

**Approximate study time:** 1½ hours**Level:** Introductory/Intermediate**Audience:** Drug Safety, Regulatory, Compliance, Manager**Category:** Drug Safety**Region:** USA, Europe, Other**CPD Points:** 1**Module outline**

- Module overview
- Principles of risk management planning
- Regulatory requirements for risk management plans
- Assessment

Proactive risk management is a major component of good pharmacovigilance practice. This module sets out the principles of risk management planning and outlines regulatory requirements for risk management plans in regions that are major markets for medicinal products.

**Who will benefit from this module?**

All staff working in medical, drug safety, or pharmacovigilance departments of pharmaceutical or biotechnology companies or contract research organisations should have access to this module. It will also be of value to healthcare professionals and regulatory authority personnel.

**Learning objectives**

- Explain important principles of risk management planning
- Give examples of risk minimisation activities
- Describe the selection of risk minimisation activities that are proportional to a product's benefit/risk balance and do not impose undue burden on stakeholders
- Outline regulatory requirements for risk management plans in regions that are major markets for medicinal products

**Module outline****Module overview**

An outline of the module's scope and objectives, and notes on terminology.

Principles of risk management planning

In this session we set out principles of risk management planning as a major component of good pharmacovigilance practice. We discuss the modern emphasis on proactive risk management in addition to routine pharmacovigilance measures. We describe risk assessment factors important in safety specification, pharmacovigilance planning, and risk minimisation for a drug. We then focus on the selection, implementation, and evaluation of non-routine risk minimisation activities.

Regulatory requirements for risk management plans

In this session we outline regulatory requirements for risk management plans in regions that are major markets for medicinal products: Europe, the USA, and (in a brief sketch) Japan. We describe the structure, main components, and submission requirements for EU Risk Management Plans and US Risk Evaluation and Mitigation Strategies, and we sketch notable aspects of risk management requirements in Japan.

Assessment

Multiple-choice mastery assessment.

