RA session

RA-EWG, APAC

5 April 2022

APAC
Asia Partnership Conference of Pharmaceutical Associations

1. OPENING BY CHAIRS

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Session Chairs

Junko Sato

Office Director

Office of International Program

PMDA

Pharmaceuticals and Medical Devices Agency

Sachiko Nakagawa

Managing Director

JPMA

Japan Pharmaceutical Manufacturers Association

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RA Session Agenda

- Topic (90 min)
  - APAC RA concept Paper toward 20th APAC
- Objective
  - How we introduce innovative new medicine based on new modality to APAC

13:25 ▶ 14:55	90	RA Session: "How we introduce innovative new medicine based on new modality to APAC."			
13:25 ▶ 13:30	5	1	Opening by chairs	J Sato S Nakagawa	PMDA JPMA
13:30 ▶ 13:40	10	2	Introduction of RA Concept Paper Introduction of GRM Position Paper	S Hatakeyama T Rikukawa	APAC RA-EWG
13:40 ▶ 14:20	40	3	Presentations x 4	Jesusa Joyce Cirunay Sara Wang Vicky Han Janis Bernat	Philippines FDA RDPAC Janssen IFPMA
14:20 ▶ 14:50	30	4	Panel Discussion	ALL presenters	
14:20 ▶ 14:55	5	5	Closing by chairs	J Sato S Nakagawa	PMDA JPMA

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2. INTRODUCTION OF RA CONCEPT PAPER & GRM POSITION PAPER

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Speakers

Shinji Hatakeyama

APAC RA-EWG Leader

JPMA

Japan Pharmaceutical Manufacturers Association

Takashi Rikukawa

APAC RA-EWG

JPMA

Japan Pharmaceutical Manufacturers Association

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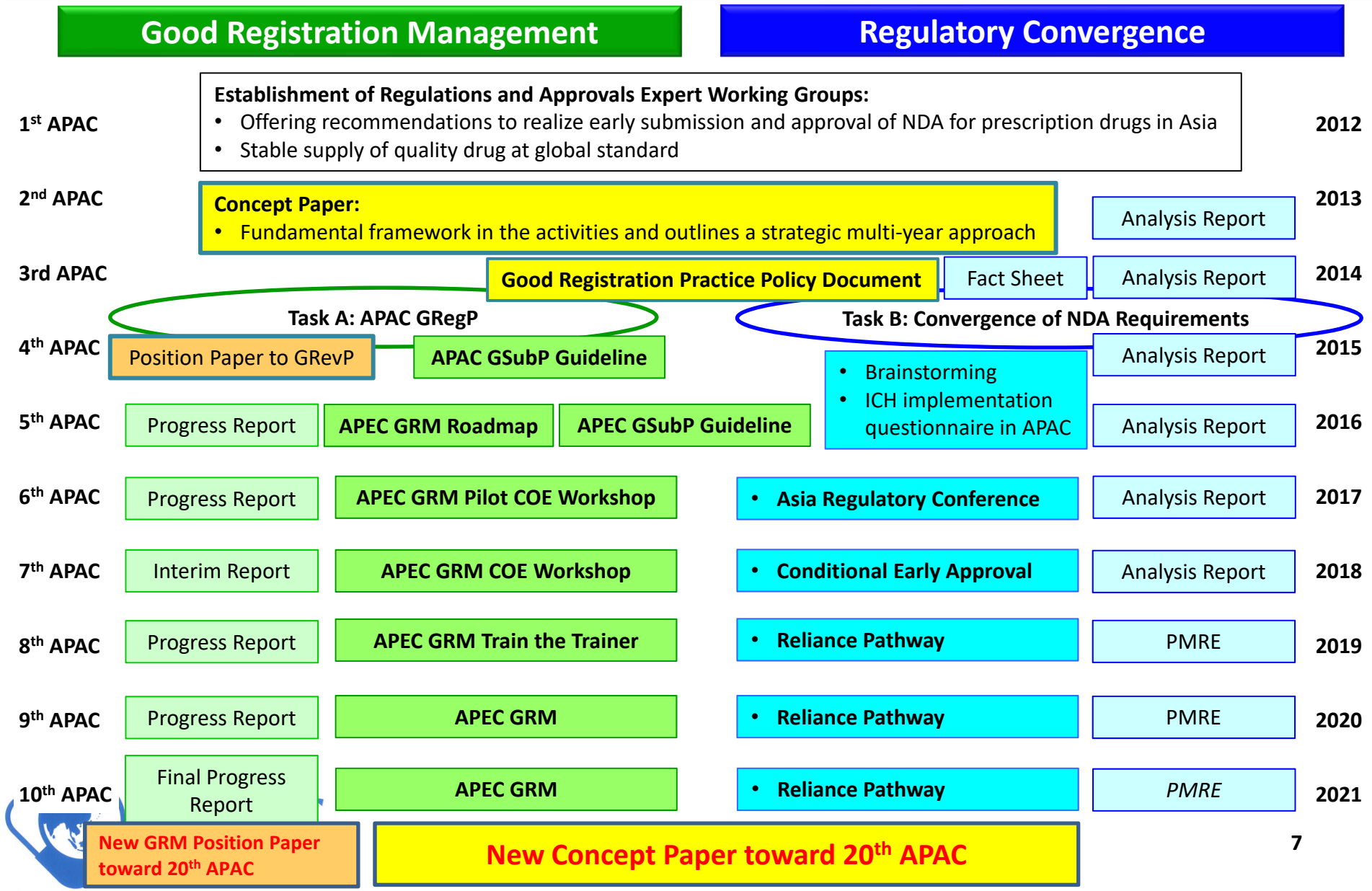
Regulations and Approvals Expert Working Group



