



GOOD REGISTRATION MANAGEMENT (GRM) CONFERENCE

APPLICANT SESSION A4

ROLLING OUT THE GRM TRAINING PROGRAM IN YOUR ORGANIZATION

TRAINER'S MANUAL ON GSubP

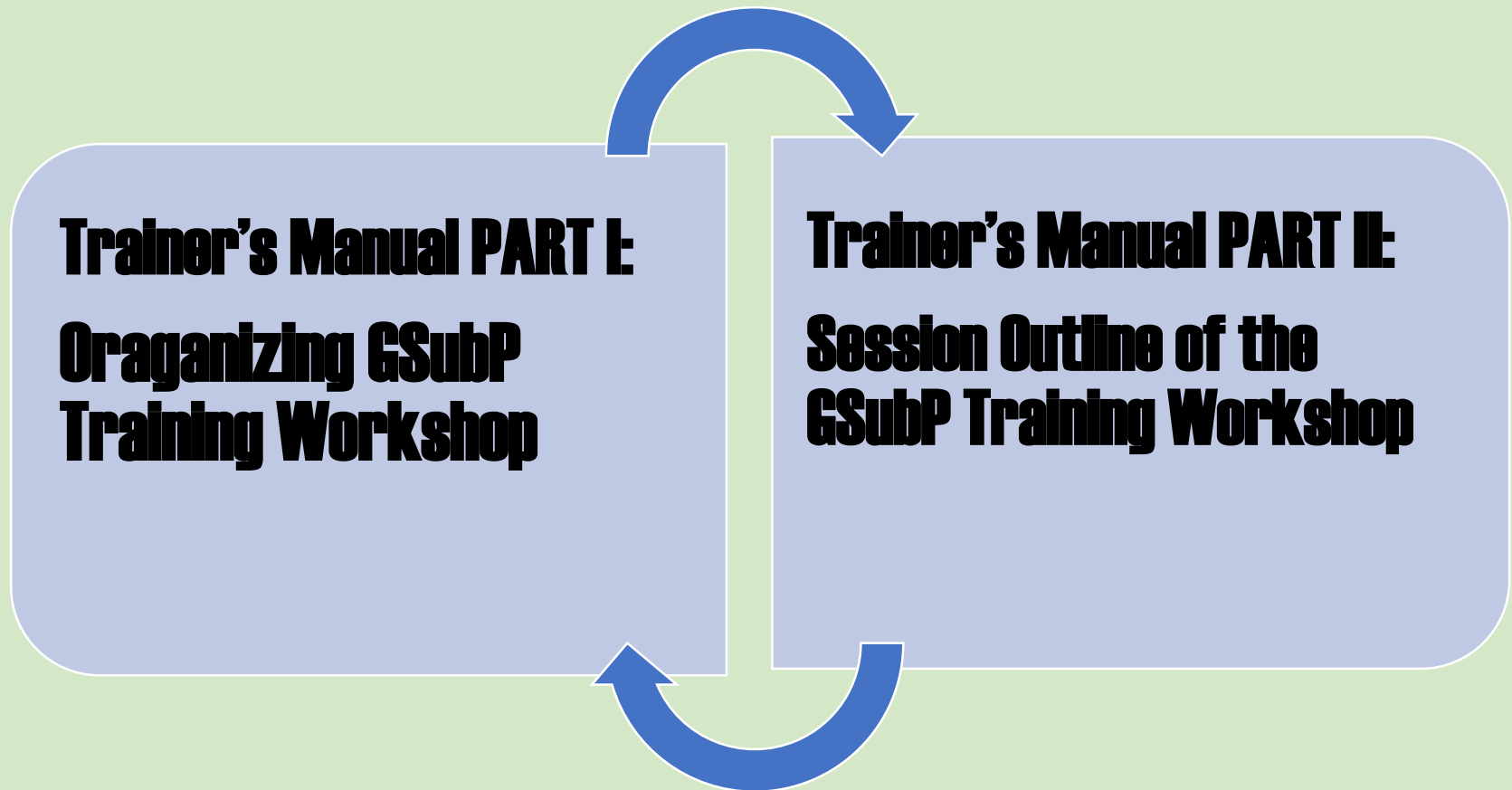
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Good Submission Practice (GSubP)

