Asia-Pacific Economic Cooperation

Regulatory Harmonization Steering Committee

Life Sciences Innovation Forum

APEC RHSC Meeting Agenda

August 13-15, 2014

Beijing Hotel, Beijing, China

Ver. August 13, 2014

Day 2: Thursday, August 14

09:00 – 09:05	Welcome and Introductions
09:05 – 09:10	Adoption of the Agenda
09:10 – 09:20	Expectations for the Meeting
09:20 – 09:25	Review of Membership
09:25 – 09:35	General APEC Update – Remarks by Advisor to LSIF
09:35 – 09:40	Review of 2014 APEC Funding Criteria and Cycles
09:40 – 10:20	Industry Coalition Presentations – Industry Vision for RHSC - Introduction by LSIF Advisor - Innovative Pharmaceutical Industry - Biotech Industry - Medical Device Industry - Generic Pharmaceutical Industry - General Discussion by RHSC
10:20 – 10:40	Coffee Break
10:40 – 10:55	Report from AHC
10:55 – 11:30	APEC RHSC Representation - Report from IMDRF - Report from IPRF - Report from ICH - Confirm future APEC Representation
11:30 – 12:00	Communication/Outreach – Report from RHSC Awareness Group
12:00 - 12:45	General discussion on RHSC Issues: - Participation of Academia - Performance Indicators –Biotech Industry Thought Paper - Principles of Roadmap Assessment - Global Curriculum
12:45 – 13:00	General RHSC Messaging to CTI: Chair
13:00 – 14:30	Lunch Break
14:30 – 14:45	RHSC Website Update and Discussion
14:45 - 14:55	Report on LSIF Blood Safety Initiative
14:55 – 15:10	JPMA Presentation on Asia Partnership Conference of Pharmaceutical Associations (APAC)
15:10-15:20	Roles and Procedures: - Review Revised Operating Procedures - Discuss Any New Changes Proposed to Procedures
15:20 – 15:45	Coffee Break

15:45 - 16:00	JPMA's Presentation on Good Submission Practices
16:00 - 16:20	Review Good Submission Practices Roadmap
16:20 – 17:00	Review Good Review Practices Roadmap
17:00	AOB and Adjourn for the Day

Day 3: Friday, August 15

09:00 - 09:20	Review Supply Chain Integrity Roadmap
09:20 – 09:40	Review GCP Inspection Roadmap
09:40 – 10:00	Review Cellular Therapies Roadmap
10:00 – 10:15	Coffee Break
10:15 – 11:15	Review Multi-Regional Clinical Trials: - MRCT Roadmap Update - Update on Center of Excellence - Presentation by Dr. John Lim on the Centre of Regulatory Excellence at Duke-NUS Graduate Medical School
11:15 – 12:00	General discussion on RHSC-AHC relationship - Roles and support - Strategic planning
12:00 – 13:30	Lunch Break
13:30 – 13:50	Review Combination Product Roundtable
13:50 – 14:10	Review Pharmacovigilance Roadmap (Pharmaceutical/Medical Devices)
14:10 – 14:30	Review Biotechnological Products Roadmap
14:30 – 14:45	Coffee Break
14:45 – 15:05	Review AHC Workshop Planning for 2014/2015
15:05 – 15:30	Any Other Business
15:30 – 16:00	Review Action Items
16:00	Adjourn

Day 4: Saturday, August 16

09:45 – 13:00	Small Working Group Meetings of Roadmaps/Priority Work Areas (TBD)
13:00 – 14:15	Lunch Break

BRIEF 2

A Report of the 5th IMDRF Meeting in San Francisco

The International Medical Device Regulators Forum (IMDRF) was established in October 2011 in Canada. It is a voluntary organization for the medical device regulators joining together to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices (GHTF) disbanded in 2012. The aim of IMDRF is to accelerate international medical device regulatory harmonization and convergence. There are 6 work items under IMDRF including Standalone Medical Device Software Harmonization (SaMD), Review of the NCAR system, Roadmap for implementation of UDI system, Medical Device Single Audit Program (MDSAP), IMDRF recognized standards and Regulated Product Submission (RPS). The current members include Australia, Brazil, Canada, China, Europe, Japan, Russia and the United States of America. World Health Organization (WHO) is the official observer and Asian Harmonization Working Party (AHWP) and APEC Regulatory Harmonization Steering Committee (RHSC) are affiliate organizations. The IMDRF Chair and Secretariat rotate annually.

