Good review practices: guidelines for national and regional regulatory authorities

Content

Definition

- GRevPs are documented best practices for any aspect related to the process, format, content and management of a medical product review.

- The objective of GRevPs is to help achieve timeliness, predictability, consistency, transparency, clarity, efficiency and high quality in both the content and management of reviews.

Definition

- This is done through the development of review tools (for example, standard operating procedures (SOPs) and templates) and reviewer learning activities (for example, training courses, mentoring, orientation packages and discussion sessions).

- To promote continuous improvement, all aspects of GRevPs should be continuously evaluated and updated.

Background

CDSCO Communication vide file no. QMS/01/Misc/2022 dated 18-11-2022 to all State Drugs Controller and Head of Zonal, Sub Zonal & Port Offices for implementation of WHO Technical Series (TRS) no. 992 Annexure 9- Good review practices: guidelines for national and regional regulatory authorities

Objectives

to provide high-level guidance on the principles and processes of good review practice (GRevP)

one building block in a set of tools and is sufficiently expandable

It is not intended to provide detailed instruction on how to conduct a scientific review

Scope

This document applies to the review of safety, efficacy, and quality data in medical product applications filed with RAs for marketing authorization.

Principles of a good review (10 key principles of a good review)

- Balanced
- Considers context
- Evidence-based
- Identifies signals
- Investigates and solves problems
- Makes linkages
- Thorough
- Utilizes critical analyses
- Well-documented
- Well-managed

Managing the review

RAs actively manage the process of reviewing medical product applications to maximize both the potential for a positive public health impact and the effective and efficient use of review resources. RAs should clearly define the separate steps in the process, each with specific activities and targets.

It Involves:-

- ✓ Project Management
- ✓ Quality Management
- ✓ Standard operating procedures
- ✓ Review process stages

Managing the review (Project management)

Project management for the review process refers to the planning, organizing, and resourcing necessary to achieve a complete and high-quality review of an application within a specified time frame.

- The technique most suitable for the RA will be one that enables:

✓ interpretation of the data to show the progress of one application as well as that of many applications under review at any one time;

✓ interpretation of the data to help in decision-making with respect to balancing workload against resources;

✓ monitoring that can be performed and/or interpreted by the relevant people.

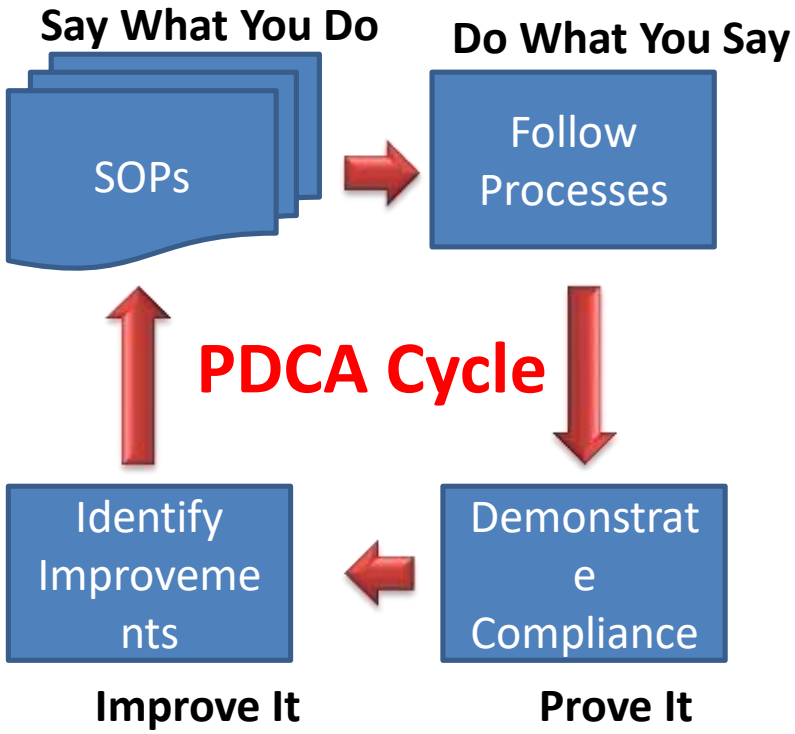
Managing the review (Quality management)

Quality management (QM) is defined as the coordinated activities that direct and control an organization with regard to quality. A QM system refers to the appropriate infrastructure, encompassing the organizational structure, procedures, processes and resources, and systematic actions necessary to ensure adequate confidence that a product or service will satisfy given requirements for quality.