To provide instructions for the Trainer* on how to organize and manage a GSubP training workshop in each organization

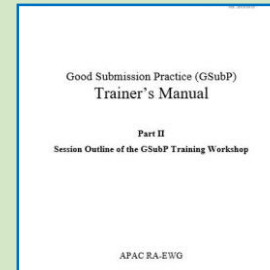


TRAINER'S MANUAL



PART I

- To support the Trainers to organize and manage effective GSubP training program in their own organization(s)
- To provide practical instructions to the Trainers for planning, preparing and holding a GSubP Training Workshop. It also covers the follow-up activities to be performed after the workshop.



PART II

- To provide outline of each session of the GSubP Training Workshop as a guidance for Speakers and Facilitators
- To describe learning objectives, expected time required for the session, methodology and material(s) to be used, how to proceed with the session and take home message

Trainer's Manual PART E

Organizing GSubP Training Workshop

1 INTRODUCTION

2 PREPARATION FOR THE TRAINING

3 CONDUCTING THE GSubP TRAINING

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Organizing GSubP Training Workshop

1 INTRODUCTION

1.1 Purpose and structure of this manual

1.2 Objectives of GSubP training

1.3 Process and methodology

The Certified GSubP Trainer (The Trainer) shall act as a moderator and ***form a training team*** consisting of competent Speakers, Facilitators and Secretariat.

It is highly recommended that the training is not dominantly depending on the lectures but also ***use practice, case studies and group discussions*** as appropriate so that trainees can actively be involved in the process of learning.

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2 PREPARATION FOR THE TRAINING