The 5th IMDRF Management Committee (MC) meeting took place in San Francisco from 25th to 27th March 2014. The 2 representatives of APEC RHSC were Ms. Pei-Weng Tu and Asst Prof Raymond Chua from Chinese Taipei and Singapore respectively. During the 1st day, the 6 working groups updated the latest progresses on the work items and presented the New Work Item Extensions. In the afternoon session, WHO, affiliate organizations such as AHWP, APEC RHSC and other invited observers including Pan African Harmonization Working Party (PAHWP), Pan American Health Organization (PAHO), Ghana, Indonesia, Kazakhstan, Republic of Korea, Singapore, Malaysia, Medical Device Epidemiology Network (MDEpiNET), Global Diagnostic Imaging, Healthcare IT, and Radiation Therapy Trade Association (DITTA) and Global Medical Technology Alliance (GMTA) were invited to give a brief presentation on medical device regulations.

On the 2nd day of IMDRF-5, each working group presented the latest progress of the work items to the stakeholders including regulators, medical device industry, medical professionals, patients and research community. The stakeholders also had the opportunities to express their

views to each working group representative on a face to face discussion platform.. In the afternoon, IMDRF-5 held three interactive workshops including Medical Device Single Audit Program (MDSAP), Software as a Medical Device (SaMD) and WHO Global Initiatives. The working group members were responsible for organizing the workshops. Besides, the stakeholders were also divided into three groups. Each group took turns to attend the workshops, each lasting 50 minutes. Through these activities, the stakeholders could clearly understand what working groups did in the past and what they are going to do in the future.

On the last day of IMDRF-5, MC discussed on existing and future work items, updated the IMDRF website and procedural documents, and review IMDRF terms of reference. In addition, the MC discussed the updated feedback from the open Stakeholder Forum and workshops and made decisions regarding the current and proposed work items. During the last day, IMDRF MC endorsed two documents for public consultation which were proposed by MDSAP and SaMD working groups. Besides, MC also had a comprehensive discussion on NCAR's ongoing work. The NCAR working group proposed to reduce the members from 29 countries to IMDRF members only, however, several representatives expressed that the post-market confidential information should be shared. Due to different opinions, this proposal was suspended and will be discussed through video conference in June. For the recognized standards working group, MC suggested to cooperate with the organizations of standards. This item will also be discussed in June. Because the RPS working group has established Table of Contents (TOC) of IVD and non-IVD medical devices for electronic submission, MC was discussing the possibilities to replace STED in future. Lastly, UDI working group issued the UDI guidance last year. Due to some overlapping or conflicts between UDI and RPS working groups on pre-market information such as data sets and formats, MC asked both working groups to harmonize the differences.

International medical device regulatory harmonization is becoming more and more important nowadays. Through the regulatory harmonization and convergence, the barriers among countries on medical devices will decrease significantly. Both the regulatory authoritiesand the industry members would benefit from these activities. Besides, IMDRF

provides a good platform for every international organization/ institution, such as APEC RHSC, AHWP, etc., to know the latest progress on each working group and trends on medical device regulations in the future and to share the points of view. WHO had worked with IMDRF closely and introduced the "WHO 2nd Global Medical Devices Conference" during the IMDRF-5 meeting to stakeholders. Hence, going forward, it will be opportune for APEC RHSC to continue cooperating closely with IMDRF to accelerate international medical device regulatory harmonization and convergence.

