Risk management system:

RMP- Risk management plan is the document in Europe region.

REMS: Risk Evaluation and Mitigation Strategy (USA).

REMS:

Food and Drug Administration Amendments Act- “FDAAA”- The Act gave FDA the authority to require a Risk Evaluation and Mitigation Strategy-(REMS) from manufacturers to ensure that the benefits of a drug or biological product outweigh its risks.

REMS:

The document explains the over all safety of the product including the risk mitigation strategies.

Practical information while writing REMS:

1. REMS goals:

This section explains how to mitigate the risk for a particular adverse event.

1. REMS requirements:

REMS Participant = who (which participant) needs to complete the REMS Requirement(s)

REMS Requirement = what the REMS participant is required to do

Timing Category = when the participant must carry out the requirement

REMS Material = with what REMS material the participants need to carry out a requirement.

1. REMS time table:

Details of submission of the timetable for the MAH to submit REMS.

1. REMS materials:

The details of the materials attached with REMS document are explained.

Examples of materials attached are:

* Enrollment forms
* Training and educational material
* Communication materials

**Risk Management Plan**

A Risk management system is a set of Pharmacovigilance activities to identify, characterize, prevent or minimize risk related to medicinal product.

Risk management plan is a detailed description of Risk management system.

RMP document is submitted in Europe region which briefs the overall safety profile of the drug.

**When is RMP required:**

1. During new marketing authorization submission
2. On request from European authority
3. Any change in new indication, dosage form, route of administration, new manufacturing process of a biotechnology product.
4. During renewal of the application.

**Risk management plan contains:**

* Complete safety profile of the medicinal product.
* Safety concerns of the Product- important Identified risk, important potential risk and missing information.
* Information related to the clinical trials which are ongoing or completed recently which has safety information.
* Risk factors for Adverse reactions.
* Risk minimization measures &
* Measures to check the effectiveness of risk minimization measures.

The RMP is updated through out the life cycle of the medicinal product.

The RMP can be explained in as:

**Objectives of the RMP:**

1. Identify or characterize the safety profile of the medicinal product.
2. Indicate how to characterize further the safety profile
3. Document measures to prevent or minimize the risks associated with medicinal product
4. Document post authorization obligation

**Over view of the parts & modules of the RMP.**

1. Part I- **Product over view**
2. Part II- **safety specification**
3. Module SI- Epidemiology of indication & target population
4. Module SII- Non-clinical part of safety specification
5. Module SIII- Clinical trial exposure
6. Module SIV- Population not studied in clinical trials
7. Module SV-Post authorization exposure
8. Module SVI-Additional Europe requirements for safety specifications
9. Module SVII- Identified & Potential risks
10. Module SVIII- Summary of safety concerns
11. Part III- Pharmacovigilance plan
12. Part IV- Plan for post authorization efficacy studies
13. Part V- Risk minimization measure
14. Part VI- Summary of RMP
15. Part VII- Annexes.

RMP has a template developed by European medical agency to write the RMP by MAH.

At present version number 2.1 is the latest.

This module is just an over view of the RMP & REMS.