2.1 TRAINING STAFF

MODERATOR

SPEAKER

FACILITATOR

SECRETARIAT

2.2 PLANING FOR TRAINING

QUALIFICATION OF TRAINEE

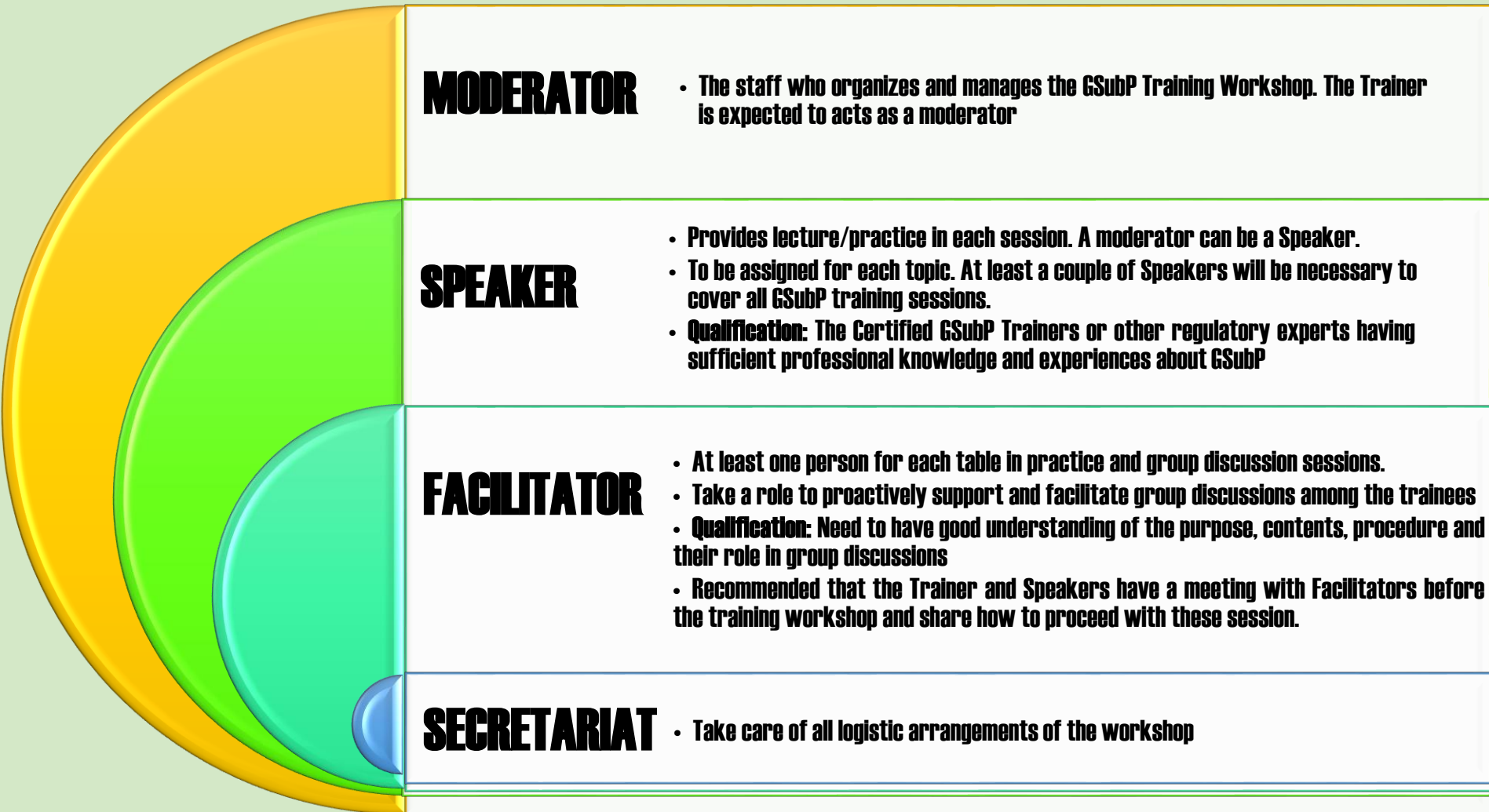
CURRICULUM AND AGENDA

TRAINING MATERIALS

TIMELINE

ADMINISTRATIVE SUPPORT

21 TRAINING STAFF: The Trainer, as a moderator, is recommended to establish a training team consisting of the following staffs.



2.2 PLANING FOR TRAINING

Qualification of trainee:

Preferred target trainee:

At the initial phase: regulatory affair personnel with more than 3 years of experience in application or a person who takes the role of main contact window with review authorities in applicant's organization

After the initial phase: Regulatory affairs personnel with experience of less than 3 years and other department staffs who have been or will be involved in preparation of regulatory submission

Preferred number of trainee in each workshop

- **Around 25 to 30 in total assuming that groups of 5 to 6 trainees will be formed in practice and group discussion sessions**
- **Can be flexible depending on available number of Facilitators and other factors.**

2.2 PLANING FOR TRAINING

Curriculum and Agenda: Two options



1. Preferred option: Organize the GSubP Training Workshop as a part of comprehensive GRM Training Workshop in collaboration with the review authorities by following the curriculum of the GRM CoE Pilot Workshop.



2. The GSubP Training Workshop for applicants can be arranged independently if preferred option is not feasible. An example of curriculum is provided in manual (APPENDIX 1).

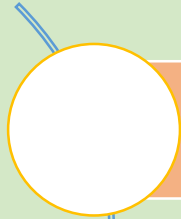
****Minimum customization is allowed to fit the condition of local regulatory system and requirements.**

2.2 PLANING FOR TRAINING

Training materials: The materials used in the GRM CoE Pilot Workshop can be used and Comply with the copy right of the materials

2.2 PLANING FOR TRAINING

Timeline



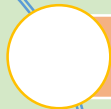
Actual time required for individual session depends on prior knowledge/experience of the trainees, depth of discussions and the number of questions during the workshop.



Need to create time schedule of each session with sufficient margin

2.2 PLANING FOR TRAINING

Administrative support: Refer to the Manual



Pre-learning



Registration for participation



Certificate of training and evaluation form

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3 CONDUCTING THE GSubP TRAINING



SEAT ARRANGEMENT

OPENING REMARK/INTRODUCTION

ROLE OF FACILITATOR IN PRACTICE & GROUP DISCUSSIONS

HANDLING OF Q&A

WRAP-UP & CLOSING REMARK

3.1 SEAT ARRANGEMENT



No special requirement in seat arrangement during lecture sessions



Five to six Trainees per group with at least one Facilitator is recommended for practice sessions.