Managing the review (Quality management)

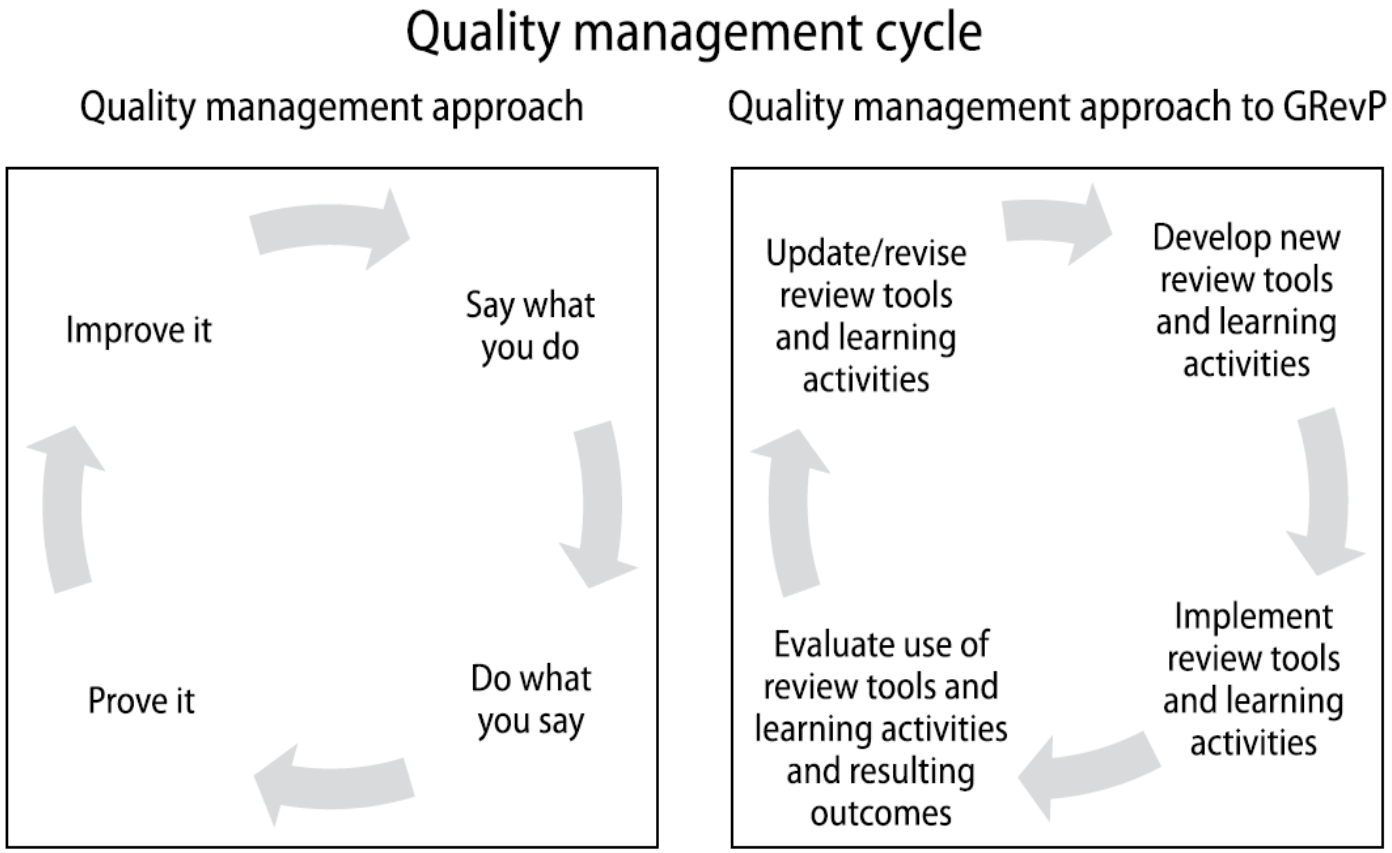
The quality cycle is made up of four key components:

- ✓ Say what you do
- ✓ Do what you say
- ✓ Prove it
- ✓ Improve it.



