December 30, 2015

Revised October 7, 2016

Revised July 12, 2018

GRM Regulatory Science Center of Excellence Workshop

Core Curriculum

Learning Objectives

To learn the followings for implementation of GRM

- The principles of GRevP and GSubP
- What is needed for regulators to accomplish good review
  - Conducting and managing the review
  - Good communication with applicants
  - Competency for regulators
- What is needed for applicants to accomplish good application
  - Planning and preparation of application dossier
  - Good communication with regulators
  - Competency for applicants

Common Training

<DAY 1 >

Session 1: Basic concept of GRM

1) An overview of the APEC Roadmap to Promote GRM
2) Historical background and basic concept of GRM
3) High level principles and processes of GRevP and GSubP
4) An overview of the objectives and curriculum design of this pilot workshop

Session 2: Principles of Good Review

WHO Annex 9: Good Review Practice (GRevP) Guidelines, including:

1) 10 key principles of a good review
2) Challenges and solutions for implementing GRevP
3) Importance of management of the review and quality systems

Session 3: Principles of Good Submission

GSubP Guideline for Applicants, including:

1) 5 key principles of a good submission
2) Basis and background of submission preparation and management by reviewing each key sections of the guideline document

Session 4: Fundamentals of Communication

1) The importance of communications between applicants and regulatory authorities throughout product life cycle, including pre-submission stage, post-submission stage, and post-marketing stage
2) The information opened to the public for the better communication between applicants and regulatory authorities

Applicant Specific Training

<DAY 2 >

Session A1: Planning of Application

1) The basic information which should be collected to prepare for the application before the kick off the preparation
2) The organizational and procedural preparation in order to better facilitate the whole preparation process
3) The key regulatory considerations in development plan and the key elements of submission plan

Session A2: Preparation of application dossier / Practice: How to prepare application dossier

1) A typical case of and process for preparation of an application dossier
2) How to efficiently prepare a high-quality application document
3) How to use the support tools (e.g., checklist, template, and glossary) to efficiently prepare a high-quality application document
4) Practical points about QC check process
5) Practical points about generating SOPs for proper management of the whole process of submission preparation

<DAY 3>

Session A3: Effective communications -Focusing follow-up actions during review period-/Practice: Case study of how to handle inquires

1) The points that applicants have to note in the process of submission
2) The points to consider in inquiries/responses and meetings with the review authorities during review period
3) The points that applicants have to consider in the management of the timeline for response preparation
4) The importance of effective communications through a common materials
5) Clarification of communication strategy and response policy
6) The sample cases of inquires issued at each stage of review process and learn how to prepare adequate answers, as well as tips to handle the inquiries

Session A4: Rolling out the GRM training program in each economy

1) How to organize the GSubP training in your country following the contents of Good Submission Practice (GSubP) Trainer's Manual
2) Essential elements of team-based learning for effective facilitation in GRM Workshop

Reviewer Specific Training

<DAY 2 >

Session R1: Managing the review (1) – An Overview

1) Role and principle of project management, quality management, standard operating procedures, and review process stages in managing the review
2) How different regulatory authorities use project management, quality management, standard operating procedures, and review process stages in managing the review
3) Practical points to be considered for managing the review in regulatory authorities
4) Best practices for effectively managing the review

Session R2: Managing the review (2) – Quality management

1) The basics of a quality system
2) How a quality system could be implemented inside a regulatory authority
3) The practical points for implementing a quality system inside a regulatory authority

Session R3: Communication - Fundamentals and case studies

1) The advantages of good communications for a regulatory authority
2) Practical points for communications with different stakeholders, including intra-agency communications, interagency communications, communications with applicants, with external experts, and with the public
3) Practice how to efficiently communicate with stakeholders for inquires and answers

<DAY3 >

Session R4: Review personnel – Critical thinking

1) Introduction of major principles of efficacy and safety review
2) Case discussion to cover topics of risk/benefit consideration, unmet medical need, post-marketing requirements, and REMS (risk evaluation and mitigation strategies)
3) Share the thought process and important considerations behind a regulatory decision making during the review process of a regulatory authority
4) Explain the key concepts of critical thinking and regulatory decision making
5) Experience sharing: General considerations for efficacy review
6) Case study – clinical data analysis

Session R5: Conducting the review

1) Explain the importance of covering the key point for the efficient review in the limitation of resources, and the points to be considered for a good review
    - Consideration of priority during review
    - Identification of major scientific questions and their possible resolution
    - Ensuring transparency
    - Understanding of other RA's action on the application
    - Consideration of specific intrinsic and extrinsic factors
2) Points to be considered for a good review based on the review experiences of various regulatory authorities

Session R6: Rolling out the GRM training program in each economy

1) Ask the attendees to describe their organization in terms of its existing knowledge of GRevP as it relates to what has been covered to this point in the program, its readiness to learn about GRevP and its willingness to change its practices.
2) Conduct mock trainings and group discussions of what worked and didn't work with regard to rolling the training out in their agency.
3) Session leader wraps up and fields questions on the training manual, or suggestions on what should be added or improved.

Common Training

<DAY 3 >

Session A5/R7: Panel discussion: How to defined the core competency of applicants

Part 1: How to define the core competency of applicants

Part 2: Reviewer expertise, competencies, and training

1) Regulatory competency framework
2) Competency gaps
3) Incorporating a formal training framework for regulatory professionals

Relevant Guidelines:

The internationally-recognized standard, guideline or best practices document that are considered critical to this topic area are as follows:

- Good review practices: guidelines for national and regional regulatory authorities. WHO Technical Report Series, No. 992, 2015, Annex 9.

  http://www.who.int/medicines/areas/quality_safety/quality_assurance/Annex9-TRS992.pdf?ua=1

- Good Submission Practice (GSubP) Guideline for Applicants. APEC RHSC, 2016.

  https://apac-asia.com/images/achievements/pdf/5th/2_APEC_RHSC%20Endorsed%20GSubP%20Guideline.pdf