3.2 OPENING REMARK/INTRODUCTION



3.2 ROLE OF FACILITATOR IN PRACTICE & GROUP DISCUSSIONS



During practice & discussion sessions, Facilitator is supposed to help assignment of roles of participants in the group (leader, timekeeper, recorder etc.) as necessary



Facilitator is also expected to provide adequate support mainly to the leader of the group to facilitate discussions by

- clarifying what to do next**
- providing a summary of discussions**
- asking questions to encourage response**
- keep discussions going in appropriate direction**

SPEAKER AND FACILITATOR are recommended to have a meeting before the training in order to smoothly proceed the workshop.

3.3 HANDLING OF Q&A



FAQ will be prepared based on the Q&A during the GRM CoE Pilot Workshop and provided to the Trainer.



They may also contact the Moderators/Speakers of the GRM CoE Pilot Workshop for advice when they receive a new question from Trainee.

3.3 WRAP-UP & CLOSING REMARK

should cover the followings



Brief summary of each session and confirmation of take home message

Issuance of the certificate of participation (APPENDIX 2) for the trainees who finished all the sessions

Collection of filled evaluation form

Request for cooperation in the follow-up survey

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4 FOLLOW-UP ACTIVITY



4.1 EVALUATION OF THE WORKSHOP



4.2 REPORTING OF THE WORKSHOP

4 FOLLOW-UP ACTIVITY

4.1 EVALUATION OF THE WORKSHOP



Evaluation form:

- The trainer is requested to gather quick feedback from the participants using the defined evaluation form (APPENDIX 3) and should be used to produce a report of workshop.



Self-evaluation by Moderators/Speakers:

- The Trainer/Speakers can informally assess effectiveness of the training by checking for comprehension after various modules. This should be done throughout the training and used for preparation of the workshop report as well as improvement for next workshop.



Follow-up survey:

- It will be conducted periodically to evaluate the overall effectiveness of the GSubP.
- The trainer is requested to cooperate with the secretariat of the GRM CoE Pilot Workshop when conducting such survey.

4 FOLLOW-UP ACTIVITY

4.2 REPORTING THE WORKSHOP

The Trainer is supposed to prepare a report of the Workshop and submit to the secretariat of the GRM CoE Pilot Workshop within a couple of months. The report shall cover the following items



List of participants & training staff

Agenda

A briefing of the workshop

Summary of participants' evaluation

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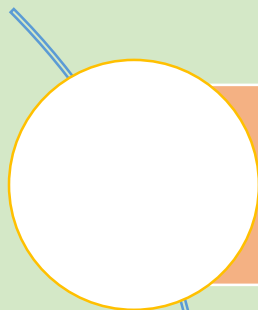
3 CONDUCTING THE GSubP TRAINING

4 FOLLOW-UP ACTIVITY

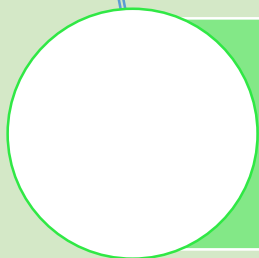
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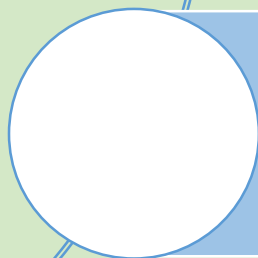
6 APPENDIX



APPENDIX 1: Model curriculum of GSubP Training Workshop



APPENDIX 2: Certificate of participation



APPENDIX 3: Evaluation form

REFERENCES

- 1. Good Submission Practice (GSubP) Trainer's Manual Part I: Organizing GSubP Training Workshop**
- 2. Good Submission Practice (GSubP) Trainer's Manual Part II: Session Outline of the GSubP Training Workshop**
- 3. Presentation of "2016 GRM REGULATORY SCIENCE CENTER OF EXCELLENCE PILOT WORKSHOP: Applicant Session A4 - Rolling out the GRM training program in each economy" by Isao Sasaki APAC RA-EWG / JPMA, 17 November 2016, Taiwan.**