

APEC RHSC Report to Global Cooperation Group

GCG Meeting
June 14, 2011
Cincinnati



Asia-Pacific
Economic Cooperation

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



RHSC



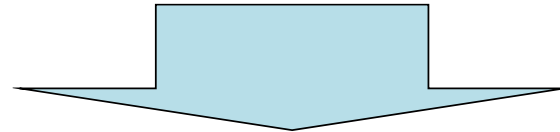
Achievements in Washington

- 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

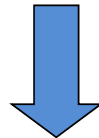
Elements of a Strategic Approach

- 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

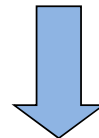
Strategic Framework
Coordinated approach
to promote regulatory convergence



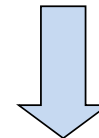
Priority Work Areas
Needs assessment from diagnostic workshops
and a roadmap for promoting best practices



Project



Project



Project

Individual projects are part of strategy & contribute to goals
Move away from Ad Hoc/Individual Proposals

Regulatory Convergence For Medical Products 2020

Pharmaceuticals

Medical Devices

Multi-Regional Clinical Trials

Good Review Practices

Product Quality

Pharmaco-vigilance

Clinical Evidence

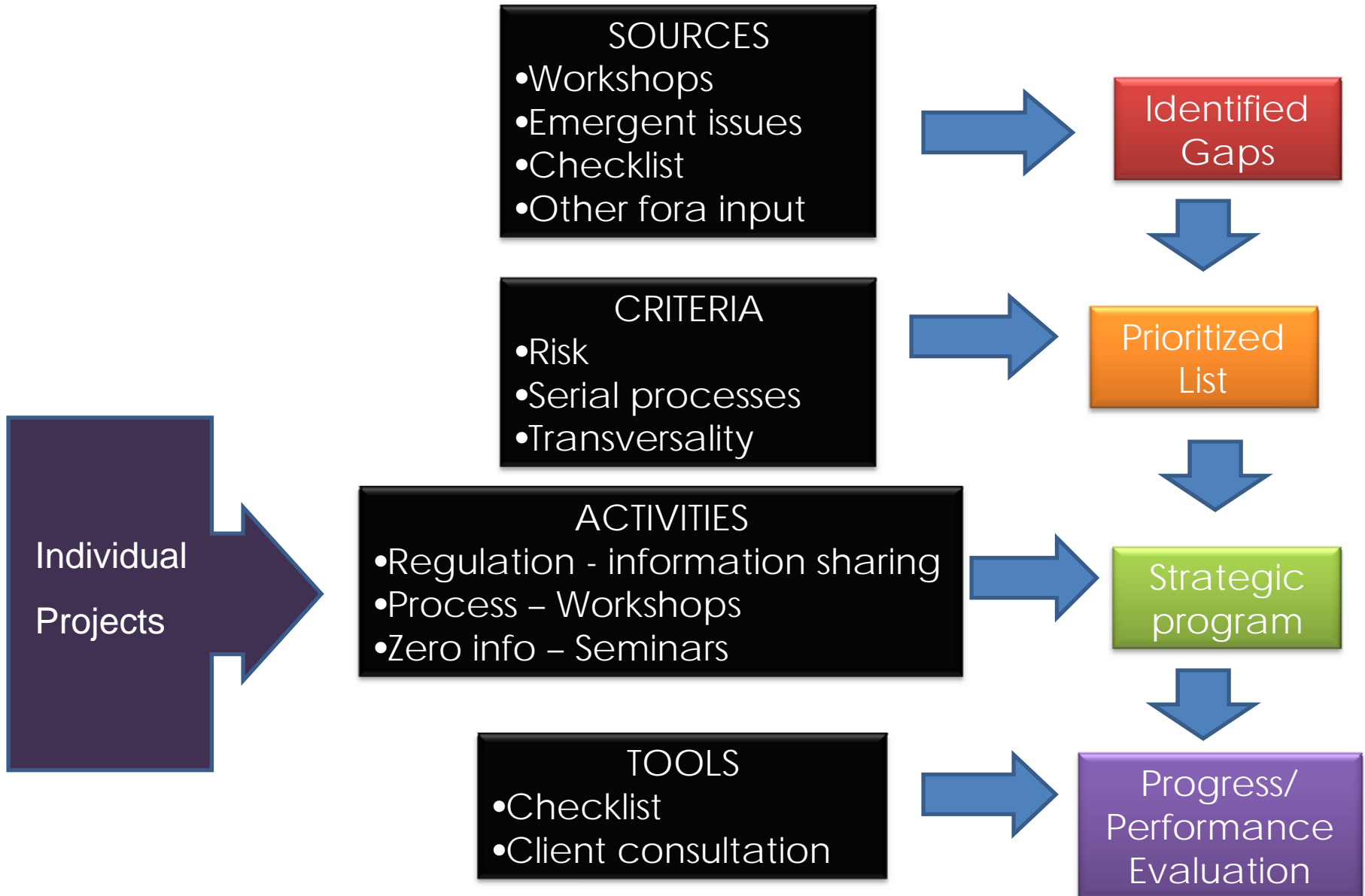
Post-market Surveillance

Quality Management System

Projects to support overall strategy and components of **ROADMAPS**

Proposals for Projects

Elements of a Roadmap



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