



Presented by  
Management Forum

# Unique Device Identification (UDI) and Labelling for Medical Device Manufacturers

4 June 2024  
+ 5 December 2024

The information supplied with medical devices, both on their labels and in any accompanying Instructions for Use form part of the device itself, and are critical to the safety and performance of the device and to compliance with regulatory requirements. This course provides an introduction to the regulatory requirements as they relate to the labelling of medical devices and how manufacturers may demonstrate compliance.



**Format:**  
Live online



**CPD:**  
3 hours for your records



Certificate of completion

# Course Overview

**The information supplied with medical devices, both on their labels and in any accompanying Instructions for Use form part of the device itself and are critical to the safety and performance of the device and to compliance with regulatory requirements.** Regulations for medical devices include particular requirements for labelling and the provision of Instructions for Use. These regulatory requirements relate to general safety and performance aspects of the products, and the requirements for clear and unambiguous information to be supplied to clinicians, patients and other users. Evidence of labelling which includes all required information is important and expected when demonstrating conformity with the regulations.

These requirements have been supported by a portfolio of standards, regulations and guidance documents on:

- Information to be supplied by the manufacturer;
- Symbols to be used with information to be supplied by the manufacturer;
- Unique Device Identifiers (UDIs); and
- Use of electronic labelling

This course provides an introduction to these regulatory requirements as they relate to the labelling of medical devices and how manufacturers may demonstrate compliance.

## Benefits of Attending

- **Gain** an overview of the information that needs to be supplied with medical devices
- **Understand** how the use of symbols can overcome language and translation barriers
- **Learn** the regulatory requirements for use of UDIs in the UK, EU and USA
- **Gain** an awareness of the ways in which information can be provided to customers

## Who Should Attend

- Regulatory Compliance specialists
- Quality Management System (QMS) specialists
- Internal Auditors
- Regulatory and Quality professionals

**Please note** that access to copies of ISO 15223-1 and ISO 20417 would be beneficial to delegates attending this training. If you do not already have access to these through your organisation, please see below the ways to acquire them:

ISO 15223-1  
- <https://www.iso.org/standard/77326.html>

ISO 20417 -  
<https://www.iso.org/standard/67943.html>

These standards are also available from national standards organizations such as BSI, DIN, AFNOR, AAMI, NSAI, etc.

# Programme

## **Labels and IFUs**

- What is a label?
- Regulatory requirements for product labels in the UK, EU and USA
- Managing labelling with an ISO 13485 quality management system
- Use of symbols on labels and IFUs
- Requirements for translation of label information
- Electronic labelling
- Marketing literature
- When do you need an IFU?

## **Labels and IFUs (continued)**

- Information to be provided with a medical device
- Validation of labelling systems
- Chemical indicators and the ISO 11140 standard

## **UDIs and Barcodes**

- Regulatory requirements for barcoding in the UK, EU and USA
- Basic UDIs, GMNs and GTINs
- UDI carriers, Human Readable Information and UDI databases
- Eudamed and its use within the EU

# Presenter



## **Annette Callaghan**

A quality management professional, chartered biologist and member of the Royal Society of Biology, with over 35 years' experience in the medical device, pharmaceutical, biotechnology and food industries. Extensive knowledge of quality and environmental management systems, internal and third-party auditing and personnel training. Eligible to act as a Qualified Person as defined in Directive 2001/83/EC, as amended (previously 75/319 et al.) since 1993. A Qualified Notified Body Lead Auditor since 2002 (IRCA ref: 1182641).

# Course dates

**4 June 2024**

**Live online**

13:30-17:00 **UK (London)** (UTC+01)

Course code 14313

GBP **349**

EUR **499**

USD **579**

**5 December 2024**

**Live online**

13:30-17:00 **UK (London)** (UTC+00)

Course code 14314

GBP **299** ~~349~~

EUR **429** ~~499~~

USD **501** ~~579~~

**Until 31 Oct**

## How to book



**Online:**

[ipi.academy/2695](https://ipi.academy/2695)

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



**Email:**

[info@ipi.academy](mailto:info@ipi.academy)



**Phone:**

[+44 \(0\)20 7749 4749](tel:+442077494749)

## Discounts

- Booking more than one delegate on any one date qualifies for a **15% 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 our terms, the event cancellation policy and the terms and conditions are on our website, please visit [ipi.academy/content/terms-and-conditions](https://ipi.academy/content/terms-and-conditions)

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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

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