Panel Discussion

Future Directions of regulatory Convergence for New Drug Review (Assessment) and Approval:
What further efforts would be needed to facilitate the Regulatory Convergence in Asia?

Question #1:
What will be the necessary actions to implement the Good Registration Management effectively in your organization?

Question #2:
What would be the essential elements to accept or recognize the regulatory documents/NDA review report of other agency?

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Question #1:
What will be the necessary actions to implement the GRM effectively in your organization?

Implementation of Good Registration Management

- APEC RHSC GRM Pilot training (Nov. 2016)
- Local collaborative training among regulatory agency, academia and industry
- KPIs
- Necessary resources
- Anything else?

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PMDA: Asia Training Center

for Pharmaceuticals and Medical Devices Regulatory Affairs

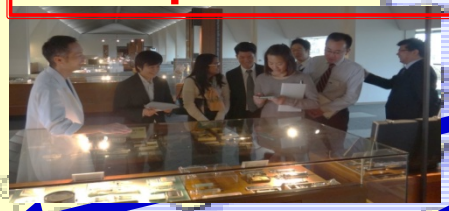
- Plan, design and coordinate training for Asian regulatory authority staff
- Provide **training opportunities** including **on-site training**

➡ Help raise the level of regulations in Asia as a whole.

Asia Training Center (within PMDA)

Japan

(1) Training seminar by PMDA, local prefectures and industry



Local Asian site

(2) Assign to local site

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(3) APEC Training Centre for Clinical Trial and Pharmacovigilance

PMDA: What will be the necessary actions to implement the GRM effectively in your organization?

- Correct recognition of the importance of GRM
  - Why is GRM important?
  - What is expected by implementation of GRM?
- Opportunity to learn GRM
  - Well known each other
    - Regulators and Applicants
- Assessment of the effectiveness of GRM

Taiwan FDA: International Good Submission Practice Workshop on Pharmaceuticals

- Date: September 17-18, 2015
- Venue: GIS NTU Convention Center, Taipei
- Organizer: TFDA, TCFST, JPMA, IFPMA, IRPMA, RAPS and TRPMA
- Objectives: Introducing implementation methods and future trends of Good Submission Practice from both governments and pharmaceutical companies sides.

Taiwan FDA: What will be the necessary actions to implement the GRM effectively in your organization?

- Announce GRevP/GSP guidelines
- Holding stakeholder meetings
- Support APEC GRM CoE training programs for Trainers
  Conduct local collaborative training for Trainees
- Set up KPIs to evaluate the effectiveness
- Resources: TFDA allocates annual budget to support training .

CU, Thailand: Implementation of Good Registration Management

- Thailand Pharmaceutical Medicine Conference
  - Organizers: Chulalongkorn University, FDA, THAIST, PReMA, TPMA, TIPA, **RAPAT**, TSMIA

1ST Conference 2015

- Date: 25-27 Aug 2015
- Venue:Mandarin Hotel, BKK
- Theme: **Regulatory Sciences in Pharm. Product Life Cycle**
- Objectives:
  - Introduce 4 pillars of Pharm Med
    - Clinical research
    - **Regulatory Sciences**
    - Health economic and outcome research
    - Leadership & Entrepreneur

2ND conference 2016

- Date: 30-31 Aug 2016
- Venue: BKK
- Theme: **Regulatory Compliance for Product Development**
- Objectives:
  - International experience sharing
    - Risk based quality management in clinical trial
    - **Regulatory requirements for product development**
    - Pharmacovigilance
    - Managed Entry Agreement (MEA) to increase patient access to medicine

CU, Thailand: What will be necessary actions to implement GRM in your organization?

- Strengthen the collaboration among regulatory authority (FDA), professional and industrial association (RAPAT, PReMA, TPMA, TIPA, TSMIA) and academia
- Include GRM in the road map of COE development
- Develop and implement competency standards to certify regulatory affairs profession
- Develop capacity building plans for each group including regulatory authorities, reviewers, and regulatory affairs
- Standardize the review process for assessment of drug approval
- Incorporate the GRM into the curriculum particularly Faculty of Pharmacy
  - CU requires regulatory compliance as a mandatory professional clerkship

NADFC: Workshop of Drug Registration (2015)

Workshop on Drug Registration, December 2015

- Organized : Coordination between NADFC and Indonesia's Pharmaceutical Association
- Focus Group Discussion on registration issues (case studies) as well as launching of IND, Biosimilar Guideline and dissemination of New Good Clinical Practice Guideline
- Introduction Good Submission Practice for Pharmaceutical company by APAC's representative.

Indonesia as one of WHO GLO center

WHO GLO Center since 2008 for NRA:

- **Clinical Trial Authorization (CTA) Course**
  - **Indonesia : 2008, 2009, 2012 and 2014, South Africa 2009 and Malawi 2010 (total 62 participant from 25 countries)**
- **GCP Inspection Course**
  - **Indonesia 2009, 2011, 2013, 2014, Jordan 2014, Vietnam 2015, Antalya Turkey 2016; (total 36 participant from 15 countries)**
- **Evaluation of Clinical Data (ECD) Course**
  - **Indonesia {2009, 2010, 2014), Philippines (2007), Zimbabwe (2008), China (2011, 2012), Vietnam 2015 (total 53 participant)**

NADFC : What will be the necessary actions to implement the GRM effectively in your organization?

