threatening or rare diseases to be approved without comprehensive efficacy and safety data</p>	<ul style="list-style-type: none"> • Conditional approval is granted before all data are available (reviewed annually to re-assess the risk-benefit balance) 	
<p>A process designed to expedite products of major interest in terms of public health and therapeutic innovation</p>	<ul style="list-style-type: none"> • CHMP opinion shortened from 210 days to 150 days 	

 <p>PMDA Priority Review</p>	<p>A process that provides faster access to new therapies responding to high medical needs; includes products such as orphans, HIV medicines and products given "Extraordinary Approval"</p>	<ul style="list-style-type: none"> • Review time shortened from 9 to 6 months
 <p>PMDA Sakigake (pioneer)</p>	<p>A system to put into practice innovative medicines/medical devices, regenerative medicines initially developed in Japan</p>	<ul style="list-style-type: none"> • All Priority Review designation features • Prioritised clinical trial and pre-application consultation • Assigned PMDA manager as a concierge • Post-marketing safety measures

Source: Centre for Innovation in Regulatory Science. R&D Briefing 57, July 2015.



Innovation in Regulatory Processes

- **Advances in Adaptive Licencing**
- **Regulatory research to support new policies and methodologies**
 - US FDA CERSI
 - Innovative Medicines Initiative (IMI) – Strategic Research Agenda 2014-2024
- **Good Reliance Practice and Referencing in regulatory decision-making**

PMDA is in a well-placed strategic and networked position to pilot and promote regulatory innovation, e.g. ICMRA



Collaboration and Synergy

Between Industry and Health Authorities

- US FDA Technology Transfer Program – Cooperative Research and Development Agreements (CRADA)
- Innovative Medicines Initiative – joint undertaking between EU and European Federation of Pharmaceutical Industries and Associations (EFPIA)





Collaboration and Synergy

Among Health Authorities/ Regulators

- International Coalition of Medicines Regulatory Authorities (ICMRA)
 - International Generic Drug Regulators Pilot (IGDRP)
 - *aims for convergence and cooperation towards timely availability of safe, effective and quality generics*
 - International Medical Device Regulators Forum (IMDRF)
 - *aims to accelerate harmonisation and convergence for regulation of medical devices*
 - International Pharmaceutical Regulators Forum (IPRF)
 - APEC Regulatory Harmonisation Steering Committee (RHSC)
 - ASEAN Pharmaceutical Product Working Group (PPWG) and Medical Device Product Working Group (MDPWG)
 - *focus on integration, harmonisation and efficiency*
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Collaboration and Synergy

Among Industry

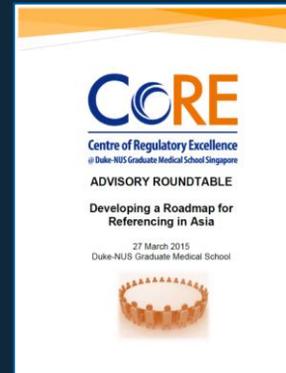
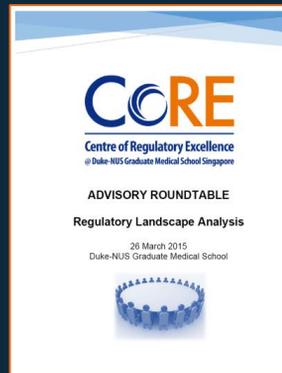
- IFPMA
- EFPIA
- PhRMA
- JPMA and APAC
- APACMed



Collaboration and Synergy

Convening of key opinion leaders and domain experts

- *National Academy of Medicine (NAM)* – IOM roundtables & white papers
- *Centre for Innovation in Regulatory Sciences (CIRS)* – workshops & papers
- *Centre of Regulatory Excellence (CoRE)* – Roundtables and Focus Group meetings