Achievements beyond APAC framework

- **APEC Good Registration Management**
  - Good Review Practice Guideline by **Taiwan FDA**
    - Endorsed by **WHO**[1] (2015)
  - Good Submission Practice Guideline by **APAC RA-EWG**
    - Endorsed by **APEC-LSIF-RHSC**[2] (2016)

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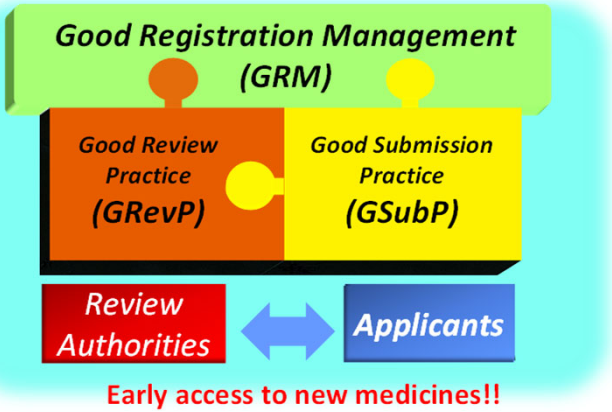
Facilitating drug registration in Asia



Collaboration among APAC RA-EWG, Taiwan FDA & PMDA

- **Site Master File template**
  - Informed & discussed in **PIC/S**[3] Committee Meeting (2018)

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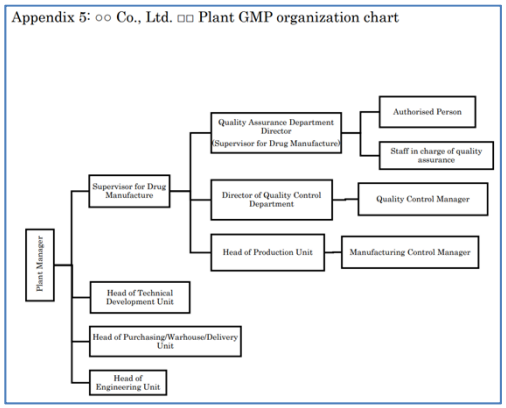
Contributing GMP harmonization in Asia



Collaboration between APAC ATIM TF & PMDA

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1) World Health Organization
2) Asia-Pacific Economic Cooperation - Life Sciences Innovation Forum - Regulatory Harmonization Steering Committee
3) Pharmaceutical Inspection Co-operation Scheme

New Concept Paper toward 20th APAC

<OBJECTIVE>

To recommend that the health authorities to establish a robust regulatory framework to facilitate access to innovative medical products based on new modality for people in Asia.

