IPI Academy

MANAGEMENT forum



Presented by
Management Forum

A Practical Guide to Producing and Maintaining the PSMF & Annexes

5 February 27
+ 15 September 27

This course provides a practical guide to both producing and maintaining the PSMF to ensure Regulatory compliance and has been fully revised to include the latest updates.

Format:
Live online

CPD:
6 hours for your records

Certificate of completion

Course overview

The pharmacovigilance system master file (PSMF) is a legal requirement for any medicinal product authorised in the European Union. The PSMF provides the regulators with a detailed description and assessment of the entire pharmacovigilance system and the outputs contained in the annexes provide an understanding of a company's compliance. This course will provide a practical guide to planning, writing, maintaining and updating the PSMF to ensure compliance.

The programme will cover the importance of the PSMF in regulatory inspections, including common PSMF inspection findings. We will discuss the processes and systems required to manage the PSMF as well as the latest advice on the impact of Brexit.

The course will also cover the role of the EU QP PV and Quality Assurance (QA) in the evolution of the PSMF and the internal audit aspects that ensure it is running efficiently and compliantly.

Benefits of attending

- **Understand** the full scope of the regulatory requirements for the PSMF, enabling you to confidently meet compliance expectations
- **Gain** a clear and practical overview of the key issues involved in producing, maintaining, and updating the PSMF, helping you streamline your approach
- **Discuss** the PSMF as a QMS document and explore how it integrates within your wider quality management system
- **Learn** about the roles of the QPPV and the PSMF, clarifying responsibilities and strengthening accountability across your organisation
- **Review** common inspection findings and deficiencies related to the PSMF, so you can proactively address gaps and strengthen inspection readiness

Who should attend

This course is ideal for anyone working in pharmacovigilance who requires a comprehensive overview of the PSMF, including:

- PVQAs
- QPPVs
- Those responsible for safety assessments

It will also be highly relevant for professionals who work closely with pharmacovigilance, including those in:

- Regulatory affairs
- Clinical
- Sales and marketing
- Legal
- Commercial
- Quality
- Audit (PVQA)

This broad coverage ensures a shared understanding of PSMF requirements across functions, supporting stronger collaboration, compliance, and inspection readiness.

Programme

Introduction, welcome and objectives

Introduction and background to the PSMF

- The DDPS and the PSMF
- Objectives of the PSMF
- Registration of the PSMF
- Regulatory requirements and accessibility of the PSMF
- Responsibilities of the marketing authorisation holder, updates and the EU QPPV

The content of the PSMF

- The PSMF template
- The level of detail required by the PSMF
- Preparation of the annexes
- The PSMF log book

The sections of the PSMF

- The EU QPPV
- Sources of safety data
- IT and databases
- Regulatory timeline compliance
- The PSMF processes
- The PSMF and audits (PVQA)
- The company quality system and the PSMF

The annex requirements for the PSMF

- The company product list
- The EU QPPV list of delegated tasks
- The list of SOPs and procedures
- List of delegated activities to third-party partners
- A list of completed audits and schedules
- A list of performance indicators for the PSMF section incl KPIs
- The roles and responsibilities of the EU QPPV
- Master file number and version changes (audit trail)

The PSMF and inspections

- The PSMF and inspection findings
- Regulatory authority requests to view the PSMF
- Transfer of responsibility for a pharmacovigilance system to the QPPV
- Notifying the QPPV of changes to the PSMF
- PSMF responsibilities with shared marketing authorisation holders
- Change control, logbook, versions and archiving
- Audit trails and the PSMF
- The PSMF post-inspection

Requests for the PSMF

The PSMF post Inspection

Final discussion session

Presenter



Graeme Ladds

Graeme Ladds, Director of PharSafer, has over 30 years' experience in the pharmaceutical industry. He began his career in 1989 at Ashbourne Pharmaceuticals as Head of Drug Safety & Medical Information, before going on to become Head of Global Pharmacovigilance at Shire Pharmaceuticals.

He later founded his consultancy and specialist CRO, PharSafer Associates Ltd, where he has supported companies in establishing pharmacovigilance systems, conducting audits across Europe and the USA, developing SOPs, acting as a QP, and supporting regulatory inspections.

Since 1994, Graeme has also been involved in the monitoring of medical devices, including drug–device combinations, structural devices and electrical medical devices. His experience spans clinical trials and global device vigilance, alongside pharmacovigilance activities across both clinical development and post-marketing phases.

Course dates

5 February 27	**Live online** 09:00-16:30 **UK (London)** (UTC+00) *Course code 17007*	GBP **649** ~~749~~ EUR **909** ~~1,049~~ USD **1,043** ~~1,199~~ **Until 11 Dec**
15 September 27	**Live online** 09:00-16:30 **UK (London)** (UTC+01) *Course code 17326*	GBP **649** ~~749~~ EUR **909** ~~1,049~~ USD **1,043** ~~1,199~~ **Until 21 Jul**

How to book

Online:
ipi.academy/2194

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 **30% 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

★★★★★

Overall, the webinar was very informative and useful. The content was relevant, the presentation was clear, and Graeme demonstrated excellent openness and willingness to share his expertise. The opportunity to ask questions and receive practical guidance made the session particularly valuable for applying the knowledge gained to our own pharmacovigilance system.

Lorena Vega
Qualified Person for Pharmacovigilance
Laboratorio de Productos Eticos CEISA
Sep 16 2026

★★★★★

An incredible session. The content was relevant, well-structured, and clearly aligned with the audience's needs. The presentation was engaging and the speaker demonstrated strong expertise and communicated complex ideas in a clear and relatable manner. Overall, the session was highly insightful and impactful. I particularly appreciate the way the speaker explained complex concepts using practical, real-life examples. It made the content much more relatable and easier to understand. The Q&A segment was another highlight—his answers were clear, thoughtful, and directly addressed each question with examples. The overall structure of the session was smooth and engaging, keeping the audience interested from start to finish. It was both informative and interactive.

Parveen begum Shaik
Head UKPV
Milpharm Limited
Oct 3 2025

★★★★☆

The webinar was good in length , content, presentation and speaker. I was hoping to get some tricks and clarity on what's to be included in PSMF and what's not. Speaker did a good job including examples in real life.

Nuria Cabello
PV Manager and QPPV
Farmaprojects SAU
Oct 3 2025

★★★★☆

Very good seminar which covered all important points around the production and maintenance of the PSMF. The speaker was excellent with a profound knowledge of the topic.

Marie-Christine Klös
Senior Specialist Pharmacovigilance
Boehringer Ingelheim Vetmedica GmbH
Feb 14 2025

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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