The 6th IMDRF meeting will be held on September 16-18 in Washington, DC.

附件3

Good Submission Practice of Medical Products for Efficient and Effective Regulatory Approval for Trade Facilitation

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Chinese Taipei
APEC 2014 SOM3
RHSC Meeting, Beijing
August 13-16, 2014

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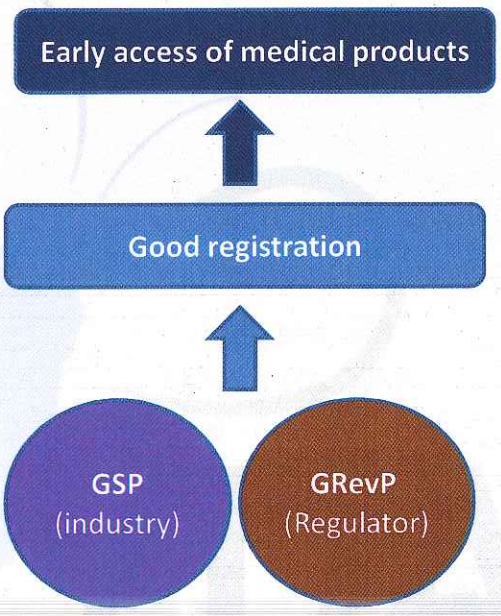
Project Synopsis

- Relevance
- Objectives
- Alignment
- Methodology
- Request

Background on Good Submission Practices

- There is no well-structured GSP commonly implemented in APEC or the broader international community.



Improving Submission Quality in U.S. FDA

- The 2006 report entitled "Independent Evaluation of FDA's First Cycle Review Performance – Retrospective Analysis Final Report" prepared by Booz Allen Hamilton Inc. indicated that, of the 77 submissions (14 BLAs, 63 NDAs) submitted from 2002 to 2004, 36 (47%) received first-cycle approval. Factors contributed to a multi-cycle review versus a first-cycle approval included (1) application quality, (2) communication, (3) variations in FDA review practices across divisions, and (4) significant delay or lack of response from sponsors to concerns highlighted by FDA reviewers. Unfamiliarity with FDA regulations and the drug application process was a key problem for inexperienced sponsors and results in poor quality submissions.
- In 2013, CDER approved most drugs (24 of 27) on the "first cycle" of review (89%), meaning without requests for additional information that would delay approval and lead to another cycle of review. (Novel New Drugs 2013 Summary, U.S.FDA CDER, January 2014)
- The agency announced "Improve 510(k) Submission Quality" project in 2010 and "Improving the Quality of ANDA Submissions" project in 2014.

Observation by CIRS

- Assessment of the quality of a regulatory submission and its review by scorecards was published by CIRS (Salek S et al. Drug Inf J. 2012 46: 73-83). Areas in which the dossier could be improved were identified in this analysis, including:
  - Incomplete submission of the dossier (e.g. missing data)
  - Negative studies were not included
  - Inadequate studies and data

Qualified Persons in Industry Regulatory Affairs (QPIRA) implemented by Philippines FDA

- The Philippines FDA issued FDA Memorandum Circular No. 2013-003 to inform the industry that the FDA has scheduled training-accreditation for liaison officers and regulatory affairs officers to be Qualified Persons in Industry Regulatory Affairs (QPIRA), with objective that only that person who completed the training-accreditation shall have the accorded authority to transact business at the FDA.
- The training and accreditation of liaison officers and regulatory affairs officers have been designed by FDA to endure that the QPIRAs demonstrate competence and professionalism in preparing and submitting the correct and complete applications and dossiers. Correct and complete submission of requirements for market authorization applications ensures evaluation and approval without undue delay.

Philippines FDA Memorandum Circular No. 2013-004, 04 February, 2013.

