# Good Submission Practice (GSubP)
# Trainer's Manual

## Part II

## Session Outline of the GSubP Training Workshop

APAC RA-EWG

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# GLOSSARY

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| 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 the GSubP Training Workshop and takes care of planning, holding and managing it. 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 PURPOSE OF THIS MANUAL

This document provides outline of each session of the GSubP Training Workshop as a guidance for speakers and facilitators. The session outline describes 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. Speakers and facilitators of individual session are recommended to refer to this manual in order to make the session more effective and fruitful for trainees.

This manual will also help the Trainer to develop a curriculum for the GSubP Training Workshop in each economy. The Trainer shall also refer to Part I of this manual to properly organize the workshop.

# 2 OUTLINE ON EACH SESSION

## *2.1 Common Session*

The purpose of the Common Session is to make the trainees understood basic concept of GRM and high level overview of GRevP/GSubP.

In case the GSubP Training Workshop is held as a part of comprehensive GRM Training Workshop (as a joint workshop with the review authorities), whole the Common Session curriculum/agenda of the GRM CoE Pilot Workshop will be followed.

In case the GSubP Training Workshop is held independently from comprehensive GRM Training Workshop, the Trainer shall at least cover the following applicants related sessions of the Common Session program.

### *2.1.1* Session 1: Basic concept of GRM

- **Learning objectives:**

  To understand the basic concept of GRM and high level principles & processes of its key elements, i.e. GRevP and GSubP

- **Time required:** Approximately 30 min
- **Methodology:** Lecture and Q&A
- **Material:** The following slide deck in the GRM CoE Workshops will be used.

  **"Common Session 1_Basic Concept of GRM "**

- **How to proceed with this session:**

1. **Introduction & lecture**: (25 min)
   a. Confirm learning objectives of this session
   b. Explain the concept of GRM with its objective, goal and historical background
   c. Review high level outline of GRevP & GSubP
   d. Summarize this session as follows;
      - GRM is the concept to promote GRevP and GSubP cooperatively
      - Objective of GRM: To enhance quality and efficiency of overall medical product registration process
      - Goal of GRM: Benefiting the patients with timely access of medicinal products of safe, efficacious and good quality
      - Guidelines of GRevP and GSubP have been prepared to provide high-level guidance on the principles and processes of good review/submission
2. **Q&A**: (5-10 min)

❑ **Take home message**:

Summary of this session (see 1. d. of **How to proceed with this session**)

### *2.1.2* Session 2: An Overview of Good Submission

❑ **Learning objectives:**

1. To have good understanding on the key principles of good submission
2. To learn the outline of GSubP guideline as introduction of the following sessions

❑ **Time required:** 1.5 hrs.

❑ **Methodology:** Lecture & small practice

❑ **Material:** The following slide deck in the GRM CoE Workshops will be used.

**"Common Session 2_An Overview of Good Submission "**

❑ **How to proceed with this session:**

1. **Introduction:** (approx. 5 min)
   a. Explain learning objectives and goal of this session
   b. Confirm that this session focuses on GSubP
2. **Practice with participants:** (approx. 25 min)

   A short practice will be held to think about the practical meaning of "good quality submission". Ask participants to conduct the following.

a. Write down at least 5 essential elements of "good quality submission" by each own opinion

b. Compare the list with the person sitting next, discuss if any difference and select 5 agreed elements with higher priority

c. Summarize the practice using slide #13

3. **Lecture:** (approx. 50 min)

Explain outline of each key section of the GSubP Guideline with background and practical examples.

a. **Introduction:** Confirm objective and scope of guideline

b. **Principles of Good Submission:** Confirm each principle with background. information

c. **Management of Submission:** Summarize points of the following subsections according to the slide material.

- Planning for Submission
- Preparation and submission of Application Dossier
- Standard operating procedure for submission preparation
- Quality Check

d. **Communications:** Emphasize the following two categories of "communications" and summarize points of each according to the slide.