Collaboration and Synergy

Convening of key opinion leaders and domain experts

**5&6
OCT 2015**
The Academic Auditorium,
Singapore

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Faculty list

 Dr Margaret H MBURG Immediate Past Commissioner, US FDA & Emerg Secretary, National Academy of Medicine	 Dr Manoj LUMBINI Deputy Director - Regulatory Affairs, BRI & Meritex Gates Foundation
 Prof Takuya KONDO Chief Executive, Pharmaceutical and Medical Device Agency, Japan	 Prof William HASELTINE Chairman and President, ACCION Health International
 Prof Sir Alexander BRECKENRIDGE Former Chair of Medicine, & Healthcare products Regulatory Agency	 Dato' Eshah AED RAHMAN Senior Director, Pharmaceutical Services, Ministry of Health, Malaysia
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 A/Prof Wei YONG Programme Director, Singapore Centre for 3D Printing, College of Engineering, Nanyang Technological University	 Mr Kim Cheau WONG Head, Asia Pacific Regulatory Affairs, Novartis Singapore

Regulatory Capacity Development

Capability Building

Leadership Development

Basic Certificate

Advanced Certificate

Executive Workshop

- Entry level
- Basic requirement for regulatory affairs personnel
- **Competency oriented**

- Mid-to-high level
- Application of skills
- Project management
- **Proficiency and Efficiency oriented**

- Leadership level
- Policy setting
- Decision-making framework
- **Strategy oriented**

Regulatory Capacity Development

Regulatory Harmonization Steering Committee

APEC Life Sciences Innovation Forum

CoRE Centre of Regulatory Excellence

HSA

APEC Multi-Regional Clinical Trials (MRCT) Regulatory Science Centre of Excellence – Pilot Program

December 15-18, 2015 | Duke-NUS Singapore

save the date

Program Overview

- 3.5 days program focusing on MRCT with lectures, group discussions and applied case studies.
- Program targeted at senior clinical reviewers with at least 3 years of hands-on experience in the assessment of clinical trial applications, benefit-risk profiles for market approvals and post-market activities
- Contents of this program similar to the MRCT Pilot workshop held in 2014, but with more focus on group discussion sessions and review of cases.

Online Registration

- Detailed information will be provided soon

Travel & Accommodation

- Funding for travel eligible economies may be available
- Detailed information will be provided soon

For enquiries, please contact CoRE@duke-nus.edu.sg

CoRE Centre of Regulatory Excellence @ Duke-NUS Graduate Medical School Singapore

ADVANCED THERAPEUTICS WORKSHOP

13-15 January 2016
Duke-NUS Graduate Medical School Singapore



CoRE Executive Education Workshop

Foundations in Leadership for Regulatory Professionals: Understanding Yourself and Others



Do you know your own leadership style?
How can you best utilize your leadership style to effectively lead your team?
How can you use your leadership style to affect strategic planning?

To find out more about the Leadership executive education program and the 2 International Leadership Experts, visit us at <https://www.duke-nus.edu.sg/cofe/>

Key Information

13-15 JAN 2016

13-15 JAN 2016

13-15 JAN 2016



Initiatives and Opportunities

- 1. Innovation in regulatory processes to facilitate access to health products and address manpower constraints***
 - Collaborative initiatives to harness strengths of different partners through good reliance / referencing practices
 - Promote regulatory convergence to minimise burden of different cross-regional requirements

 - 2. Dedicated efforts to enhance regulatory competencies and increase capacity***
 - Customised curriculum and training focusing on key needs
 - Novel teaching methodologies to accommodate working professionals in regulatory affairs
 - Certification and professional development framework
- 

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Initiatives and Opportunities

3. *Pursuit of regulatory excellence*

- Define, teach and promote Good Regulatory Practices
 - Convene key opinion leaders and regulatory experts across stakeholder spectrum to discuss innovative options
 - Develop regulatory leadership networks
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A decorative graphic in the top-left corner consisting of several overlapping hexagons in various shades of blue and cyan. The largest hexagon is a bright cyan, surrounded by smaller ones in darker and lighter blues.

Building Momentum

Building on experience of earlier initiatives

- Allows more realistic scoping, e.g. convergence instead of harmonisation

Building on initiatives already in progress

- Avoids duplication and promotes collaboration
- Promotes convergence of requirements and processes
- Extends reach respective programmes
- Promotes globalisation of sound regulatory innovation





Key Expectation:

Ongoing engagement of MHLW/PMDA with regional and international initiatives to promote innovation, collaboration and capacity development

***“Alone we can do so little;
together we can do so much”
– Helen Keller***



Thank you

