

Good Submission Practice (GSubP) Trainer's Manual

Part I

Organizing GSubP Training Workshop

APAC RA-EWG

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GLOSSARY

APEC RHSC:	Asia-Pacific Economic Cooperation Conference, Regulatory Harmonization Steering Committee
Certified GSubP Trainer: (the Trainer)	The GSubP trainer who completed the common and applicant sessions of the GRM CoE Pilot Workshop
CoE:	Center of Excellence
Facilitator:	The training staff who takes a role to proactively support and facilitate group discussions in the GSubP Training Workshop
GRevP:	Good Review Practice
GRM:	Good Registration Management
GRM CoE Pilot Workshop	The train-the-trainer pilot workshop on GRM held by a CoE established under APEC RHSC.
GSubP:	Good Submission Practice
GSubP Training Workshop:	The training workshop on GSubP for applicants held in each APEC economy
Coordinator:	The training staff who organizes and manages the GSubP Training Workshop. Usually, the Trainer acts as a Coordinator
Secretariat:	The training staff who takes care of all logistic arrangements of the GSubP Training Workshop
Speaker:	The training staff who provides lecture and/or practice in each session of the GSubP Training Workshop
Trainee:	Participants of the GRM Training Workshop

1 INTRODUCTION

1.1 Purpose and structure of this manual

The purpose of this document is to help Certified GSubP Trainers (hereafter “the Trainers”) to organize and manage effective GSubP training program for applicants in their own economy or organization(s).

This manual is designed 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 each workshop.

In this section, general instructions to the Trainers are provided. More practical and detailed instructions on each process of preparation, implementation and follow-up activities of the training workshop will be described in subsequent sections.

1.2 Objectives of GSubP training

The objectives of the GSubP training are

- To understand overall concept of GRM and GSubP
- To acquire knowledge and practical skills for preparing application dossier and managing submission in high quality

The Trainer is recommended to confirm these objectives with all participants at the beginning of the training workshop.

1.3 Process and methodology

The Trainer is expected to organize one and half day or two-days GSubP training workshop in their organization(s) by referring to this manual.

In order to hold successful training workshop, it is essential to work with other training staffs (see Section **3.1 Planning for training**). The Trainer shall act as a Coordinator and form a training team consisting of competent Speakers, Facilitators and Secretariat.

It is highly recommended that the training be 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. Facilitators are expected to play an important role to proactively facilitate discussions among the trainees in practice and group discussion sessions.

2 PREPARATION FOR THE TRAINING

2.1 *Training staff*

For successful GSubP training, The Trainer, as a Coordinator, is recommended to establish a training team consisting of the following staffs.

Trainer

- The Certified GSubP Trainer who completed the relevant sessions of GRM CoE Workshop. Trainers who completed the GSubP session are responsible to train the GSubP workshop.

Coordinator

- The training staff who organizes and manages the GSubP Training Workshop. The Trainer is expected to act as a Coordinator.

Speaker

- The person who provides lecture and/or practice in each session of the GSubP training workshop. A Coordinator can also be a Speaker.
- The Certified GSubP Trainers or other regulatory experts having sufficient professional knowledge and experiences about GSubP can become Speakers.
- Speaker needs to be assigned for each topic. Basically, at least a couple of Speakers will be necessary to cover all GSubP training sessions.

Facilitator

- Facilitator needs to be assigned at least one person for each table in practice and group discussion sessions. They are expected to take a role to proactively support and facilitate group discussions among the trainees.
- Facilitators need to have good understanding of the purpose, contents, procedure and their role in group discussions so that they can provide effective contribution in the practice sessions. It is recommended that the Trainer and Speakers have a meeting with facilitators before the training workshop and share how to proceed with these sessions.

Secretariat

- It is highly recommended to have staffs that take care of all logistic arrangements of the workshop.

2.2 *Planning for training*

Qualification of trainee:

- ❑ If GSubP training is being conducted for the first time in an economy and is planned to be conducted in a series thereafter, it may be advisable in the initial stages to target regulatory affairs personnel with more than three years of experience in appreciation submission or the person who takes the role of main contact window with review authorities in applicants' 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 can also be candidate trainees.

- ❑ Appropriate number of total trainees in each workshop should be determined by the number of facilitators and staffs and other factors. For effective coordination of group discussion sessions, groups of 5 to 10 trainees with one facilitator per group are recommended.
- ❑ In order to have fruitful training workshop, it is important to know background, knowledge and experience of the participants in the area of regulatory operations and application submissions. It is recommended that such information is collected at registration for participation.