Good Review Practices

- Establishment of procedure and timeline for evaluation
- Transparency in process and decision making.
- Efficient system and mechanism for registration
- High quality review and decision making

Good Submission Practices

- Strong scientific rationale and robust data with clarification of benefit-risk profile
- Compliance to Up to date Regulatory Requirements
- Well structured submission dossier
- Reliability, quality, integrity, and traceability of information and data
- Effective and Efficient Communications

- Support and promote GRM implementation
- Continue to conduct joint training on GRM between regulatory authority and stakes holder
- Improve quality and quantity of the human resource.
- Promote the use of harmonized international standard for evaluation

JPMA: What will be the necessary actions to implement the GRM effectively in your organization?

- Two major achievements of APAC RA-EWG in 2015
  - ✓ Revision of GSubP Guideline to extend its scope
  - ✓ APEC RHSC endorsement on GRM Roadmap document
- Necessary actions for effective implementation of GRM
  - ✓ Implementation of the GRM Roadmap under the APEC RHSC CoE Model
    1. Preparation for the GRM Pilot training in Nov. 2016
    2. Create effective curriculum and materials for the training
    3. Keep close cooperation with concerned stakeholders in regulatory authorities and academia
  - ✓ Continued dissemination of GRM concept through workshops/symposium

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Regulatory Harmonization (US FDA, WHO)

- The process by which the interpretation and/or application of technical guidelines can be made uniform or mutually compatible. (US FDA CBER)
- Harmonization of technical requirements for medicines regulations, i.e. legislation, guidelines, procedures, etc. (WHO)

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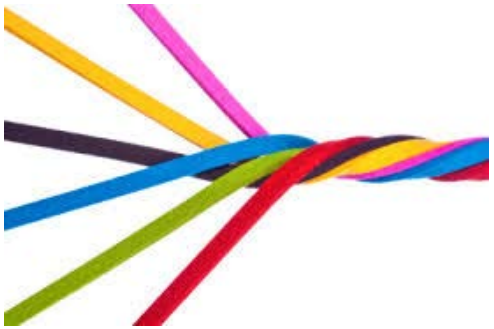
Regulatory Convergence (APEC)

- Represents a process whereby regulatory requirements across economies become more similar or aligned over time as a result of the gradual adoption of internationally recognized technical guidance documents and standards.
- Does not represent harmonization of laws and regulations, which is not necessary to allow for the alignment of technical requirements and greater regulatory cooperation.



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Question #2:
What would be the essential elements to accept or recognize the regulatory documents/NDA review report of other agency?

International Acceptance/Recognition of regulatory documents, such as GXP Inspection reports and others

- Taiwan FDA and PMDA conducted pilot program of accompanying the counterpart to their GCP inspection each other and the program of exchanging their NDA review report.
- ASEAN GMP inspection MRA
- PIC/S

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PMDA: What would be the essential elements to accept or recognize the regulatory documents/NDA review report of other agency?

- Importance of work-sharing among regulatory agencies
  - Avoid duplications of work
- Inspection Report
  - GMP >>> GCP ?
- Review result
  - ???
    - Consider the difference in each country/region
- Capacity Building
  - Share experience and consideration between agencies

Taiwan FDA: What would be the essential elements to accept or recognize the regulatory documents/NDA review report of other agency?

Key Elements:

– adopts harmonized standards

– implements good registration management

Actions:

– exchange of review templates/reports

– conducting joint review

– conducting mutual site visits

CU, Thailand: What would be the essential elements to accept / recognize the regulatory documents / NDA review report of other agencies?

- Understand and recognize the review management and process of each country
- Promote the use of template for review report
  - Country specific could be added
- Capacity building
  - Shared training program
  - Experience sharing
  - Knowledge management

NADFC : What would be the essential elements to accept or recognize the regulatory documents/NDA review report of other agency?

- International recognition can improve efficiency and timeliness of the review process. However, there are many considerations to recognize other regulatory documents.
- Essential elements to recognize NDA review report for other countries:
    - The same standard used for evaluation.
    - Good quality evaluation result.
    - Condition of country and regulation.
    - Transparency
    - Trust.
    - Understanding of the system.
- Currently, Indonesia recognizes
    - Inspection report from PICS countries
    - ASEAN MRA on GMP.
    - ASEAN MRA on BE Studies Report (on going)
    - ACTD/ACTR
- Regarding product assessment report, Indonesia uses the assessment report from countries with established evaluation process as one of reference for evaluation.
- Conducting joint review for NDA

JPMA: What would be the essential elements to accept or recognize the regulatory documents/NDA review report of other agency?

Major elements for accepting or recognizing the regulatory documents/NDA review report of other agency

- ✓ Foster close communications and trust building among the regulatory authorities
- ✓ Facilitate GRevP by the regulatory authorities through promotion of GRM
- ✓ Share the experience of pilot program by TFDA and PMDA as a model of collaboration in Asia
- ✓ Facilitate adoption of international standard/technical guidelines to enhance opportunities of work sharing among regulators. e.g.) PIC/S in GMP, ICH Guidelines

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Take home messages

- **Successful implementation of Good Registration Management will enhance regulatory process and would be the basis of establishing the regulatory convergence in Asia.**
- **Through the implementation of GRM, international efforts to accept or recognize the GXP inspection report and/or NDA review (assessment) report should be encouraged.**

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Thank you!!

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