



IMDRF International Medical
Device Regulators Forum

**Update from
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**Asia-Pacific
Economic Cooperation**



Priority Work Areas (PWAs)

- PWAs and Champion Economies:
 - MRCTs (Japan)/GCP Inspection (Thailand)
 - Supply chain integrity (US)
 - Good Review Practices (Chinese Taipei)
 - Pharmacovigilance (Korea)
 - Cellular Therapies (Singapore)



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Multi-Regional Clinical Trials (MRCT- Japan)/GCP Inspection (Thailand) Roadmaps

- MRCT/GCP workshop that was held in May '14,
- an additional gap analysis will be conducted to determine potential barriers to convergence,
- Prior CoE discussions resulted in a decision that the **MRCT be merged with the GCP Inspection** PWA. Japan expressed an interest in developing a Clinical Trial curriculum that incorporates MRCT and GCP issues.

Action Items:

- Japan and Thailand will work on **combining the MRCT and GCP Inspection roadmaps** prior to the next RHSC meeting.



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Global Supply chain integrity Roadmap and Workshop (US)

- The United States presented an update on Roadmap activities of the ten work streams. Deliverables include gap assessments; training toolkits; training in each of the work streams; and then integrating all of that work into a strategic plan.
- A workshop on Promote Medical Product Quality and Supply Chain Security: Product Security, Good Distribution Practices, and Single Point of Contact Systems, delivered over four days (January 26-29).
- The plan is to hold another Stocktaking meeting comprised of five training programs on: GMP; product traceability and authentications; detection technologies; internet sales; and good import/export practices. Each work stream has completed a gap analysis and is developing training materials.



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Global Review Practice Roadmap (Chinese Taipei)

Chinese Taipei announced that the draft **GRevP guideline** submitted to the **WHO** was adopted by the Expert Committee on Specifications for Pharmaceutical Preparations in October 2014, and will be presented to the Executive Board in May 2015. In addition, presentations on the work of this group has been mentioned at several international conferences since the last RHSC meeting, and is the focus of the 8th Asia Regulatory Conference in February 2015.



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Pharmacovigilance Roadmap (Korea)

- A gap analysis report showed that **PV regulatory systems vary greatly among APEC economies – training on internationally standardized reporting format (E2B) is needed.** A working group, that now includes a WHO representative, is developing a **PV capacity building training module** that will avoid overlap with other currently available training programs. The group is proposing a 5-day workshop in September on a global cooperative system that will include 2 days of workshops for PV regulatory, industry and academia experts, and 3 days devoted to training regulatory authorities and healthcare professionals.
- **Action Items:**
- **Korea to lead an effort in developing a Thought Paper on the possible inclusion of medical device vigilance in the PV roadmap activities.**



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Cellular Therapies Roadmap (Singapore)

Singapore reported on the last workshop held in July 2014. Experts will continue to **share information and collaborate with the IPRF working group**, especially on issues such as **CMC and GMPs**. Categorization of CTT products is a critical issue. A working group has been formed and will consult with IPRF.



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Centres of Excellence-APEC Training CoE for Regulatory Science

The Vision:

a sustainable platform for **promoting regulatory convergence** (harmonization), **capacity and cooperation in areas of medical products**, that is focused on **science** and **best practices**.



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The Approach:

A partnership of **academia, regulators and industry**. Benefit must be realized by all 3 partners. RHSC and AHC will oversee and certify performance



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Potential PWAs for CoE include

**MRCT/GCP, GRevP/GSP, Supply Chain
Integrity, Pharmacovigilance, and
Biotherapeutics.**

Other PWAs (Cell and Tissue Therapies,
Combination Products, Medical Devices,
others) would be considered at a later point.



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- Key requirements for an MOU (or similar agreement)
- Potential roles for the RHSC
- Potential roles for the PWA Roadmap Champion
- Potential roles for the AHC.



Conclusion

- RHSC, in partnership with AHC, candidate CoEs and other partners, positioning itself to become a **leading enabler of regulatory convergence and capacity building by promoting international standards and best practices**
- *NB - RHSC activities not restricted to APEC economies*

Thank you!