MDTI

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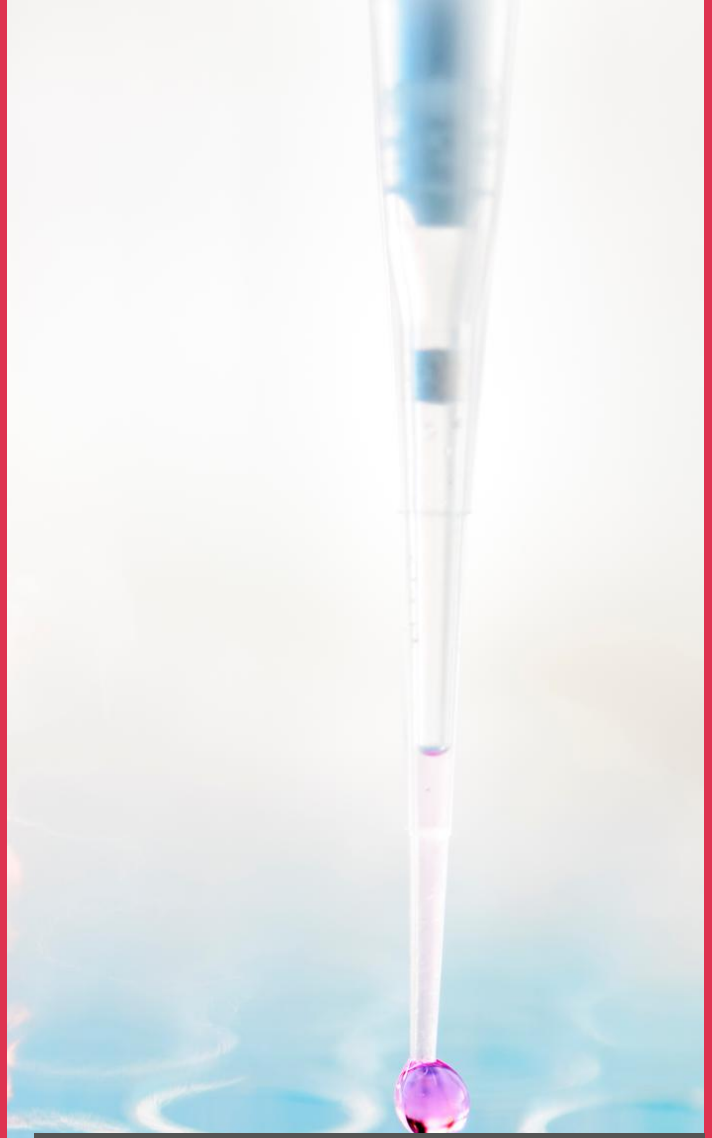
Understanding Labelling and UDI for Medical Devices and IVDs

