IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Cosmetovigilance

13-14 October 2025

This course will provide a comprehensive overview of cosmetogivilance in Europe, the USA and the Rest of the World (ROW).
It will provide key guidance for manufacturers and distributors on how to comply with the regulatory requirements, and will be valuable for pharmaceutical and medical device companies looking to access the cosmetic market.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

The regulations for cosmetic products globally have been in place for nearly 50 years and have been changing and growing worldwide. Previously there had not been a requirement to test cosmetics in the same manner as medicines because of perceived lack of effect or 'danger' to the consumer.

The identification and analysis of adverse reactions (Serious Undesirable Effects (SUEs)), related to cosmetic products is a process that used to be mainly industry driven. However, it is now the responsibility of manufacturers to determine that products and ingredients are safe before they are marketed, and to then collect reports of undesirable effects similar to the pharmaceutical industry, and conduct safety summaries of their products.

The rules that apply to cosmetics differ from country to country, including how to collate data for the Product Information File (PIF), safety reviews, causality assessments, reporting, and other areas of the legislation.

This course will provide a comprehensive overview of Cosmetovigilance in Europe, the USA and the Rest of the World (ROW). It will cover the applicable legislation, the regulatory requirements, what needs to be reported, the role of the Responsible Person, borderline products and promotional claims.

Essentially it will provide key guidance for manufacturers and distributors on how to comply with the regulatory requirements, and will be valuable for pharmaceutical and medical device companies looking to access the cosmetic market.

Benefits of attending

- **Hear** the differences in the global requirements
- **Understand** Causality Assessments in Cosmetovigilance
- **Know** how to manage The Product Information File (PIF)
- **Learn** about Safety Signal Analysis
- **Understand** the role and responsibilities of The Responsible Person for Cosmetovigilance
- **Discuss** borderline products and cosmetics
- **Be aware** of the advertising regulations for cosmetics

Who should attend?

- Customer call personnel/product safety/product complaints
- Undesirable effect assessors
- R&D
- Regulatory affairs professionals
- Quality control and assurance
- Responsible persons

Programme

Day 1

An introduction to cosmetovigilance

- New EU Legislation
- USA and rest of world reporting
- What needs to be reported
- Data capture techniques

Causality assessments in cosmetovigilance

- Legal basis for causality assessments
- Types of causality
- Where causality assessments appear
- Determining causality

The Product Information File (PIF)

- Availability and purpose
- Composition
- Maintenance and updates

Safety signal analysis – what is a signal?

- What is a signal?
- Where to look for signals
  - Literature
  - Individual reports
  - Pre-Clinical findings

Safety signal analysis –the signal and actions?

- Trending over time
- Quality of the reports
- Potential signals and their handling – communication
  - Regulators
  - Public

Borderline products & cosmetics

- What is a borderline product?
- What does this mean for cosmetics
- Safety reporting for a product that is device and cosmetic?

Day 2

Annual product safety report

- Product safety information
- Subsections for the safety information
- Product safety assessment
- Information for the safety assessment

The regulators perspective for cosmetovigilance

- Regulatory inspections for cosmetics
  - USA
  - Europe
  - ROW

The Responsible Person for cosmetovigilance

- The role of the Responsible Person
- Qualifications and expectations from the regulatory agencies

The practical role of the Responsible Person for cosmetovigilance

- The role of the Responsible Person with:
  - Ingredients, labelling and claims compliance
  - Configuration and custody of the Cosmetic Product Information File (PIF)
  - Configuration of the Cosmetic Product Safety Report (CPSR)

The practical role of the Responsible Person for cosmetovigilance (continued)

- The role of the Responsible Person with:
  - Product notification on the Cosmetic Products Notification Portal (CPNP)
  - Post-market surveillance
  - Review of Nanomaterials and Carcinogenic, Mutagenic and Reprotoxic (CMR) substances

Promotional claims for cosmetics

- The regulations for advertising cosmetics
- Medical claims
- Penalties for false advertising

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 date

13-14 October 2025	**Live online** 09:30-16:45 **UK (London)** (UTC+01) *Course code 15004*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 08 Sep**

How to book

Online:
ipi.academy/2139

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

Email:
info@ipiacademy.com

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+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.

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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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