Quality Management Cycle

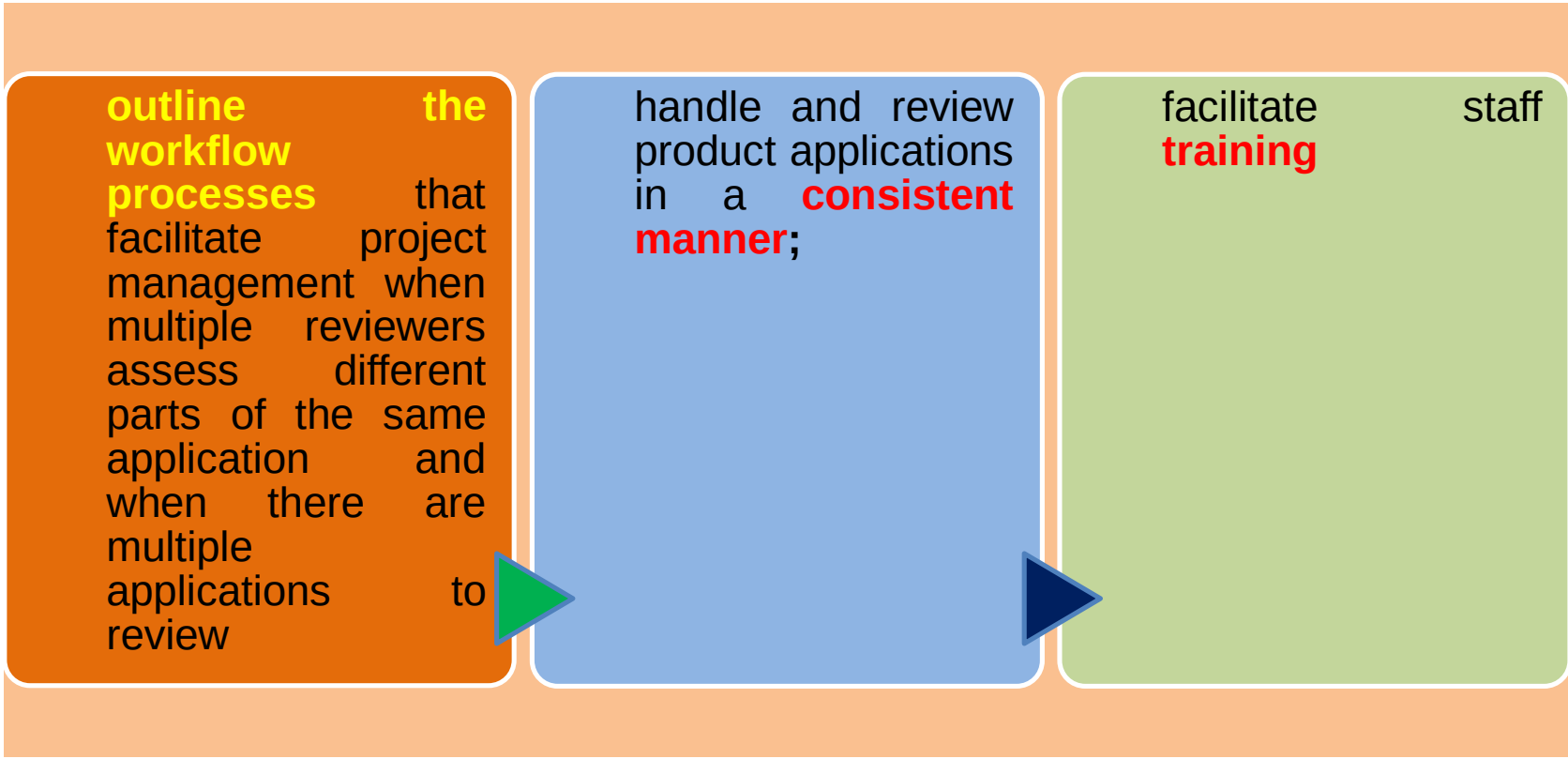
Quality management cycle



Source: Based on United States of America Food and Drug Administration figure.

Managing the review (Standard operating procedures)

Creating and adopting a set of SOPs enables the RA to:



