Risk Management Plan
for Drug Establishments

Center for Drug Regulation and Research
Food and Drug Administration
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Balancing Innovation and Sound Regulation
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REGULATORY BASIS
Republic Act No. 9711

- Issued to strengthen FDA, ensuring monitoring and regulatory coverage over establishments and products, including drugs
Republic Act No. 9711

• Section 5, (k) all marketing authorization holders (MAHs) and other concerned stakeholders are required to implement an RMP for the issuance of the appropriate authorization
Republic Act No. 9711

- Section 5, (l)

Strengthen the post-market surveillance system in monitoring health products
FDA Circular No. 2013-004

• Section V, (2)
  all MAH shall establish a PMS system for every product in the market, which shall be translated into a RMP
RISK AND RISK MANAGEMENT
• event that has a **probability** of occurring
• could have either a **positive or negative impact** to the lifecycle of a medicinal product
• may have one or more **causes**
• one or more **impacts** (e.g., on cost, schedule, or performance)
• all drug products assume some element of **risk**
a set of pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to medicinal products including the assessment of the effectiveness of those activities and interventions
a detailed description of the risk management system

Risk Management Plan
Generic Risk Management Framework

1. Identify & Evaluate
   - Identify Risk Factors
   - Prioritize Risk Factors
   - Profile Risk Opportunities

2. Mitigate & Finance
   - Quantity Impacts
   - Contain
   - Finance

3. Manage
   - Analyze Opportunities
   - Develop Plan
   - Implement

4. Keep Ahead
   - Monitor Change
     - Risk Factors
     - Environment
     - Organization
   - Cycle, as necessary

From Risk Management Seminar (& Workshop) presentation by Juancho Robles

Other Risk Managements
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Draft FDA Circular: Risk Management Plan (RMP) for Drug Establishments
I. Background/Rationale

- Article VII, Section 4 (h) of IRR of RA 9711
  
  h. To mandate, order, review, and implement a Risk Management Plan on any health product for conformance with the FDA standards;

- Article II, A, Section 2 (l) of IRR of RA 9711
  
  l. To require all concerned to implement the risk management plan which is a requirement for the issuance of the appropriate authorization;
I. Background/ Rationale

• Section V, D of AO 2014-0034

D. All establishments are required to implement a risk management plan which is a requirement for the issuance of an LTO or other authorization.

• FDA: implementation of an RMP → coordinated and economical applications of resources to monitor, minimize, and control the probability and/or impact of risks to drug products with respect to safety, efficacy, and quality
II. Objective

- prepare and implement an RMP as part of the reqts for the issuance of LTO
- provide appropriate guidance
III. Scope

- Manufacturers
- Distributors
- Drugstores/Pharmacies/ Boticas including hospital and institutional pharmacies
- RONPDs
- CROs
- Sponsors
A. RMP for Drug Establishments

- reqt for the licensing of drug establishments
  - During initial for new establishments
  - During renewal for existing establishments
- Must always be available for inspection

IV. Implementing Details
B. Framework for RMP for Drug Establishments

1. Introduction
2. Risk Identification
3. Risk Minimization
4. Risk Communication
5. Risk Monitoring and Management Evaluation

IV. Implementing Details
B. Framework for RMP for Drug Establishments

1. Introduction
   a) Internal Environment – sets the basis on how risks are viewed and addressed
      - Description of the establishment (objectives, mission, and vision, activities)
      - Responsibilities attached to the LTO

IV. Implementing Details
B. Framework for RMP for Drug Establishments

1. Introduction
   a) Internal Environment – sets the basis on how risks are viewed and addressed
      ➢ Description of the organization (heads, functions and responsibilities/duties)
      ➢ Risk management officer/team

IV. Implementing Details
B. Framework for RMP for Drug Establishments

1. Introduction
   a) Internal Environment – sets the basis on how risks are viewed and addressed
      ➢ Other attached establishments/institutions critical to the functioning of the establishment

IV. Implementing Details
B. Framework for RMP for Drug Establishments

1. Introduction

   a) Internal Environment – sets the basis on how risks are viewed and addressed

      ➢ Contact information of responsible officers during and beyond office hours

IV. Implementing Details
B. Framework for RMP for Drug Establishments

1. Introduction

   b) Risk Management Approach – overall risk management approach (processes, personnel involved, periodic reporting and monthly procedures to be performed)

   IV. Implementing Details
B. Framework for RMP for Drug Establishments

1. Introduction
   
   c) Risk Management Objectives – ensure the safety, efficacy, and quality of drug products they engage with in order to protect public health

