IPI Academy

MANAGEMENT forum

Presented by
Management Forum

A Practical Guide to Writing Risk Management Plans (RMPs)

11 July 2025
+ 12 November 2025

Understand the relationship between RMPs and safety reviews; PBRERs/DSURs; licence submissions (CTD) and their maintenance.

Format:
Live online

CPD:
6 hours for your records

Certificate of completion

Course overview

In the EU, all companies are required to provide risk management plans (RMPs) for every new product, whether generic products or new chemical entities, and these RMPs must also be modified and updated throughout the lifetime of a medicine. This intensive one-day course will provide you with an invaluable overview of writing and maintaining RMPs, with practical advice to ensure you achieve regulatory compliance. You will discuss best practice for using the EU templates and risk minimisation tools to enhance the benefit/risk of your product.

The programme has been fully revised to cover the latest updates and new requirements, including amendments made to the previous template.

Benefits of attending

- **Gain** an overview of ICH and EU RMPs – their production and ongoing maintenance
- **Clarify** the documentation to be supplied to regulators and the process for RMPs
- **Learn** what happened in the EU RMP update and explore the new requirements
- **Discuss** the EU templates and their completion – generic and innovator products
- **Understand** the relationship between RMPs, post-authorisation safety and efficacy studies, safety reviews and PBRERs
- **Discuss** the RMP and risk minimisation follow-up

Who should attend?

This course will be relevant for those working in pharmacovigilance who are involved with writing RMPs, including medical directors/QPPVs who approve such plans. It will also be of interest to those who work with pharmacovigilance, eg in regulatory affairs, clinical, pre-clinical, sales and marketing, legal, commercial and quality.

Programme

An introduction to RMPs

- Outline and purpose of ICH E2E
- The implementation of ICH E2E
- National adoption of ICH E2E
  - Europe
  - USA
  - Japan
  - Arab States

Outline of EU RMPs

- The current EU module V requirements
- Generic, innovator and advanced therapy products
- Additional documents to supply to the regulators
- Safety reporting timelines for RMPs
- EU RMP update and new requirements

The EU templates and their completion – generic and innovator products

- The EU generic template – EU requirements (module V)
- The EU generic RMP versus innovator RMP
- The EU template for innovator products

Completion of RMPs in other countries

The EU RMP and relationship with other documents

- The RMP post-authorisation safety and efficacy studies
- The RMP and PBRERs
- The RMP and safety reviews

The RMP and Risk Minimisation Follow up

Overview of the sections of the EU RMP template

- Part I – Product overview
- Part II – Safety specification modules SI-SVIII
- Part III – Pharmacovigilance plan including safety studies
- Part IV – Plans for post-authorisation efficacy studies
- Part V – Risk minimisation activities including effectiveness measures
- Part VI – Summary of the risk management plan
- Part VII – Annexes

Presenter

Graeme Ladds

Graeme Ladds, Director of PharSafer, has over 30 years' experience working in the pharmaceutical industry. Having started his career at Ashbourne Pharmaceuticals in 1989 as Head of Drug Safety & Medical Information, he went on to become Head of Global Pharmacovigilance at Shire Pharmaceuticals. He then set up his consultancy and specialist CRO company, PharSafer Associates Ltd, where he has been involved in establishing pharmacovigilance in companies, performing audits across Europe and the USA, SOP writing, acting as QP for companies, and helping with regulatory inspections.

Course dates

11 July 2025	**Live online** 09:00-16:30 **UK (London)** (UTC+01) *Course code 14885*	GBP **649** ~~749~~ EUR **909** ~~1,049~~ USD **1,043** ~~1,199~~ **Until 06 Jun**
12 November 2025	**Live online** 09:00-16:30 **UK (London)** (UTC+00) *Course code 14988*	GBP **649** ~~749~~ EUR **909** ~~1,049~~ USD **1,043** ~~1,199~~ **Until 08 Oct**

How to book

Online:
ipi.academy/2193

Alternatively contact us to book, or if you have any queries:

Email:
info@ipiacademy.com

Phone:
+44 (0)20 7749 4749

Discounts

- Booking more than one delegate on any one date qualifies for a **15% discount** on the second and subsequent places.
- Most events qualify for an **early booking discount** prior to 6 weeks before the course date. Be sure to check on our website, where the latest discounts will be shown.

Further information

Fee
The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

Please note
IPI Academy (and our training partners) reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, we will refund the registration fee and disclaim any further liability.

Terms and conditions
The rest of the our terms, the event cancellation policy and the terms and conditions are on our website, please visit ipi.academy/content/terms-and-conditions

Reviews

★★★★☆

[Speaker] has a really large and great experience and knowledge on all areas of PV. Overall good.

Dorte Jensen
QPPV Deputy
2care4 Generics ApS
Nov 5 2024

★★★★★

Specific, accurate and useful.

Valdas Liukaitis
SMCA of Lithuania
Oct 5 2023

★★★★★

Experienced and knowledgeable speaker. Answered all questions and presented in a clear and concise manner.

Sheraz Hussain
Snr PV PM
N/A
Jan 19 2023

★★★★★

Excellent speaker who managed to keep the listener's attention through a complex document and process. Very useful slides that I will consult when requested assistance with RMP from clients. I particularly enjoyed the explanation of US vs Japan vs EU expectations in terms of safety.

Magali Le Goff
Director Scientific Writing & Regulatory Sciences
BlueReg
Jul 11 2022

Run this programme in-house for your whole team

Coming to IPI Academy for your in-house training provides an all-inclusive service which gives you access to a wide variety of content, learning platforms and delivery mechanisms as well as your own personal training adviser who will work with you from the initial enquiry through to feedback and follow-up after the programme.

With over 600 trainers, all practitioners and experts across a huge range of fields, we can provide the training you need, where you need it, when you need it, and at a price which suits your budget. Our approach to tailored learning and development consists of designing and delivering the appropriate solution for each client.

For your FREE consultation and to find out more about how we can work with you to solve your training needs, please contact our training advisers:

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IPI Academy

IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the UK.

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