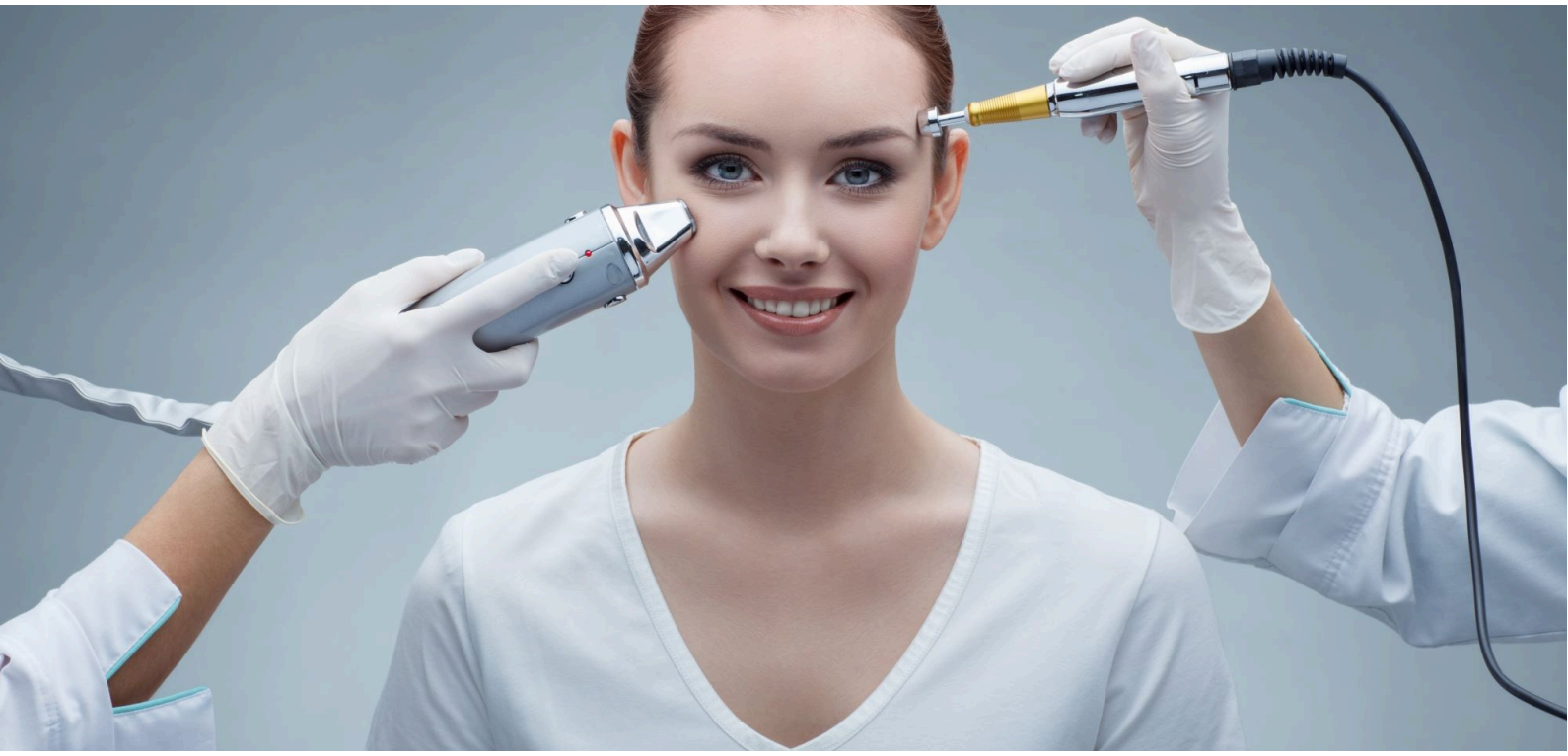
IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Regulatory Compliance and Safety Standards for Aesthetic Devices

12 September 2025
+ 5 December 2025

Navigate regulatory complexities and device classifications in the aesthetic medical device industry.

Format:
Live online

CPD:
4 hours for your records

Certificate of completion

Course overview

Medical devices with no medical purpose, commonly referred to as aesthetic devices, present unique regulatory challenges for the cosmetic industry. While these devices do not treat or diagnose medical conditions, they must meet rigorous safety and efficacy standards, often comparable to those for medical devices (e.g., liposuction devices, dermal fillers). As such, aesthetic devices often exist in a regulatory grey area, as they serve non-therapeutic purposes. This ambiguity makes determining their classification - whether as medical devices or consumer products - complex.