Curriculum and Agenda:

- ❑ As a preferred option, the Trainer can organize the GSubP Training Workshop as a part of the comprehensive GRM Training Workshop in collaboration with the review authorities. In this case, the curriculum of the GRM CoE Pilot Workshop could be used as a model and the curriculum of the actual GRM CoE workshops could be used as a reference.

If this option is not feasible, a GSubP Training Workshop for applicants can be arranged independently.

A model curriculum* of the GSubP Training Workshop is shown in Appendix 1 of this manual.

* * Although the model curriculum indicates "applicant-specific sessions," it is recommended that the review authorities participate in a GSubP training sessions with applicants so that both parties understand each other and have more meaningful discussions.

- ❑ Curriculum and agenda of the GSubP Training Workshop should basically follow corresponding sessions of the GRM CoE Pilot Workshop. If necessary, a minimum customization is allowed to fit the condition of local regulatory system and requirements.

The followings are some examples of such customization.

◇ Example#1

If ICH-CTD is the required format of application dossier by your review authority, you may add a session to explain about CTD structure and its requirements in detail.

✧ Example #2

If your review authority has defined specific procedure and requirements for consultation meetings with applicants, you may explain it in the training session of 'Effective Communications'.

Training Materials:

- All the materials of GsubP training used in the GRM CoE Pilot Workshop can be used in the GsubP Training Workshop in each economy.

It is also possible for the Trainers to prepare and use additional materials taking the local regulatory environment into consideration (see ***Curriculum and Agenda***).

- Copy right of the material: The materials of the GRM CoE Pilot Workshop should not be used for any commercial or profit-making activity unless specific permission is granted by the copyright owners.

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. Trainers and/or other staffs need to create time schedule of each session with sufficient margin.

Administrative support:

Pre-learning

- An e-learning system is available for pre-training. All participants shall be instructed to finish the e-learning curriculum prior to the on-site workshop training.

Registration for participation

- The Trainer can adopt appropriate method and procedure for the trainees' registration.
- It is recommended to collect information about background, knowledge and experience of applicant in the area of regulatory operations and application submissions through the registration process of the GsubP Training Workshop (see ***Qualification of participants***)

Certificate of training and evaluation form

- A sample certificate of participation is available in Appendix 2 of this manual.

- ❑ The Trainers are requested to gather feedback from participants of the GsubP Training Workshop using the defined evaluation form. The form is available in Appendix 3 of this manual.

3 CONDUCTING THE GSUBP TRAINING

The Coordinators, Speakers and Facilitators are supposed to carry out the workshop following the developed agenda (see **2.2 Planning for training: Curriculum and Agenda**). Outline of each session of the GsubP Training Workshop with guidance and tips for the Speakers/Facilitators of each session are provided in Part II of this manual.

Speakers and Facilitators of each session are recommended to refer the guidance in Part II to make the session more effective and fruitful for the participants.

Seat arrangement:

- ❑ There is no special requirement in seat arrangement during lecture sessions. For practice sessions, it is recommended to make groups with 5 to 6 Trainees and at least one Facilitator in each table. (see **2.2 Planning for training: Qualification of participants**).

Opening remark/introduction:

- ❑ Opening remark can be provided by the Trainer or a representative of the training organization. It is recommended to cover the followings in introduction session.
 - ✧ Confirmation of workshop objectives (see **1.2 Objectives of GsubP training**)
 - ✧ Introduction of agenda, schedule and handout materials
 - ✧ (Self-)introduction of Speakers, Facilitators and Trainees (optional)
 - ✧ Explanation about the evaluation form
 - ✧ Other housekeeping issues

Role of Facilitator in practice & group discussions:

- ❑ In practice and group discussion sessions, Facilitator in each table 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, e.g. clarify what to do next, provide a summary of discussions, asking questions to encourage response, keep discussions going in appropriate direction. Speakers and Facilitators are recommended to have a meeting before the training workshop and share how to proceed with these sessions smoothly.

Handling of Q&A

- ❑ It may be helpful to create a list of FAQ raised during past GRM CoE Workshops and provided it to next Trainers. The Speaker and Facilitator can use the document for preparation for Q&A sessions.
- ❑ They may also contact the Coordinators/Speakers of the GRM CoE Workshops for advice when they receive a new question from Trainee.

Wrap-up & closing remark:

- ❑ Wrap-up and closing remark can be provided by the Trainer or other representative of the training organization. It is recommended to 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 (see ***4.1 Evaluation of the Workshop: Evaluation form***)
 - ✧ Request for cooperation in the follow-up survey (see ***4.1 Evaluation of the Workshop: Follow-up survey***)

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). The feedback should be used to produce a report of the GsubP Training Workshop which is to be submitted to the secretariat of the GRM CoE Pilot Workshop.