Development of APAC Good Submission Practice by JPMA

- **Goal:** to promote preparation of good quality of submission dossier by applicants
- Activities to be facilitated by industry in response to GRevP led by review authorities
- One of the two key elements of APAC Good Registration Practice
- Points to be addressed in future activities include implementation strategies, application dossier, communication with review authorities, and training program
- An APAC Good Submission Practice Guideline describing **principle of good submission**, **management of submission preparation** (including quality management), **communication**, and **training of applicants** will be drafted.

Tsunenari T. APAC Good Submission Practice. Presented at: RHSC Meeting; August 13-16, 2014; Beijing, China.

Implementation of A GSP Pilot Project in Chinese Taipei

- A GSP pilot project targeting the medical device sector has been conducted in Chinese Taipei since 2012.
- Accomplishment:
  1. A guidance document of GSP is being developed for medical device industry.
  2. A survey on GSP was conducted among stakeholders in Chinese Taipei.

Objectives

- Allow applicants to decrease the resources spent on the amendment/resubmission of product registration by guiding applicants to prepare high quality application dossiers.
- Increase review efficiency and may lead to higher approval rate of medical products.
- Enhance the quality and speed of product registration, and promote the availability of new medical products to healthcare providers and patients.

Relevance

- **Related work advanced by international organizations:**
  - **Common submission formats:** ICH developed CTD/eCTD. GHTF/IMDRF developed STED and Regulated Product Submission. This development will enable implementation of good submission practices and good review practices.
  - **Regulatory training:** RAPS has been focusing on education and training of regulatory affairs professionals. These activities contribute to improved submission quality.
  - **Good review practices:** The RHSC advances several work areas including good review practices (GRevP). Promoting GSP enables applicants to follow the harmonized guidelines and submission formats developed by ICH and GHTF/IMDRF and improve submission quality. It in turn enables implementation of GRevP.
- Overall, this project will promote implementation of GSP in pharmaceutical and medical device sectors, and synergize with the work advanced by RHSC, APAC, ICH, GHTF/IMDRF, and RAPS.

Alignment

APEC

- Supports China's APEC 2014 priorities
- In line with the priorities of APEC SCSC and LSIF
- Supports the APEC Regulatory Cooperation Plan endorsed by APEC Ministers in 2011
- Aligned with 2014 Rank 1 funding criteria for APEC-funded projects

RHSC

- Supports RHSC strategic framework
- Synergize with GRevP Roadmap to promote regulatory convergence for medical products

Methodology (1)

Timeline

- Feb-Aug 2015: Project task force, Survey
  - *A survey and a pilot diagnostic workshop will be conducted to identify the needs and gaps in implementing GSP among APEC economies.*
- Sep-Dec 2015: Information exchange platform
  - *The information exchange platform will combine a website and real time virtual meetings/training to satisfy the users' updated needs.*
  - *Identify key elements of GSP document.*
- Spring 2016: 2-day GSP Workshop
  - *Objectives: (1) Sharing information on the regulatory requirements of registration submission in different APEC economies and (2) Extract key elements on registration preparation to improve submission quality.*
- Late 2016: Complete a GSP document and provide project report, including workshop outcome and points to consider, to stakeholders.

Methodology (2)

(2) Stakeholders

- This project will benefit the pharmaceutical and medical device industries in APEC member economies by improving their submission quality and communication with regulatory authorities. Improved submission quality will enable their products to be approved to the market in a timely manner. This in turn facilitates trade of medical products and improves public health in the APEC region.

Methodology (3)

(4) Communication:

- Workshop materials and an electronic summary report will be distributed through CD-ROM or made available on the websites of RHSC and Chinese Taipei Food and Drug Administration
- A project assessment report will be submitted to the APEC LSIF and RHSC.
- A mailing list of GSP stakeholders will be created to effectively communicate among stakeholders.