- Communications with the Review Authorities
- Communications within Applicants' Group

e. **Competency and Training:** Confirm the core competency of applicants and explain recommended training and capacity building activities based on the slide.

f. **Summary:** The GSubP Guideline provides the followings

- Five key principles of good submission
- High level guidance on planning, preparation and post-submission management to realize good quality submission

4. **Q&A** (10 min)

- **Take home message**:

Summary of this session (see 3. f. of **How to proceed with this session**)

## *2.2 Applicants' Session*

Applicants' session* provides more detailed description of main sections of the GSubP Guideline. It covers practical contents of the guideline using practices, case studies and group discussions.

- Although this section is described as "applicant's 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 when the GSubP Training Workshop as a part of the comprehensive GRM Training Workshop in collaboration with the review authorities is held.

The following Sessions A1 to A4 should be covered in the workshop.

### *2.2.1* Session A1: Planning of Submission

- ❑ **Learning objectives:**
  1. To understand the importance of overall objective of the submission project
  2. To understand the required information and intelligence which are needed for submission planning
  3. To have clear idea on the key consideration when developing the plan for submission
- ❑ **Time required:** 2 hrs.
- ❑ **Methodology:** Lecture and practice
- ❑ **Material:** The following slide deck in the GRM CoE Workshops will be used.

  **"Session A1_Planning for submission"**
- ❑ **How to proceed with this session:**

  The speaker will give a lecture on the following 3 topics.

  1. What do we want?

     In this session, the speaker will provide an overview on the key preparation elements including the important high level guidance document such as TPP (Target Product Profile) and Target Product Label (TPL). The introduction will also include functional preparation such as project team, responsibilities of each function the decision making process and the resource planning for the applications.

  2. What do we need?

     With above high level guidance document and functional preparation, there are still information such as regulation, guidelines and regulatory requirements needed. Beyond the basic information, the company always would like to establish intelligence database to collect the country specific regulatory requirements and estimated timeline. There are cases that the pre-submission meetings are required in

order to understand the position from the reviewers for specific projects. Those components are critical for the planning and will be shared by the speaker in this session.

3. How do we do it?

   Once all information and functions are available, it is required to implement the planning by interpreting all those intelligences into the strategic plan. Several other factors should be considered during the planning stage. The speaker will share the experience in utilizing information to strategize ahead in order to facilitate processes required for generating good submission.

- ❑ **Take home message:**
  - ✧ The planning of application should start as early as possible. There should be proper organizational preparation and resource planning.
  - ✧ Necessary documents and tools are the key success factors. Those documents and tools include but not limited to TPP, Regulatory Intelligence Database and Checklist etc.
  - ✧ Strategic plan will be the guidance document for the application preparation.

  The same principle can be adapted for all kinds of applications including post approval variations.

### *2.2.2* Session A2: Preparation of Application Dossier

- ❑ **Learning objectives:**
  1. To understand the standard processes for a high-quality submission preparation
  2. To improve management of the preparation process for application dossier
  3. To improve the QC processes/procedures for future application
  4. To understand importance of SOP
- ❑ **Time required:** 4 hrs.
- ❑ **Methodology:** Lecture & practice
- ❑ **Material:** The following slide deck and separated practice tools used in the GRM CoE Workshops will be used.

  **"Session A2_Preparation of Application Dossier"**
- ❑ **How to proceed with this session:**
  1. **Introduction:** Explain learning objectives and goal of this session
  2. **Ice Breaking:** Explain essential for QC of application dossier
  3. **Dossier Preparation**

a. **Lecture:** Explain the standard process of application dossier preparation covering the following topics

- ✧ Point to consider when writing technical documents, i.e. report and summary
  - ✧ Acquire robust scientific data from well planned and controlled studies and provide them in technical report with adequate scientific rationale and justification.
  - ✧ Ensure reliability, quality, integrity, and traceability of information and data
  - ✧ Create easy-to-read application dossier to facilitate the review process

b. **Practice:** Group discussion on how to utilize supporting tools

- ✧ Create groups of 5-10 members and assign role of each group member, i.e. leader, presenter and timekeeper. Have group practice on the following topics and share the outcome of discussion.
  - ✧ Practice-1: How to use Timeline table and Check list for dossier preparation
  - ✧ Practice-2: How to utilize Glossary and Template for dossier preparation
  - ✧ Briefing: Outline of the supporting tools which can be used for efficient preparation of high-quality application dossier.