Self-evaluation by Coordinators/Speakers:

- During the workshop, the Trainer/Speakers can informally assess effectiveness of the training by checking for comprehension after various modules. The Speakers should make note of areas where content is being retained and as well as areas it is not and assess why. This should be done throughout the training and used for preparation of report of the GsubP Training Workshop as well as improvement for next workshop.

Follow-up survey:

- Follow up surveys will be conducted periodically to the participants of the GsubP Training Workshop to evaluate the overall effectiveness of GsubP. The Trainer is requested to cooperate with the secretariat of the GRM CoE Pilot Workshop when conducting such survey.

4.2 *Reporting of the Workshop*

The Trainer is supposed to prepare a report of the GsubP Training 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

5 REFERENCES

1. Good Submission Practice (GsubP) Guideline for Applicants, Endorsed by APEC RHSC
http://apac-asia.com/images/achievements/pdf/5th/2_APEC_RHSC%20Endorsed%20GsubP%20Guideline.pdf
2. Good Review Practices Guidelines for National and Regional Regulatory Authorities, WHO Technical Report Series, No. 992, 2015 Annex 9.
<https://www.who.int/publications/m/item/annex-9-trs-992>
3. Good Submission Practice (GsubP) Trainer's Manual Part II: Session Outline of the GsubP Training Workshop

6 APPENDIX

Appendix 1: Model curriculum of GsubP Training Workshop

- ✧ In case the GsubP Workshop is held independently (not as a part of comprehensive GRM Training Workshop with the review authorities)
- ✧ Based on two-day workshop model
- ✧ Including time for Q&A

DAY 1

TIME	TOPICS / SPEAKERS
8:30-9:00	REGISTRATION
9:00-9:20	OPENING REMARKS
Overview of GsubP	
9:20-10:00	Session 1: Basic concept of GRM and GsubP Speaker: xxx
10:00-11:30	Session 2: An Overview of Good Submission Speaker : xxx
11:30-12:30	LUNCH BREAK

Applicant-Specific Sessions *	
12:30-14:30	Session A1: Planning of Application Speaker : xxx
14:30-15:00	BREAK
15:00-17:10	Session A2: Preparation of applicant dossier/ Practice: How to prepare application dossier Part I Speaker: xxx

DAY2

Applicant-Specific Sessions (contd.)*	
TIME	TOPICS / SPEAKERS
9:00-9:30	REGISTRATION
9:30-11:30	Session A2: Preparation of applicant dossier/ Practice: How to prepare application dossier Part II Speaker: xxx
11:30-12:30	LUNCH BREAK
12:30-15:45	Session A3: Effective communications -Focusing follow-up actions during review period- /Practice: Case study of how to handle inquiries Speaker: xxx
15:45-16:00	BREAK
16:00-16:30	Session A4: Rolling Out the GRM Training Program in Each Economy: Trainer's Manual Speaker: xxx
16:30-16:45	SUMMARY & CLOSING REMARKS

* Although the model curriculum indicates "applicant-specific sessions," it is recommended that the review authorities participate in a GSubP training sessions with applicants so that both parties understand each other and have more meaningful discussions.

Appendix 2: Certificate of participation

- ✧ Reference examples of certificates utilized in the 2016 APEC GRM CoE Pilot Workshop



_certificate of
participation_templa

Appendix 3: Evaluation form

- ✧ Reference examples of Evaluations form based on the curriculum of the 2016 APEC GRM CoE Pilot Workshop
 - [101_Evaluation form](#)
 - [102_Knowledge level](#)
- ✧ Separate surveys for Day 1 and Day 2 might be a good idea.
- ✧ Evaluation items can be modified as needed.



101_Appendix3_
GSubP_Evaluator



102_Appendix3_
GSubP-Knowledge

End of text



Certificate of participation

is presented to
XXXXXXXXXX

in recognition of your attendance at the

2016 APEC Good Registration Management Regulatory Science Center of Excellence Pilot Workshop

15-17 November 2016
Chinese Taipei

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20×× Good Submission Practice (GSubP) Training Workshop

MM DD-DD, YYYY

Workshop Evaluation Form

Your evaluation, comments and suggestions are highly appreciated.
Your feedback will be provided for future improvements. Thank you.

Personal data

Name

Registered No.

