SINGAPORE ASSOCIATION OF PHARMACEUTICAL INDUSTRIES

Good Registration Management (GRM) Update from Singapore

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Sannie SF Chong (Ph.D.)
Asia Pacific Tech Regulatory Policy
Roche Singapore Technical Operations

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Why did your economy hold GRM?

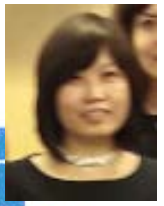
1. To understand regulatory perspectives on gaps in dossier submission
2. To enhance knowledge and skills on Good Submission Practice

What did you expect for GRM at the beginning?

1. To optimize learning through group discussion and case studies
2. To explore/develop solutions through interaction and dialogue

GRM in Singapore: 12-13th April 2017

Trainer HSA	1
Trainer SAPI	4
Facilitator	6
Trainees	56



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What was improved by GRM Implementation?

- ✓ Continual discussion after GRM in the above conference held in May 2017
- ✓ Dialogue to consider enhanced communication and reduce wastage of resources
- ✓ New initiatives to promote efficiency (process) and transparency (timelines):
- ✓ (1) Reliance pathway for post-approval variations applications
- ✓ (2) Predictability at screening stage to accept application for review

Before: Timeline only includes 1st query letter to be issued within 25 working days. No total screening timeline. Limited predictability

2018: Fix total screening timeline of 50 working days (WD), resulted in improved predictability and streamline screening to improve access

- ✓ Recently we also noted improvements in median number of WD taken to review NDA, GDA and MAVs.