BADAN POM

8th Asia Partnership Conference of Pharmaceutical Associations (APAC) CONFERENCE

Tokyo, 9th April 2019

1. Why did your economy hold GRM?

✓ What did you expect for GRM at the beginning?

IMPLEMENTATION OF GOOD REGISTRATION MANAGEMENT

GRM Practice in Indonesia

Good Review Practices

- Timeliness
- Predictability
- Consistency
- Transparency
- Clarity
- Efficiency
- High quality

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 with appropriate cross references
- reliability, quality, integrity, and traceability of information and data
- Effective and Efficient Communications

GRev Practice in Badan POM

- Increase quality and quantity of the human resource.
- Establishment of procedure and timeline for evaluation.
- Using national & international standard for evaluation.
- Implementation of QMS.
- Establish SOP for evaluation process and decision making.
- Establishing mechanism for communication with stakeholders.
- Develop electronic registration.
- Maintain conflict of interest and confidentiality through out the evaluation process and decision making.

- The same standard used for evaluation.
- Good quality evaluation result.
- Condition of country and regulation.
- Transparency
- Trust.
- Understanding of the system.

2 What was improved by GRM implementation?

Better Communication with Stakeholder

Focus Grup Discussion on Drug Registration, 6th June 2014

- To have the same perception about drug registration requirements and evaluation timeline between NADFC and Industry

2nd Focus Grup Discussion on Drug Registration, 4th March 2015

- As a follow-up to the 1st meeting and to discuss any issues regarding drug registration requirements and evaluation timeline

Workshop Regulatory, 14-15 December 2016

- Discuss registration issues (case study) as well as launching and socialization of IND, Biosimilar and Good Clinical Practice Guideline

FGD , December 2018

- Discuss registration issues to develop “a pre-market simplification”

To make better Communication with Stakeholder

Training of Good Submission Practice, June 2019

- To have the same perception about drug registration requirements and evaluation timeline between NADFC and Industry

….. Routine consultation desk….

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- Provide clear, un-ambiguous and feasible regulation
- Good resources.
- Efficient system and mechanism for registration.
- Transparency in process and decision making.
- Good communication between regulatory authority and stakes holder.
- Periodic Review on the registration management.


Thank You!
Terima kasih