4. **Short Lecture:** Why SOP is important for submission preparation

   Generating SOPs for proper management of the whole process of submission preparation

5. **Wrap up and Q&A**

❑ **Take home message:**

- ✧ Typical case of and process for preparation of an application dossier
- ✧ How to efficiently prepare a high-quality application document using the support tools (e.g., checklist, template, and glossary)

### *2.2.3* Session A3: Effective communications - Focusing follow-up actions during review period

❑ **Learning objectives:**

1. To understand effective regulatory communications after filing application dossier
2. To improve the communications with the review authorities
3. To improve handling of the inquiries from the review authorities

- **Time required:** 3.25 hrs.
- **Methodology:** Lecture & practice
- **Material:** The following slide deck used in the GRM CoE Workshops will be used.

  **"Session A3_Effective communications"**
- **How to proceed with this session:**

1. **Opening:** To share session objective
2. **Ice Braking Game:**
   a. Output: Recognize the importance of instruction and communication
   b. Practice:
      - Draw a picture by individuals under the simple instruction
      - Compare pictures side by side, indicate a model answer
      - Discuss how to get preferable results
3. **Lecture: GRP Communication introduction:** Effective communication outline
4. **Group Discussions** How to handle RA-related meetings, inquiries from HAs and responses to HAs within/outside the company? -Focusing on stakeholders involved in the RA activity-
   a. Output: recognize to communicate effectively with stakeholders under considerations of each stakeholders' roles/responsibilities and gaps between the applicant and stakeholders
   b. Practice: Group discussion

      (Create groups of 5-10 members and assign role of each group member, i.e. leader, presenter and timekeeper)

      1. Pick up stakeholders and discuss who are stakeholders related to the meeting with HA during the review period
      2. Conduct stakeholder analysis at the points to consider
5. **Lecture**: Explain effective communication 1
   a. Stakeholder analysis
   b. How to communicate with internal stakeholders /external stakeholders
   c. Key points to be considered for communication with stakeholders
6. **Practice:** Communications in post-submission stage
   a. Output: find the practical effective communication with the stakeholder

b. Practice: Group discussion

(Create groups of 5-10 members and assign role of each group member, i.e. leader, presenter and timekeeper).

① Make the communication plan in the post-submission stage for an imaginary project

- What kinds of action applicants should do?
- Who, When and What applicants should contact / confirm?

② How to communicate/negotiate with the relevant external/internal stakeholders?

7. **Lecture:** Explain effective communication 2

a. The points to consider in inquiries/responses and meetings with the review authorities during review period

b. Preparation of good quality meeting

c. The points that applicants have to consider in the management of the timeline for response preparation

**8. Conclusion**

❑ **Take home message:**

1. Effective communications will help applicants to improve quality and efficiency of the product development as well as registration process, thereby realize timely approval and earlier patient access to new products.
2. Applicants should foster good communications with the review authorities and those within applicants' organization(s).

### *2.2.4* Session A4: Rolling Out the GRM Training Program in Each Economy: Trainer's Manual (optional)

❑ **Learning objectives:**

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

* The Trainer: Certified GSubP Trainer who completed the GRM CoE Pilot Workshop

❑ **Time required:** 20～30 min

❑ **Methodology:** Lecture

❑ **Material:**

- ✧ The following slide deck and separated practice tools used in the GRM CoE Pilot Workshop will be used, or slides from subsequent GRM workshops may also be possible to used.

  **"Session A4_Trainer's Manual on GSubP"**

- ✧ The following manuals could also be provided.
  - ➢ GSubP Trainer's Manual_Part I
  - ➢ GSubP Trainer's Manual_Part II

❑ **How to proceed with this session:**

1. Introduce the contents of **Trainer's Manual on GSubP**

❑ **Take home message:**

1. Understand how to organize a GSubP Training Workshop as a part of comprehensive GRM Training Workshop in collaboration with the review authorities or a GSubP Training Workshop for applicants independently.
2. Understand the objectives of the GRM and/or the GSubP training

End of text