RHSC Meeting March 3-4 2011 in Washington DC

- First of two face-to-face meetings in 2011 in US (next mid September in San Francisco)
- Preceded by Training Subcommittee meeting
- Strong support expressed on progress achieved from LSIF at March 5 Planning Group meeting
RHSC Members

- Regulators from Canada, China, Chinese Taipei, Japan, Republic of Korea, Peru, Thailand and USA with official observers from Mexico and Singapore
- Industry representatives from innovative drug and medical device sectors
- Director of APEC Harmonization Center
Membership Update

• Some changes in membership

• Endorsed proposal to include representative from generic pharmaceutical industry as observer

• Expression of interest from Philippines and Indonesia
Training SubCommittee
Achievements in Washington

- Significant progress in defining a strategic framework, roadmaps and priority work areas (PWAs)
- Identified economy champions to advance work
- Introduced robust project review process
- Reviewed and adopted overall workplan for 2011/12
- Reviewed and endorsed series of project proposals and first roadmap (on MRCTs)
- New procedures and representative endorsed regarding LSIF participation at ICH GCG
Elements of a Strategic Approach

• Establish goals and a plan or “roadmap” to achieve these goals

• All activities should support goals and form part of the roadmap

• Approach takes advantage of existing international guidelines and best practices, the AHC and other key players to promote complementary, coordinated actions and most effective use of overall resources
Strategic Framework
Coordinated approach to promote regulatory convergence

Priority Work Areas
Needs assessment from diagnostic workshops and a roadmap for promoting best practices

Individual projects are part of strategy & contribute to goals
Move away from Ad Hoc/Individual Proposals
Regulatory Convergence
For Medical Products
2020

Pharmaceuticals
- Multi-Regional Clinical Trials
- Good Review Practices
- Product Quality
- Pharmacovigilance

Medical Devices
- Clinical Evidence
- Post-market Surveillance
- Quality Management System

Projects to support overall strategy and components of ROADMAPS

Proposals for Projects
Elements of a Roadmap

**Identified Gaps**

**Prioritized List**

**Strategic program**

**Progress/Performance Evaluation**

**Sources**
- Workshops
- Emergent issues
- Checklist
- Other fora input

**Criteria**
- Risk
- Serial processes
- Transversality

**Activities**
- Regulation - information sharing
- Process – Workshops
- Zero info – Seminars

**Tools**
- Checklist
- Client consultation

**Individual Projects**
Strategic Framework

- Revised draft circulated to RHSC in May
- Framework outlines strategic multi-year approach for achieving greater regulatory convergence by 2020
- Describes guiding principles and general multi-step approach
- Includes appendices for pharmaceuticals and medical devices and suggested indicators of success
Strategic Framework

• Makes clear that all efforts are voluntary

• Each economy would proceed at its own pace

• Comments due June 10; target next meeting in San Francisco to adopt Framework

• Note: much discussion in Washington on terminology: regulatory convergence versus harmonization
Priority Work Areas (PWAs)

- Roadmap to be developed by champion economy for each PWA
- Champions/PWAs identified to date:
  - MRCTs (Japan - roadmap completed)
  - Supply chain integrity (US)
  - Pharmacovigilance (Republic of Korea)
  - Biologics/Biotech products (Singapore)
- FDA also working on roadmap template
Other Progress since Washington

• APEC endorsement of two self-funded project proposals submitted by Japan:
  – AHC-sponsored training seminar on implementation of GHTF guidances, July 4-5, 2011 in Seoul
  – Tokyo MRCT workshop highlighting Tripartite Symposium, November 1-2, 2011

• MRCT roadmap to be circulated for official APEC endorsement

• Very successful AHC/DIA/IFPMA conference held on Asia’s Role in Global Drug Development, April 24-26 in Seoul: model for future
Other Progress since Washington

- Preparations underway for July 5-7, 2011 Stem Cell QA/QC workshop, hosted by Thailand

- Draft program and survey under development for first training session on Good Review Practices for drugs and devices, October 12-15, 2011 in Chinese Taipei (2 year project)

- October 4-5, 2011 set for AHC-sponsored ICH Q8/9/10 workshop

- Discussions held with AHWP on opportunities for cooperation on development and delivery of training and orientation programs (for devices)
Other Progress since Washington

- Promoting awareness:
  - Representation at medical devices training session June 26-27, 2011 hosted by HSA
  - APEC Townhall, US annual DIA (June 2011)
  - Pending launch of RHSC website
  - Pending APEC endorsement of RHSC logo
Conclusion

• Continuing progress in advancing a more strategic, coordinated and effective approach to regulatory convergence and cooperation

• Adoption of strategic framework and roadmaps key elements of such an approach

• Welcome delivery of ICH Quality workshop in Seoul