IV. Implementing Details
B. Framework for RMP for Drug Establishments

1. Introduction

   d) Data Lock point – timeframe to which the RMP is expected to be valid

IV. Implementing Details
B. Framework for RMP for Drug Establishments

2. Risk Identification

• Events that may adversely affect the set objectives

• Assessment of significance and likelihood of occurrence of the identified risks

IV. Implementing Details
B. Framework for RMP for Drug Establishments

2. Risk Identification

- Tabulated summary risk register:
  - Specific objectives the risk belongs
  - Naming convention for each risks identified
  - Description of the risks and the assessment of their probability and impact

IV. Implementing Details
B. Framework for RMP for Drug Establishments

2. Risk Identification

• Risks not currently known, the planned activities by the establishment to identify them
B. Framework for RMP for Drug Establishments

3. Risk Minimization
   • For each key risks identified, the risk minimization action plan should be prepared and implemented
B. Framework for RMP for Drug Establishments

3. Risk Minimization
   a) Routine risk minimization
      - Those planned and conducted by the establishment regularly to minimize the identified risks

IV. Implementing Details
B. Framework for RMP for Drug Establishments

3. Risk Minimization
   
a) Routine risk minimization

   ➢ Batch release testing
   ➢ Detailmen training on promotion
   ➢ Formulation and approval procedure of marketing claims

IV. Implementing Details
B. Framework for RMP for Drug Establishments

3. Risk Minimization
   a) Routine risk minimization
      - Benefit-risk assessment
      - PSUR
      - Regular updating of FDA issuance
      - Many others as determined by FDA

IV. Implementing Details
B. Framework for RMP for Drug Establishments

3. Risk Minimization

b) Additional risk minimization

➢ Those planned and conducted by the drug establishment should a significant risk or an unidentified risk occur

IV. Implementing Details
B. Framework for RMP for Drug Establishments

3. Risk Minimization
   b) Additional risk minimization
      ➢ Processing and reporting to FDA of ADR/ADE and SSFFCs received from consumers/HCPs

IV. Implementing Details
B. Framework for RMP for Drug Establishments

3. Risk Minimization
   
b) Additional risk minimization
   
   ➢ Review and revision of labeling and product information
   ➢ Provision of assistance

IV. Implementing Details
B. Framework for RMP for Drug Establishments

3. Risk Minimization

b) Additional risk minimization

➢ Conduct of voluntary recall

➢ Segregation of products suspected to be SSFFC

➢ And many others as determined by FDA

IV. Implementing Details
B. Framework for RMP for Drug Establishments

3. Risk Minimization
   • For identified risks with no risk minimization activities, appropriate justification must be provided
B. Framework for RMP for Drug Establishments

4. Risk Communication
   • Communication system of establishment to:
     a) Internally
     b) FDA
     c) Consumers and HCP
     d) Other relevant stakeholders

IV. Implementing Details
B. Framework for RMP for Drug Establishments

4. Risk Communication
   • Criteria when communication must be done
   • Means for communicating
   • Internal reporting procedure to management and appropriate regulatory agencies

IV. Implementing Details
B. Framework for RMP for Drug Establishments

5. Risk Monitoring and Management Evaluation
   • Periodic monitoring of identified risks
   • Criteria where evaluation is needed
   • When RMP revision is required

IV. Implementing Details
C. Submission of RMP

• When RMP is revised – submit to FDA
• Cover letter and summary of revisions made must be included

IV. Implementing Details
D. RMP Implementation

• Trigger → drug establishments are mandated to implement their submitted RMP

• It is in this context – RMP is comprehensive to cover all possible risks, whether already identified or yet to be identified
V. Roles and Responsibilities of Applicant/MAH and FDA

- MAH → overall responsible for quality, safety, and efficacy of products
- Expected to have a larger role
- Other drug establishments involved in the supply chain → expected to cooperate and coordinate with MAHs
V. Roles and Responsibilities of Applicant/MAH and FDA

• Evaluation:
  a) Drug establishment is capable of maintaining/performing its post-marketing commitments to ensure the safety, efficacy, and quality of the drug product
  b) ensuring public health safety
VI. Penalties and Sanctions

- Failure to act on the part of the establishment as stipulated in the submitted RMP, as well as violation to any section in this FDA Circular shall be a ground for the filing of appropriate regulatory action, administrative sanctions, fines, and/or penalties.
• Provisions in previous circulars and memoranda that are inconsistent with this Circular are hereby withdrawn, repealed, and/or revoked accordingly

• If any provision in this FDA Circular, or application of such provision to any circumstances, is held invalid, the remainder of the provisions in this FDA Circular shall not be affected

VII. Repealing/ Separability Clause
• Upon approval and signature of the FDA DG

VIII. Effectivity