Member Economy (Country)

Day 1

Session 1: Basic concept of GRM and GSubP

- The adequacy of training materials

Excellent Very Good Good Fair Poor

- The adequacy of the time allocation for this session

Excellent Very Good Good Fair Poor

- The presentation skill

Excellent Very Good Good Fair Poor

- Total evaluation

Excellent Very Good Good Fair Poor

Any suggestions or improvements for this session:

Session 2: An Overview of Good Submission

▫ The adequacy of training materials

Excellent Very Good Good Fair Poor

▫ The adequacy of the time allocation for this session

Excellent Very Good Good Fair Poor

▫ The presentation skill

Excellent Very Good Good Fair Poor

▫ Total evaluation

Excellent Very Good Good Fair Poor

Any suggestions or improvements for this session:

Session A1: Planning of Application

▫ The adequacy of training materials

Excellent Very Good Good Fair Poor

▫ The adequacy of the time allocation for this session

Excellent Very Good Good Fair Poor

▫ The presentation skill

Excellent Very Good Good Fair Poor

▫ Total evaluation

Excellent Very Good Good Fair Poor

Any suggestions or improvements for this session:

Any improvements or comments would you suggest for future GRM Day 1 sessions?

Day 2

Session A2: Preparation of Applicant Dossier/ Practice: How to Prepare Application Dossier Part I

▫ The adequacy of training materials

Excellent Very Good Good Fair Poor

▫ The adequacy of the time allocation for this session

Excellent Very Good Good Fair Poor

▫ The presentation skill

Excellent Very Good Good Fair Poor

▫ Total evaluation

Excellent Very Good Good Fair Poor

Any suggestions or improvements for this session:

Session A2: Preparation of Applicant Dossier/ Practice: How to Prepare Application Dossier Part II

▫ The adequacy of training materials

Excellent Very Good Good Fair Poor

▫ The adequacy of the time allocation for this session

Excellent Very Good Good Fair Poor

▫ The presentation skill

Excellent Very Good Good Fair Poor

▫ Total evaluation

Excellent Very Good Good Fair Poor

Any suggestions or improvements for this session:

Session A3: Effective Communications

▫ The adequacy of training materials

Excellent Very Good Good Fair Poor

▫ The adequacy of the time allocation for this session

Excellent Very Good Good Fair Poor

▫ The presentation skill

Excellent Very Good Good Fair Poor

▫ Total evaluation

Excellent Very Good Good Fair Poor

Any suggestions or improvements for this session:

Session A4: Rolling Out the GRM Training Program in Each Economy

▫ The adequacy of training materials

Excellent Very Good Good Fair Poor

▫ The adequacy of the time allocation for this session

Excellent Very Good Good Fair Poor

▫ The presentation skill

Excellent Very Good Good Fair Poor

▫ Total evaluation

Excellent Very Good Good Fair Poor

Any suggestions or improvements for this session:

Any improvements or comments would you suggest for future GRM Day 2 sessions?

Thank you!
Please return this form to the workshop staff.

20×× Good Submission Practice (GSubP) Training Workshop

MM DD-DD, YYYY

Workshop Knowledge Level Evaluation Form

Your evaluation, comments and suggestions are highly appreciated.
Your feedback will be provided for future improvements. Thank you.

Personal data

Name

Registered No.

Member Economy (Country)

Supplementary Explanation

- Please rate the following categories on a scale of 5 to 1, before and after the corresponded program.
- The definition of score is listed as follows.
 5. Expert knowledge: can advise on a topic
 4. Good knowledge: can discuss nuances with details
 3. Working knowledge: can discuss issue detail
 2. Limited knowledge: can discuss broad issue
 1. No knowledge

Continue on the next page!

