

EDA Issues Updated Good Review Practice (GRevP) Guideline

EDA Issues Updated Good Review Practice (GRevP) Guideline: What Regulatory Professionals Need to Know

The Egyptian Drug Authority (EDA) has released its updated Good Review Practice (GRevP) Guideline, a comprehensive framework designed to enhance the efficiency, consistency, and transparency of product review processes across pharmaceuticals, biologicals, and medical devices. This guideline is adapted from the WHO's GRevP recommendations and is a crucial step in strengthening regulatory performance in Egypt.

Purpose of the Guideline

EDA's GRevP Guideline provides high-level guidance on how regulatory reviews should be planned, managed, and documented to ensure:

Timeliness – predictable review timelines for applicants

Transparency – clear communication of requirements and decisions

Consistency – standardized processes across departments

Efficiency & Quality – evidence-based, well-documented decision-making

Scope

The GRevP applies to the review of safety, efficacy, and quality data for:

Marketing Authorization Applications (MAAs)

Variations and renewals

Medical devices, biological products, and innovative therapies

Key Principles of Good Review

EDA follows ten WHO-endorsed principles to ensure robust, unbiased evaluations:

Balanced & Objective – decisions based on evidence, not bias

Context-Aware – considering product use conditions and public health needs

Evidence-Based – aligning with science and regulatory standards

Problem-Solving & Risk-Based – identifying issues and proposing solutions

Integrated & Thorough – connecting preclinical, clinical, and quality data

Critical Thinking & Documentation – well-reasoned conclusions that withstand scrutiny

Project & Quality Management – structured review plans with clear timelines

Managing the Review Process

1. Project Management

Planning and monitoring review activities

Tracking progress against timelines

Assigning clear roles to reviewers, team leaders, and QA experts

2. Quality Management

Applying a continuous improvement cycle: say what you do → do what you say → prove it → improve it

Using SOPs, templates, and checklists to standardize work

3. Review Stages

Validation: Ensures applications are complete and properly structured before scientific assessment

Scientific Review: Multidisciplinary evaluation of safety, efficacy, and quality data

Communication and Transparency

EDA highlights the importance of clear communication at all levels:

Intra-agency: Collaboration across EDA departments

Interagency: Cooperation with other national and international regulatory authorities

Applicants: Public availability of guidelines, Q&A; documents, and checklists to support high-quality submissions

External Experts: Engagement of academic, clinical, and industry experts for specialized input

Public: Transparent publication of decisions and regulatory processes to build trust

Reviewer Expertise & Critical Thinking

EDA emphasizes:

Competency and training for reviewers in scientific and regulatory principles

Conflict-of-interest declarations for external experts

Development of critical thinking skills to ensure objective, evidence-based decisions

Strategic and Risk-Based Review

The guideline encourages a risk-based approach, considering:

Public health priorities

Reliance on trusted regulatory decisions (e.g., SRA approvals, WHO procedures)

Efficient benefit–risk assessment and documentation

Why This Matters for Regulatory Professionals

For regulatory affairs teams, this guideline is both a compliance requirement and a strategic opportunity:

Align submissions with EDA expectations to avoid delays

Use EDA's templates and checklists to ensure dossier completeness

Prepare for risk-based reviews and potential post-approval commitments

Engage proactively with EDA during review to address questions quickly

Final Thoughts

The updated GRevP guideline represents a significant step toward global regulatory convergence and faster patient access to innovative therapies in Egypt.

Regulatory professionals should carefully study this guideline, integrate its principles into their internal SOPs, and train teams on EDA's expectations. Doing so will improve dossier quality, minimize review cycles, and strengthen compliance with Egypt's evolving regulatory framework.