IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Cosmetovigilance

10-11 December
+ 17-18 June 27, 9-10 December 27

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 worldwide have been in place for nearly 50 years and continue to evolve and expand across different regions. Historically, cosmetics were not required to undergo testing in the same way as medicinal products, largely due to the perceived minimal effect or 'risk' to the consumer. The same was true for safety reporting.

Over time, this position has changed significantly. The identification and analysis of adverse reactions, known as Serious Undesirable Effects (SUEs), associated with cosmetic products was once largely driven by industry initiatives. Today, however, the responsibility sits firmly with manufacturers to ensure products and ingredients are safe before they reach the market. In addition, they must actively collect and assess reports of undesirable effects in a manner similar to routine pharmacovigilance within the pharmaceutical sector, as well as produce safety summaries for their products.

Regulatory expectations also vary internationally, with different requirements across countries for areas such as the collation of data within the Product Information File (PIF), safety reviews, causality assessments, reporting obligations, and other legislative considerations.

This course delivers a comprehensive overview of Cosmetovigilance across Europe, the USA, and the Rest of the World (ROW). It explores the relevant legislation, regulatory requirements, reporting obligations, the role of the Responsible Person, as well as borderline products and promotional claims.

Overall, the course provides essential guidance for manufacturers and distributors seeking to understand and comply with global regulatory requirements. It is also highly valuable for pharmaceutical and medical device companies looking to expand into the cosmetic market.

Benefits of attending

- **Hear** the differences in global regulatory requirements across regions
- **Understand** causality assessments within Cosmetovigilance and how they are applied
- **Learn** how to manage the Product Information File (PIF) effectively and in line with regulations
- **Gain** insight into safety signal analysis and its importance in product safety monitoring
- **Understand** the role and responsibilities of the Responsible Person in Cosmetovigilance compliance
- **Discuss** borderline products and how they are classified as cosmetics
- **Become** aware of advertising and promotional regulations for cosmetic products
- **Learn** about the sanctions that Regulatory Agencies can impose with non-compliance

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 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

10-11 December	**Live online** 09:30-16:45 **UK (London)** (UTC+00) *Course code 16418*	GBP **1,499** EUR **2,099** USD **2,399**
17-18 June 27	**Live online** 09:30-16:45 **UK (London)** (UTC+01) *Course code 17246*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 22 Apr**
9-10 December 27	**Live online** 09:30-16:45 **UK (London)** (UTC+00) *Course code 17564*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 14 Oct**

How to book

Online:
ipi.academy/2139

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

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.

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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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