SINGAPORE ASSOCIATION OF PHARMACEUTICAL INDUSTRIES

Reporting on GRM in Singapore

Kum Cheun (KC) WONG
Presented on behalf of
Singapore Association of Pharmaceuticals Industries (SAPI)
GRM GSubP Team: Tricia Chean, Por Suat Gnoh, Sannie Chong, Thean Soo Lo

SINGAPORE ASSOCIATION OF PHARMACEUTICAL INDUSTRIES

GRM Good Submission Practice Workshop

Singapore, 12-13th April 2017

Program Overview

A 1.5 day workshop focusing on understanding regulatory perspectives on gaps in dossier submission and enhancing knowledge and skills on Good Submission Practice. This interactive workshop is designed with lectures, group discussions and case studies to optimize learning.

This workshop is made possible with collaboration and support from the Health Sciences Authority, Singapore (HSA) and the Asia Partnership Conference of Pharmaceutical Association (APAC).

Target Audience

1) Regulatory professionals from biopharmaceutical industry,
2) Executives who are interested in understanding key elements from GSubP,
3) Individuals who are actively involved in training of regulatory staff within their organizations

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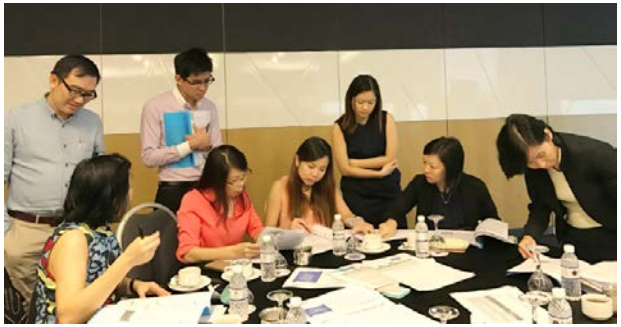
Tricia


Suat Gnoh


Sannie


TS



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Trainer HSA	1
Trainer SAPI	4
Facilitator	6
Trainees	56

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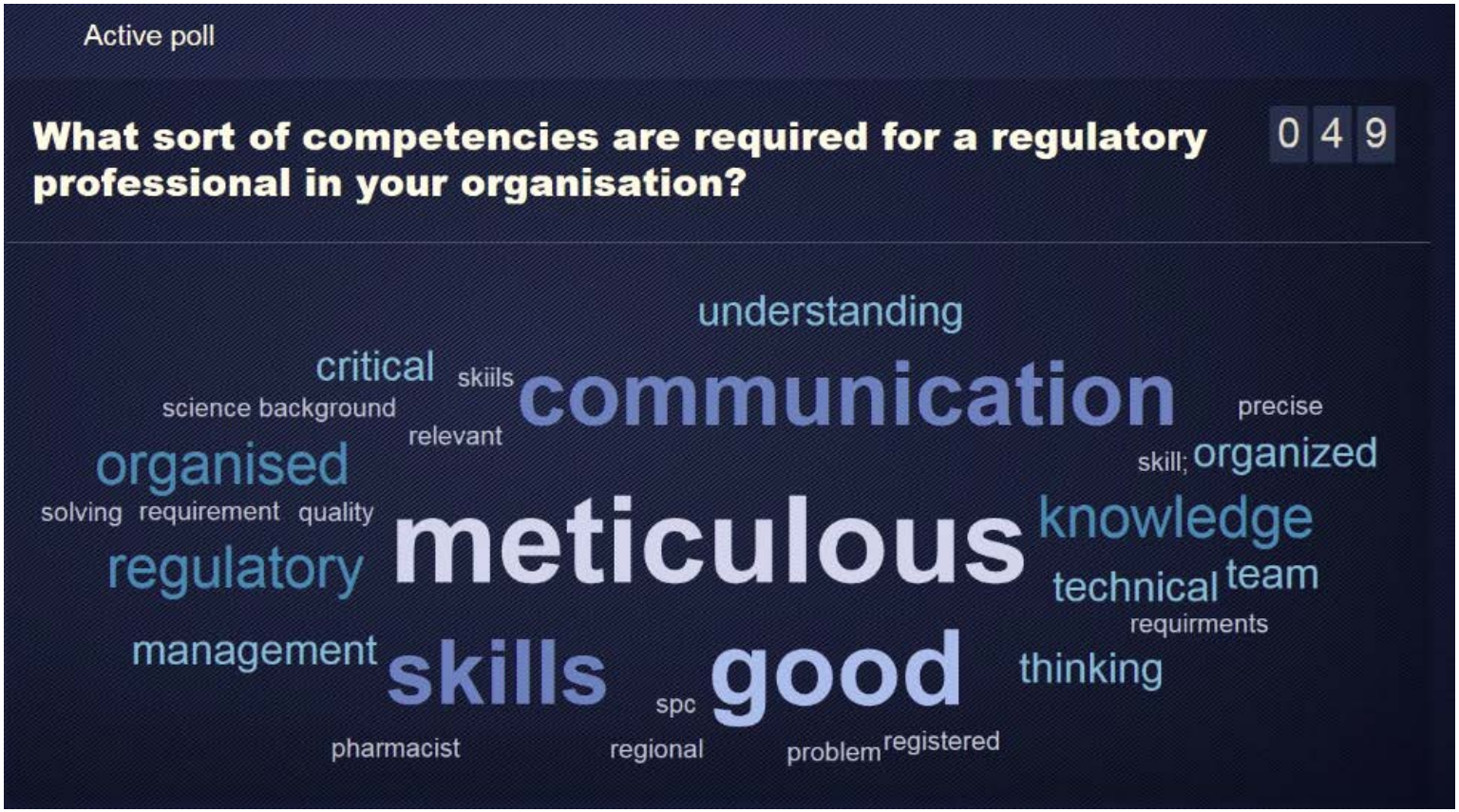

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Feedback from participants		
Will you recommend your colleagues to join the future GRM GSubP workshop?	Members Yes (46), Maybe (1)	Non-Members Yes (9)

Which part of the 2017 GRM GSubP workshop would you like to recommend to your colleagues?

1. Feedback from HSA, by Freddie Foo
2. Good practices and insights, planning of applications
3. Informative, opportunity to interact with other regulatory professionals
4. Implementation of SOP
5. Case studies - help to consolidate the principles and discussed on the presentation
6. The whole workshop, our company does generics and a lot of information shared in the workshop is an eye-opener as it is not practiced in my company.
7. Planning for submission, understanding the importance of communication, preparations and timelines
8. How to handle enquiries

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Considerations/Challenges
1. Trainer's time & resources to organize this event despite other priorities 2. Facilitators training 3. Finalizing workshop content & progress 4. Frequency of conducting workshop 5. Technical challenges of organizing a large workshop

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HEALTH PRODUCTS REGULATORY CONFERENCE 2017

DukeNUS Medical School | CoRE | HSA

In Conclusion .....

- ✓ GRM is the concept to promote both GRevP by regulators with GSubP by industry to enhance the quality and efficiency of the medical product registration process.
- ✓ GRM will improved evaluation, improve communication, reduce wastage of resource, improve timelines
- ✓ GSubP and GRevP complement each other, it is necessary to promote both GSubP and GRevP concomitantly in order to enhance overall quality and efficiency of medical product registration process
- ✓ **Ultimate Goal** to benefit patients with timely access to safe, efficacious and high quality medicines
- ✓ GSubP is industry's commitment to support improved efficiency of the Regulatory Review Process, to expedite access of safe, efficacious and high quality medicines to needy patients

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Acknowledgement

SAPI GRM GSubP Team

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- Sannie Chong
- Thean Soo Lo