The field of aesthetic devices is governed by stringent regulatory compliance and safety standards to ensure consumer safety and product efficacy. This involves adherence to global and regional regulations, such as FDA guidelines in the United States or CE marking requirements in Europe. Manufacturers must follow rigorous processes, including risk assessment, clinical evaluation, and quality management system (e.g., ISO 13485). Regulatory compliance not only mitigates risks but also fosters trust and credibility in the marketplace. Therefore, staying updated on regulations and safety standards is essential for professionals developing and working with aesthetic devices.

Unlock the knowledge and skills to navigate the complex regulatory landscape of aesthetic devices with confidence. This course is designed to empower professionals in the cosmetic industry to excel in global markets by understanding and addressing compliance challenges.

This comprehensive course explores the unique regulatory landscape for medical devices with no medical purpose, commonly known as aesthetic devices. Designed for cosmetic industry professionals, it provides an in-depth understanding of compliance challenges, safety standards, borderline definitions in aesthetics devices, and marketing strategies to ensure successful product development and market entry.

Dive into the intricacies of device classification under frameworks like the EU Medical Device Regulation (MDR 2017/745), ensuring you're equipped to meet regulatory requirements with ease. Learn how to demonstrate safety and efficacy for devices with subjective benefits using robust scientific evidence and gain the tools to craft marketing strategies that align with global standards while avoiding misleading claims.

Enhance your expertise in maintaining product safety through advanced post-market surveillance systems and effective adverse event monitoring. Explore how to navigate diverse international regulations, with insights into key regional differences, including the EU and U.S.A., to ensure seamless global compliance. Finally, discover best practices for fostering consumer trust through clear communication, and ethical transparency.

By the end of this course, you'll have the confidence to bring innovative aesthetic devices to market while maintaining the highest standards of safety, compliance, and credibility.

Participants will be equipped with the knowledge and tools to effectively manage the regulatory, safety, and ethical complexities of aesthetic devices, ensuring compliance and success in the global cosmetic industry.

Benefits of attending

- **Gain** in-depth knowledge to navigate borderline definitions in aesthetics devices
- **Ensure** successful regulatory submissions in different global jurisdictions
- **Maintain** consumer trust and minimise legal risks by understanding marketing and claims

Who should attend?

This training is suitable for any professionals involved with aesthetic devices, including:

- Regulatory Affairs Professionals
- Product Development Teams
- Clinical Affairs Specialists
- Quality Assurance Managers
- Cosmetic Industry Professionals
- Healthcare and Aesthetic Practitioners
- Academic and Research Professionals
- Entrepreneurs and Startups

Programme

Device classification and regulation

- Classification of aesthetic devices without medical purpose according to EU 2017/745 MDR's (Annex XVI) risk-based classification rules

Safety and performance standards

- General Safety and Performance Requirements (GSPR)
- Clinical Evaluation
- Post-Market Surveillance (PMS)

Global regulatory variability, marketing and claims management

- USA FDA's selective and predicate-based approach for classification of aesthetic devices
- Substantial equivalence claims
- Ethical marketing
- Transparent disclosure of device performance claims.

Ethical and consumer transparency

- Ethical marketing
- Transparent disclosure of device performance claims

Post-market vigilance and surveillance

- PMS Plan
- Periodic Safety Update Reports (PSURs)
- Post-market Clinical Follow-up (PMCF)

Presenter

Catarina Carrao

Catarina Carrão from BioSciPons, is a clinical evaluation and benefit-risk assessment specialist. Previously, she studied Biochemistry and worked in academic research. In 2006, she was a Marie-Curie Early Stage Researcher in the Universitätsmedizin Charité Berlin. In 2011, she was a Postdoctoral fellow at the University of Yale Cardiovascular Research Centre (YCRC). In 2012, she received the European Science Slam title. In 2013, she was awarded Fellow of the American Heart Association (FAHA). In 2021 she was nominated Young Science Journalist of the Year by the Association of British Science Writers (ABSW).

Her scientific expertise in neuroscience, cardiovascular, oncology, molecular biology and biostatistics allows her to understand the needs of innovative medical device manufacturers; and support them in navigating the regulatory waters of certification. By understanding the importance of evidence, not only in written form to peers but also to deliver valuable information to the consumer, BioSciPons is favoured by start-ups in the fields of artificial intelligence, wearables, implants, among other innovative technologies.

Course dates

12 September 2025	**Live online** 08:30-13:30 **UK (London)** (UTC+01) *Course code 15551*	GBP **649** ~~749~~ EUR **909** ~~1,049~~ USD **1,043** ~~1,199~~ **Until 08 Aug**
5 December 2025	**Live online** 08:30-13:30 **UK (London)** (UTC+00) *Course code 15552*	GBP **649** ~~749~~ EUR **909** ~~1,049~~ USD **1,043** ~~1,199~~ **Until 31 Oct**

How to book

Online:
ipi.academy/3169

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.

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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