IPI Academy

MANAGEMENT forum

Presented by
Management Forum

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

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 date

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

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

Email:
info@ipi.academy

Phone:
+44 (0)20 7749 4749

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 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

★★★★★

There was a lot of useful information within the webinar and I learnt some new things, the programme was very well managed and presented to us very well. Annette did a great job!

Laura Acey
Labelling Coordinator
GBUK Group
Jun 4 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:

ALEKSANDRA BEER
Tel: +44 (0)20 7749 4749
Email: inhouse@ipi.academy

YESIM NURKO
Tel: +44 (0)20 7749 4749
Email: inhouse@ipi.academy

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.

10-12 Rivington Street
London EC2A 3DU

ipi.academy
Tel: +44 (0)20 7749 4749
Email: info@ipi.academy