Request

- Your valuable comments for an APEC Concept Note to be submitted in 2015
- At least 2 co-sponsoring economies

附件4

APEC RHSC Project Update: Combination Product Roundtable

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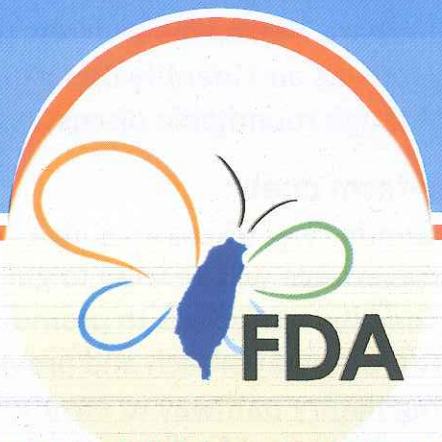
Chinese Taipei
LSIF-RHSC, Beijing
August 13-16, 2014



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Outline

- Action items from the last RHSC Meeting
- Summary of significant activity since last RHSC meeting
- Plans for future activities
- Issues need to be discussed

Goals of this project

- **Purpose of project:**
  - To share challenges and best practices in regulating combination products and identify opportunities for regulatory convergence through roundtable discussions and RHSC website
- **Long-term goals:**
  - Summary of discussion, ideas and recommendations from the roundtable will be used to guide the development of future actions.
  - The ultimate goal is to promote the understanding of principles of a risk-based approach and provide tools, in order to establish effective regulatory pathway to ensure safe and efficacy of combination products, and facilitate regulatory convergence in regulating combination products throughout the product life cycle among APEC member economies.

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Action items from the last RHSC Meeting

Chinese Taipei, Medical Device Coalition and Thailand (tbc) are to discuss the proposal and revise it to include more specificity on the purpose and outcomes expected of holding a roundtable meeting and convening a Discussion Group.

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Summary of significant activity since last RHSC meeting

- A call between Chinese Taipei representative and Medical Device Coalition representatives discussing the next step of Combination Products Roundtable took place on June 26, 2014. Both parties agreed that we will work out a roundtable proposal this year and run a discussion group through RHSC web site.
- Medical Device Coalition initiated activities to reach out their AdvaMed combination product expert working group to identify issues to be considered in the proposal. The issues identified has been shared. In addition, they will also reach out to FDA's Office of Combination Products to solicit their feedback on key challenges in regulating combination products.

Feedback on Key Challenges with Regards to the Regulation of Combination Products

1. **Inconsistent regulatory classification for the same product in different countries**
   a. Local Operating Company regulatory expertise
   b. Differing development and post-market requirements
2. **Application of multiple or inconsistent or overly burdensome (not taking a risk-based approach) drug and device product regulatory requirements**
   a. Application of Design Controls for Combination Products
   b. Clinical trial / Human factors study requirements
   c. Complaints/safety reports: managing expectations on use errors for drug delivery devices; complaints on supplier sourced components; consistent safety reporting pathways
   d. Post approval changes, minor changes could lead to long review time
3. **Insufficient regulatory expertise**
4. **Inconsistent timelines and compliance requirements versus single component product competition**

Plans for future activities with timelines (1)

	Jul-14	Aug-14	Sep-14	Oct-14	Nov-14	Dec-14	Jan-15	Feb-15
Identify issues and strategies for a roundtable proposal	■							
Share preliminarily identified issues and strategies among interested parties		■						
Progress report in RHSC Meeting		■						
WG to develop a roundtable proposal with bi-monthly teleconferences			■	■	■	■		
WG to finalize roundtable proposal and submit to RHSC							■	
Seek RHSC endorsement of the roundtable proposal								■

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Plans for future activities with timelines (2)

- Chinese Taipei report the preliminarily identified issues among interested parties and seek endorsement for forming a Combination Product Working Group (CPWG) for further development of a roundtable proposal in RHSC Meeting. (August 13-16)
- CPWG to develop combination product roundtable proposal based on the identified key challenges and convene teleconferences on a regular basis. (September 2014 – December 2014)
- CPWG to post the issues identified for key challenges in regulating combination products on the website for the discussion group later this year when the RHSC website opens for use.