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New Concept Paper toward 20th APAC

<SCOPE>

- **Regulatory Platform**
  - Regulatory agility
  - Reliance pathway between/among health authorities
  - Good Registration Management

Regulatory Platform

- **Enhancement of Digitalization/Digital Platform/Real-World Evidence in the Pharmaceutical Area**
  - E-documents
  - Digitalization/Digital platform
  - Real-World Data/Real-World Evidence

Digitalization
Digital Platform
Real-World Evidence

- **Adequately Integrated and Streamlined Regulatory Processes throughout Product Life Cycle**
  - Regulatory & scientific requirements
  - Regulatory classification and requirements for combination medical products
  - Regulatory manufacturing framework

Integrated and
Streamlined
Regulatory Processes

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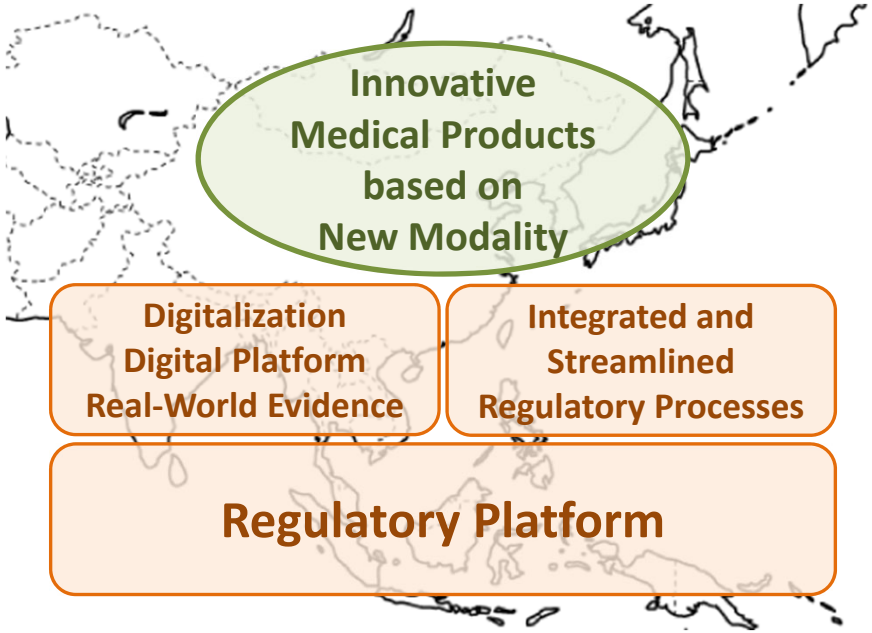
New Concept Paper toward 20th APAC

<APPROACH>

- APAC annual conference
- APAC letter to authority
- APAC RA-EWG daily activities
  - GRM position paper
  - Publication
- APEC GRM COE workshop



<TIMELINE>

2022 ～ 2031

(11th APAC ～ 20th APAC)

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GRM Position Paper

<Background>

- **Position Paper 2015**
  - Released at the 4th APAC in 2015
  - Providing high level suggestions to the regulatory authorities from the viewpoint of industry for improving regulatory environment for GRM
  - Covering following 5 topics;
    - Consultation
    - Transparency
    - Tracking system
    - Collaborative training
    - Review report in English
- Each APAC member association picked up topics to be addressed and worked to improve them
  - The achievements and improvements from 2015 to 2021 were summarized in **Final Progress Report**

