IPI Academy

MANAGEMENT forum



*Presented by*
**Management Forum**

# Variations to Marketing Authorisations

**14-15 June 27**
+ 10-11 November 27

A two-day event that will provide an invaluable overview of the EU system for variations, with practical advice on the preparation and submission of variation applications using the various European procedures.

**Format:**
Live online

**CPD:**
12 hours for your records

Certificate of completion

# Course overview

**It is a key post-marketing responsibility of the marketing authorisation holder (MAH) to keep dossiers up to date, and changes must be submitted as variations to the appropriate regulatory authority.**

This interactive event will provide an invaluable overview of the EU system for variations, with practical advice on the preparation and submission of variation applications using the various European procedures. The course will cover the latest variation regulations and offer guidance from an industry expert on how to optimise your regulatory procedures to help achieve faster approval. The programme will include filing tips and strategies with information and advice on creating a global dossier and implementation periods.

Practical sessions throughout the two days will provide an opportunity to discuss different scenarios and strategies with other participants.

**Benefits of attending:**

- **Gain** an overview of the EU system for variations
- **Assess** how pharma companies are working in this evolving regulatory environment
- **Profit** from practical advice on the preparation and submission of variation applications
- **Understand** the impact of Module 3 on your variations dossier
- **Discuss** filing tips and strategies to help achieve faster approval

## Who should attend?

This course will be particularly relevant for those working in registration and regulatory affairs. It will also be of interest to anyone with an involvement in the variations process including QA, clinical safety and pharmacovigilance personnel.

# Programme

## Day 1

**Basis of EU Regulations 1234/2008 and 712/2012**

- Classification in accordance with the legislation
- Understand the differences between type IA, type IB and type II variations
- Clarify foreseen and unforeseen variations

**Special topics in variations**

- Handling active ingredient master files as variations
- Submission of new clinical data

**Practical session: Analysing and classifying the different changes**

**Grouping and work-sharing**

- Understanding when grouping is appropriate
- Clarifying what types of variations may be grouped
- Guidance on assembling a grouped submission
- Understanding when work-sharing is appropriate

**Understanding Module 3**

- The dossier impact on variations
- QbD
- CQA pyramids

**Practical session: Understanding reviewers**

**Filing strategy**

- Creating a global dossier (gold/silver/ bronze versions)
- Understanding implementation and grace periods
- Fixed and rolling implementation strategy

**Practical session: Plan the timelines/project management of a variation submission**

## Day 2

**Other procedures**

- Article 5
- Urgent safety restrictions
- Understanding when to use extension applications

**Submission planning**

- Identify and understand strategic considerations

**Data requirements for type II variations**

- Learn how to identify and support a type II change

**Practical session: Data requirements for more complex changes**

**Variations through national procedures and differences from centralised procedure**

- Understand the procedures
- Languages and translations
- Explore the linguistic review process

**Mutual recognition and decentralised procedures for variations**

- Understand the procedures and responsibilities of the MAH, RMS and CMS
- Learn how to efficiently plan for and run an MR variation procedure

**Practical session: A variation to an example MRP authorised product including planning timelines and impact of referrals**

**Advanced compliance**

- Creating your own compliance requirements
- SUPAC guidance

# Presenter



**Andrew Willis**

Andrew Willis is an independent consultant providing expert advice and training on global regulatory solutions and pharmaceutical development. Previously, he worked for Catalent Pharma Solutions as VP Regulatory Affairs & Consulting Services, where he was head of a team of internal and external regulatory affairs consultants.

He qualified as a Chemist from the University of Glamorgan, after which he furthered his understanding of pharmaceutical development, working as a research chemist with Parke Davis. He had 10 years manufacturing and analytical experience prior to entering regulatory affairs as a Senior Executive Officer with responsibility for submission of European MAAs and project management of development programs. He has over 30 years' pharmaceutical experience with extensive knowledge in the development and manufacture of sterile, solid oral, inhalation, topical and biotech pharmaceutical products. These experiences have allowed knowledge of many biotech products requirements with experiences of growth hormones and multiple cancer treatments, including development and clinical registration of the first genetically modified live bacterium for such treatment.
He has extensive experience of major European and US regulatory projects, in the clinical and marketing authorisation stages, and has significant experience in coordinating and managing meetings with European and US Health Authorities.

# Course dates

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|---|---|---|
| **14-15 June 27** | **Live online**<br>09:00-17:00 **UK (London)** (UTC+01)<br>*Course code 17212* | GBP **1,299** ~~1,499~~<br>EUR **1,819** ~~2,099~~<br>USD **2,087** ~~2,399~~<br>**Until 19 Apr** |
| **10-11 November 27** | **Live online**<br>09:00-17:00 **UK (London)** (UTC+00)<br>*Course code 17472* | GBP **1,299** ~~1,499~~<br>EUR **1,819** ~~2,099~~<br>USD **2,087** ~~2,399~~<br>**Until 15 Sep** |

## How to book

**Online:**
ipi.academy/857

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

★★★★☆

**I was hoping to gain a better understanding of regulatory variations, and the webinar was very useful, clear and comprehensive. It will definitely help me in my work. I appreciated that speaker was interactive with the class and very kind.**

**Maria Pina Desiante**
PV Scientist
APL Swift Services Ltd
Oct 29 2025

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★★★★★

**The webinar content corresponded to what I was expecting ; I thought it was very good that Andrew asked the participants lots of questions as it made the webinar more enjoyable and engaging.**

**Liz Hui**
Regulatory Affairs Executive
Dermal Laboratories Ltd
Feb 1 2024

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★★★★☆

**Very informative. Engagaement with participants was great.**

**Kamila Tomaszewska**
RA Specialist
Bausch & Lomb
Nov 28 2024

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★★★★☆

**Very good webinar. The schedules were good and respected. The content meets my expectations**

**Sarah Bourgin**
Associate Regulatory Affairs Specialist
Medtronic BioPharma Sàrl
Jun 10 2024

## 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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