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Plans for future activities with timelines (3)

- CPWG to finalize combination product roundtable proposal and submit the finalized proposal to RHSC. (January 2015)
- RHSC endorsement of the combination product roundtable proposal. (February 2015)

Issues that need to be discussed at this RHSC meeting

- Support to form a Combination Product Working Group (CPWG) for further development of a roundtable proposal

Thank You for Your Attention!!

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Asia-Pacific
Economic Cooperation

2014/SOM3/LSIF/SS/001

Agenda

Purpose: Information
Submitted by: LSIF PG Chair

APEC
CHINA 2014

Life Sciences and Innovation Forum Special Session and Executive Board Meeting
Beijing, China
14 August 2014

Updated 8 August 2014

2014 LSIF Special Session (LSIF SS) Meeting
Thursday, 14 August 2014
14:00 – 16:15
The Beijing Hotel, Beijing, China

AGENDA

Time	#	Topic
14:00 – 14:05	**1**	**Opening Session** 1.1. Welcoming remarks and introductions of LSIF Board Members (Led by LSIF PG Chair)
14:05 – 14:10	**2**	**Statements from the LSIF Executive Board Chair and Co-Chairs**
14:10 – 14:20	**3**	**Updates from the APEC Secretariat** 3.1 Introduction to BMC endorsed Concept Note Ranking and Prioritization Pilot
14:20 – 14:35	**LSIF Research & Development Steering Committee (RDSC)**	
	4	4.1 Update on Key Activities of the RDSC and future work – RDSC Chair (Chinese Taipei) 4.2 Biomedical Technology Commercialization Center – Korea and Thailand 4.3 Consideration of RDSC requests
14:35 – 15:05	**LSIF Regulatory Harmonization Steering Committee (RHSC)**	
	5	5.1 Update on Key Activities of the RHSC - RHSC Chair (Canada) 5.2 Report from the APEC Harmonization Center (AHC) – Korea 5.3 CTI Presentation on Global Data Standards – New Zealand 5.4 Consideration of RHSC requests
15:05 – 15:35	**Health Policy and Innovation**	
	6	6.1 Update on Key Activities on Health Policy and Innovation 6.2 Mental Health – United States 6.3 Cervical Cancer – United States 6.4 Traditional medicines – Indonesia 6.5 Healthcare-associated infections – United States 6.6 Blood Safety – United States

		6.7 Multi-Drug-Resistant Tuberculosis – Chinese Taipei 6.8 Establishment of Health Policy and Innovation Committee 6.9 Update on and review of LSIF priorities for the High-Level Meeting on Health & the Economy 6.10 Consideration of requests
15:35 – 15:45	**7**	**Proposals from the LSIF Board** 7.1 Health Workforce Mobility Principles and Considerations 7.2 Proposal to Establish a Health Innovation Academic Network
15:45 – 15:50	**8**	**Report from the APEC Business Advisory Council (ABAC)**
15:50 – 15:55	**9**	**Strategic Review of LSIF** 9.1 LSIF-related priorities in 2015 – Philippines 9.2 LSIF-related priorities for 2016 – Peru (invited) 9.3 Development of a strategic framework for work going forward
15:55 – 16:05	**10**	**Other Business**
16:05 – 16:15	**11**	**LSIF Recommendations to Ministers and Leaders**
16:15	**12**	**Adjourn**
LSIF Executive Board Meeting		
16:30 – 18:00		**LSIF Executive Board Meeting** – CLOSED MEETING FOR LSIF BOARD MEMBERS ONLY
Welcome Reception Dinner		
18:00		**Welcome Reception Dinner** Location: Raffles Beijing Hotel, Writer's Bar