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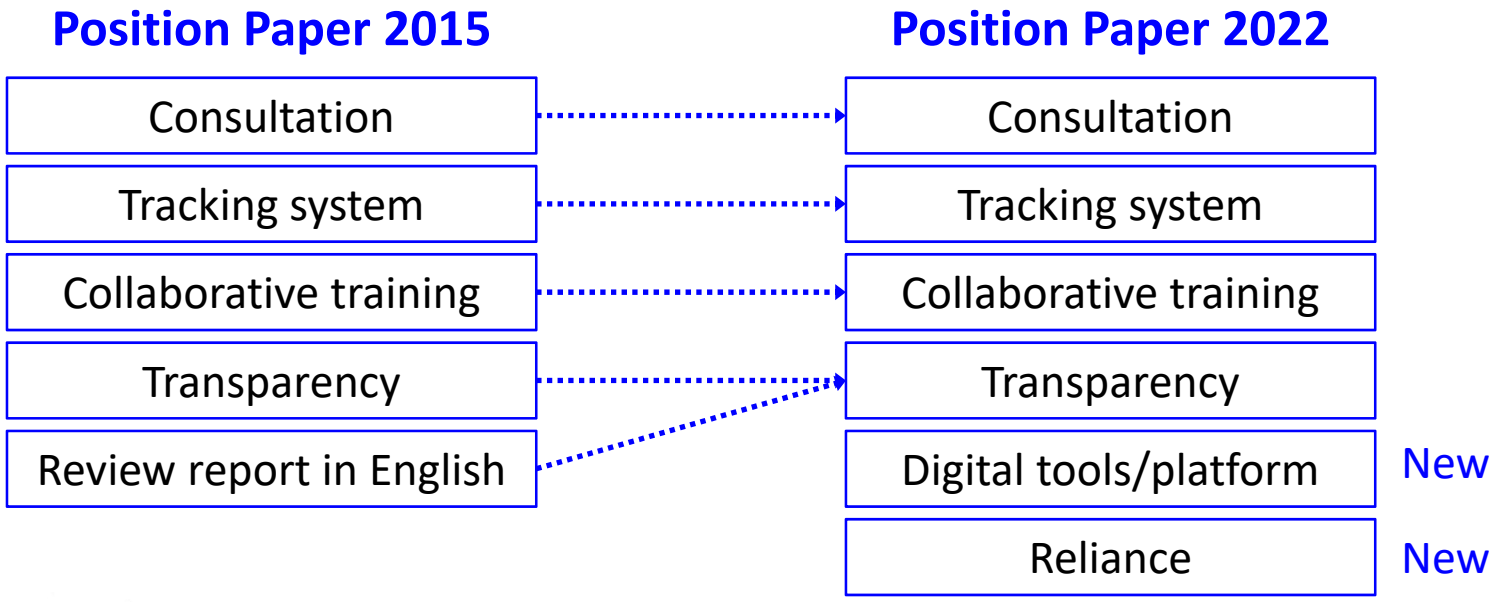
GRM Position Paper (Cont'd)

- **Position Paper 2022**
  - The environment surrounding pharmaceutical industry has been constantly changing
  - Revised to provide updated suggestions that reflect current circumstances
    - The existing topics have been reorganized with improvements and new topics have been added



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3. PRESENTATIONS BY PANELISTS (10 MIN X 4 PANELISTS)

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Panelists

Jesusa Joyce Cirunay

Director IV

The Center for Drug Regulation and Research

The Food and Drug Administration

Philippines

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Panelists

Sara Wang

Executive Director

Science & Regulatory Affairs

RDPAC

R&D-based Pharmaceutical Association Committee

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Panelists

Vicky Han

Senior Director

Head of the Global Regulatory Policy & Intelligence for Asia Pacific

Global Regulatory Affairs

Janssen Pharmaceuticals

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Panelists

Janis Bernat

Director

Scientific & Regulatory Affairs

IFPMA

International Federation of Pharmaceutical Manufacturers & Associations

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4. PANEL DISCUSSION

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Panel discussion items

1. **What is expectation to health authority for registration of PRODUCT A***

2. **What should industry put effort into registration of Product A***

**PRODUCT A is Innovative Medical Products based on New Modality*

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5. CLOSING BY CHAIRS

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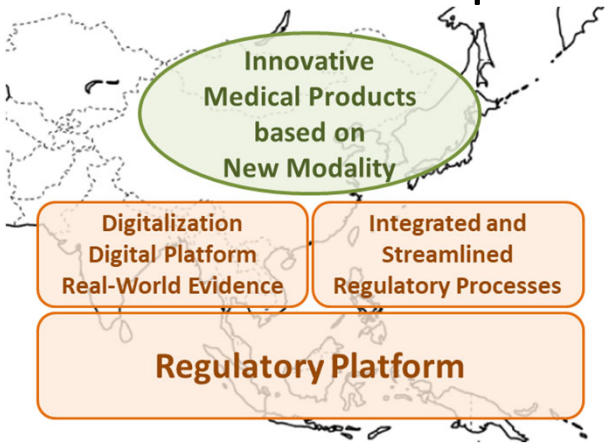
Consensus of RA session

Regulations and Approvals Expert Working Group (RA-EWG) will promote activities based on the newly formulated concept paper with a view to 10 years ahead.

- We will continue to provide people in Asia with innovative medical products based on new modality, not only in emergencies but also in normal times, for the health and benefit of people.
- We propose to continue the regulatory agility cultivated through the pandemic experience to establish an integrated process and approach to deliver innovative medical products based on new modality.



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Thank you very much!

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