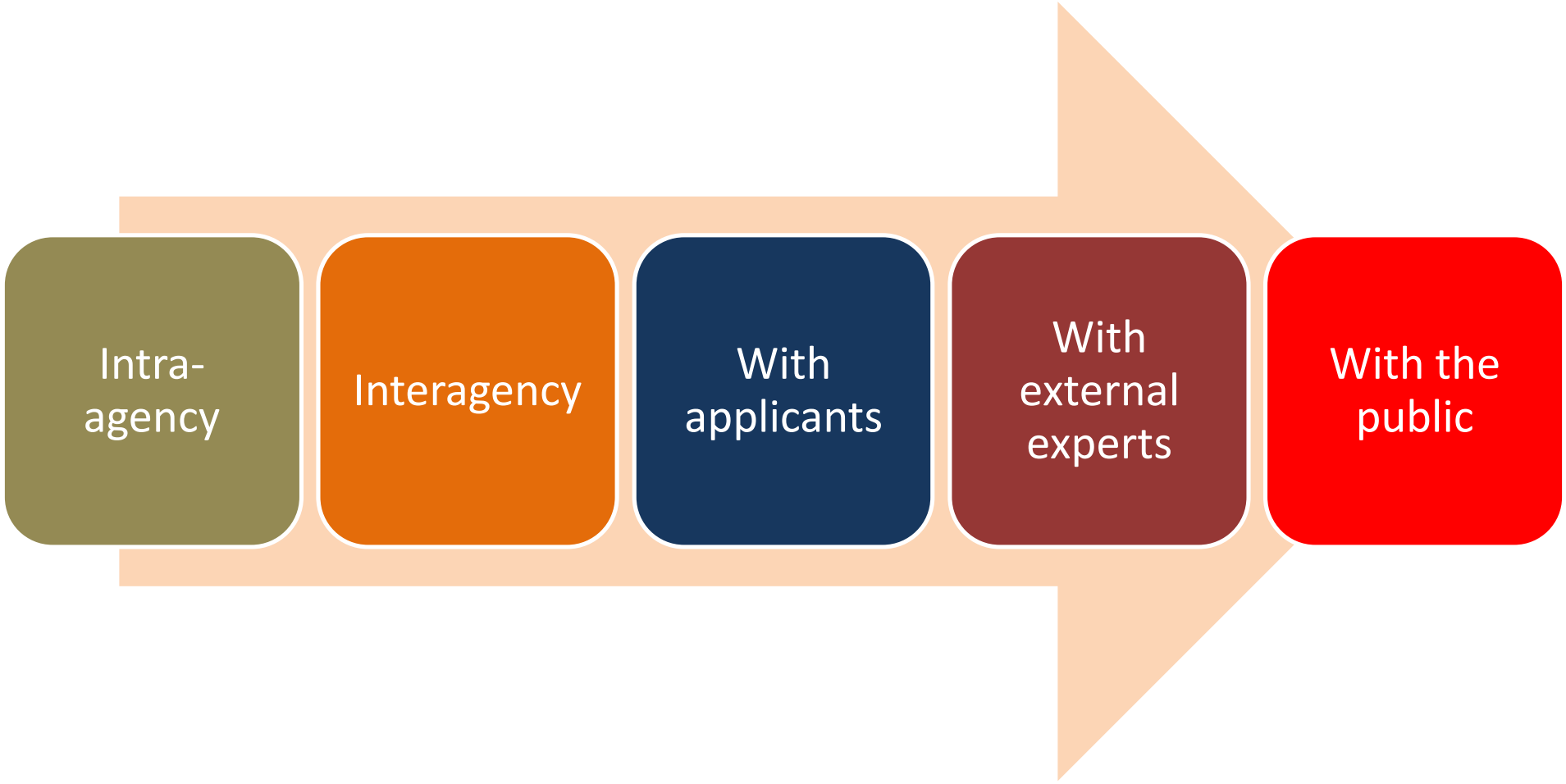
Managing the review (Review process stages)

- Two key stages in the process of reviewing medical product applications are validation and scientific review.
- The validation stage occurs first, with the aim of ensuring completeness of the application in order to facilitate the subsequent scientific review.
- Validation involves an examination of the application to ensure that it is well-organized and that all the required forms and relevant documents have been submitted. Identifying missing information in the application prior to scientific review enables the RA to avoid spending time and review resources on an application that does not allow critical analysis, signal identification or regulatory decision-making

Communications

- Good communication is critical and has many advantages for RAs, applicants, and the public.
- It can improve the efficiency of the development and review process, allowing patients faster access to important medical products.
- It can also improve the quality of the review by providing access to additional expertise.
- Communications can take many active forms:-

Active forms of communication



Review personnel

- Dependent on adequate RA review capacity. capacity relates to many personnel factors including the knowledge, skills, abilities and attitudes of reviewers.

- Sufficient number of reviewers

- Reviewers may be RA staff, external experts or both

- Free of actual or perceived conflicts of interests

Conducting the review

Key elements in defining a review strategy

Public health priority of the medical product application

Understanding other RAs' action on the application

Understanding specific intrinsic and extrinsic factors

Identification of major scientific questions and their possible resolution

Applying the review strategy…cont.

- The findings and conclusions of the review must be described in a well documented review report.
- Once the final decision is made it should be conveyed to the applicant.
- If an RA decides not to grant authorization, a statement of reasons should be provided, which details the documents, information and applicable regulatory requirements taken into account in reaching the decision.
- An appeal mechanism should be provided to ensure that applicants have an opportunity to present their case to an independent arbiter.
- Some RAs may offer to hold a post-action discussion with the applicant to help improve the quality of future applications.
- The RA may also have mechanisms for communication with the public on the approval of the product and/or action taken in relation to the application. Publication of information on the approval of products increases transparency of regulatory actions.

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Thank You