Pre-Program Score		
Session 1: Basic concept of GRM and GSubP		
Knowledge level of concept of GRM		
<input type="checkbox"/> 5. Expert Knowledge	<input type="checkbox"/> 4. Good knowledge	<input type="checkbox"/> 3. Working knowledge
<input type="checkbox"/> 2. Limited knowledge	<input type="checkbox"/> 1. No knowledge	
Session 2: An Overview of Good Submission		
Knowledge level of Good Submission		
<input type="checkbox"/> 5. Expert Knowledge	<input type="checkbox"/> 4. Good knowledge	<input type="checkbox"/> 3. Working knowledge
<input type="checkbox"/> 2. Limited knowledge	<input type="checkbox"/> 1. No knowledge	
Session A1: Planning of Application		
Knowledge level of Planning of Application		
<input type="checkbox"/> 5. Expert Knowledge	<input type="checkbox"/> 4. Good knowledge	<input type="checkbox"/> 3. Working knowledge
<input type="checkbox"/> 2. Limited knowledge	<input type="checkbox"/> 1. No knowledge	
Session A2: Preparation of Applicant Dossier/ Practice: How to Prepare Application Dossier Part I		
Knowledge level of Preparation of Applicant Dossier Part I		
<input type="checkbox"/> 5. Expert Knowledge	<input type="checkbox"/> 4. Good knowledge	<input type="checkbox"/> 3. Working knowledge
<input type="checkbox"/> 2. Limited knowledge	<input type="checkbox"/> 1. No knowledge	
Session A2: Preparation of Applicant Dossier/ Practice: How to Prepare Application Dossier Part II		
Knowledge level of Preparation of Applicant Dossier Part II		
<input type="checkbox"/> 5. Expert Knowledge	<input type="checkbox"/> 4. Good knowledge	<input type="checkbox"/> 3. Working knowledge
<input type="checkbox"/> 2. Limited knowledge	<input type="checkbox"/> 1. No knowledge	
Session A3: Effective Communications		
Knowledge level of Effective Communications		
<input type="checkbox"/> 5. Expert Knowledge	<input type="checkbox"/> 4. Good knowledge	<input type="checkbox"/> 3. Working knowledge
<input type="checkbox"/> 2. Limited knowledge	<input type="checkbox"/> 1. No knowledge	
Session A4: Rolling Out the GRM Training Program in Each Economy		
Knowledge level of How To Define the Core Competency of Applicants		
<input type="checkbox"/> 5. Expert Knowledge	<input type="checkbox"/> 4. Good knowledge	<input type="checkbox"/> 3. Working knowledge
<input type="checkbox"/> 2. Limited knowledge	<input type="checkbox"/> 1. No knowledge	

Post-Program Score		
Session 1: Basic concept of GRM and GSubP		
Knowledge level of concept of GRM		
<input type="checkbox"/> 5. Expert Knowledge	<input type="checkbox"/> 4. Good knowledge	<input type="checkbox"/> 3. Working knowledge
<input type="checkbox"/> 2. Limited knowledge	<input type="checkbox"/> 1. No knowledge	
Session 2: An Overview of Good Submission		
Knowledge level of Good Submission		
<input type="checkbox"/> 5. Expert Knowledge	<input type="checkbox"/> 4. Good knowledge	<input type="checkbox"/> 3. Working knowledge
<input type="checkbox"/> 2. Limited knowledge	<input type="checkbox"/> 1. No knowledge	
Session A1: Planning of Application		
Knowledge level of Planning of Application		
<input type="checkbox"/> 5. Expert Knowledge	<input type="checkbox"/> 4. Good knowledge	<input type="checkbox"/> 3. Working knowledge
<input type="checkbox"/> 2. Limited knowledge	<input type="checkbox"/> 1. No knowledge	
Session A2: Preparation of Applicant Dossier/ Practice: How to Prepare Application Dossier Part I		
Knowledge level of Preparation of Applicant Dossier Part I		
<input type="checkbox"/> 5. Expert Knowledge	<input type="checkbox"/> 4. Good knowledge	<input type="checkbox"/> 3. Working knowledge
<input type="checkbox"/> 2. Limited knowledge	<input type="checkbox"/> 1. No knowledge	
Session A2: Preparation of Applicant dossier/ Practice: How to Prepare Application Dossier Part II		
Knowledge level of Preparation of Applicant Dossier Part II		
<input type="checkbox"/> 5. Expert Knowledge	<input type="checkbox"/> 4. Good knowledge	<input type="checkbox"/> 3. Working knowledge
<input type="checkbox"/> 2. Limited knowledge	<input type="checkbox"/> 1. No knowledge	
Session A3: Effective Communications		
Knowledge level of Effective Communications		
<input type="checkbox"/> 5. Expert Knowledge	<input type="checkbox"/> 4. Good knowledge	<input type="checkbox"/> 3. Working knowledge
<input type="checkbox"/> 2. Limited knowledge	<input type="checkbox"/> 1. No knowledge	
Session A4: Rolling Out the GRM Training Program in Each Economy		
Knowledge level of How To Define the Core Competency of Applicants		
<input type="checkbox"/> 5. Expert Knowledge	<input type="checkbox"/> 4. Good knowledge	<input type="checkbox"/> 3. Working knowledge
<input type="checkbox"/> 2. Limited knowledge	<input type="checkbox"/> 1. No knowledge	

Thank you!
Please return this form to the workshop staff.