5 - 8 October 2020

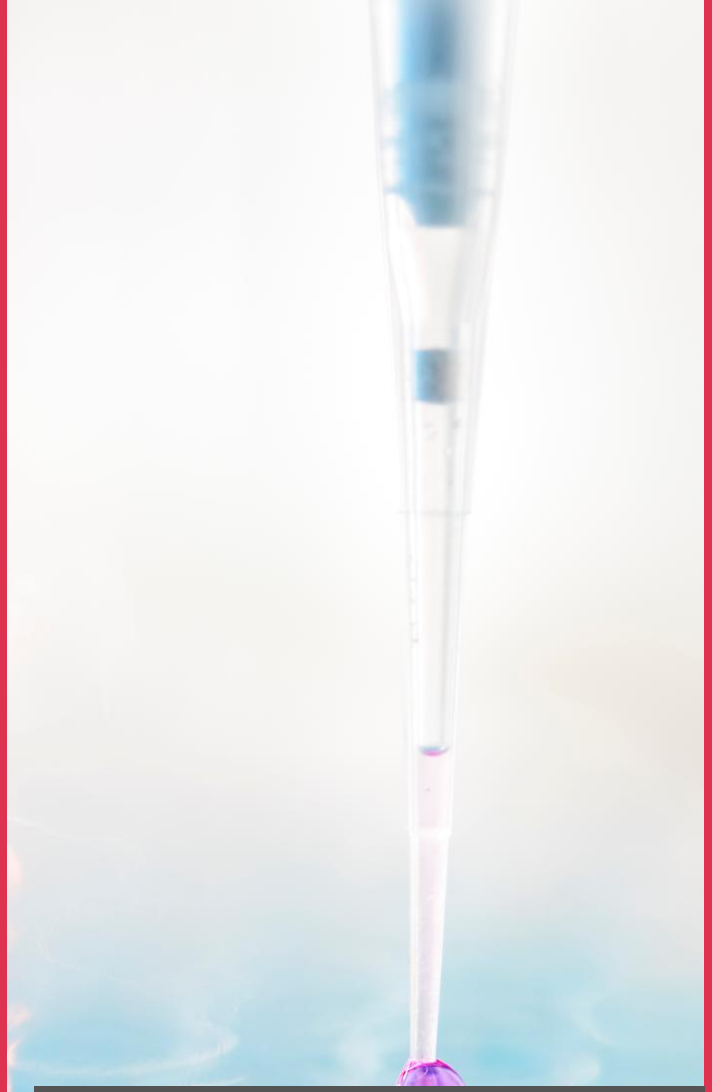
LIVE Online Academy



COURSE OVERVIEW

As the Medical Devices and IVD industries transition to the new Regulations, organisations must implement new processes across a wide spectrum of regulatory areas to remain compliant. Labelling is one of these areas which has undergone a change in requirements and now includes Unique Device Identification (UDI) and expanded content requirements.

On this course you will explore the new requirements, cross examining them with the requirements of the Directives. You will deep dive into the UDI requirements, fully understanding what is needed on the label and how it links up with the new EUDAMED database. Crucially, you will develop strategies to transition to the new labelling requirements, considering supply chain issues and Notified Body concerns. You will also explore how labelling is connected important areas/departments like PMS and design development and how these areas can influence the label.



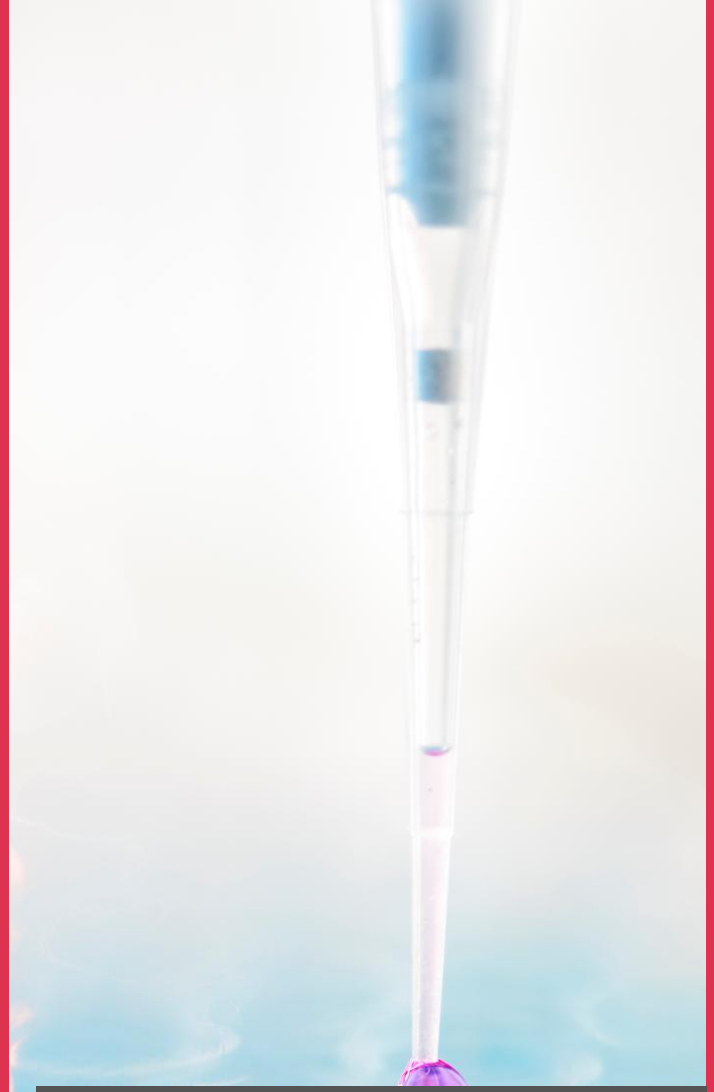
LIVE ONLINE COURSES

Gain real time access to a subject matter expert delivering online training in a structured virtual classroom environment.

What is a Live Online Course?

Live online courses are a new interactive and engaging education tool designed to provide training in real time with access to a subject matter expert (trainer). By using webinar technology, a virtual classroom is created providing direct contact with the trainer so you can ask questions, clarify complicated theories and fully understand the topicarea.

A live online course is broken down into manageable sessions that are delivered online at set times, providing a structured learning pathway for delegates. All sessions are recorded and uploaded to our virtual learning environment where you will have unlimited access to the materials for a month.



LIVE ONLINE COURSES

What are the benefits of studying a live online course?

- **Engagement & interaction**

All learning content is delivered in real time with our expert faculty, enabling you to have direct contact with the trainer during each session via live Q&A.

- **Structure & convenience**

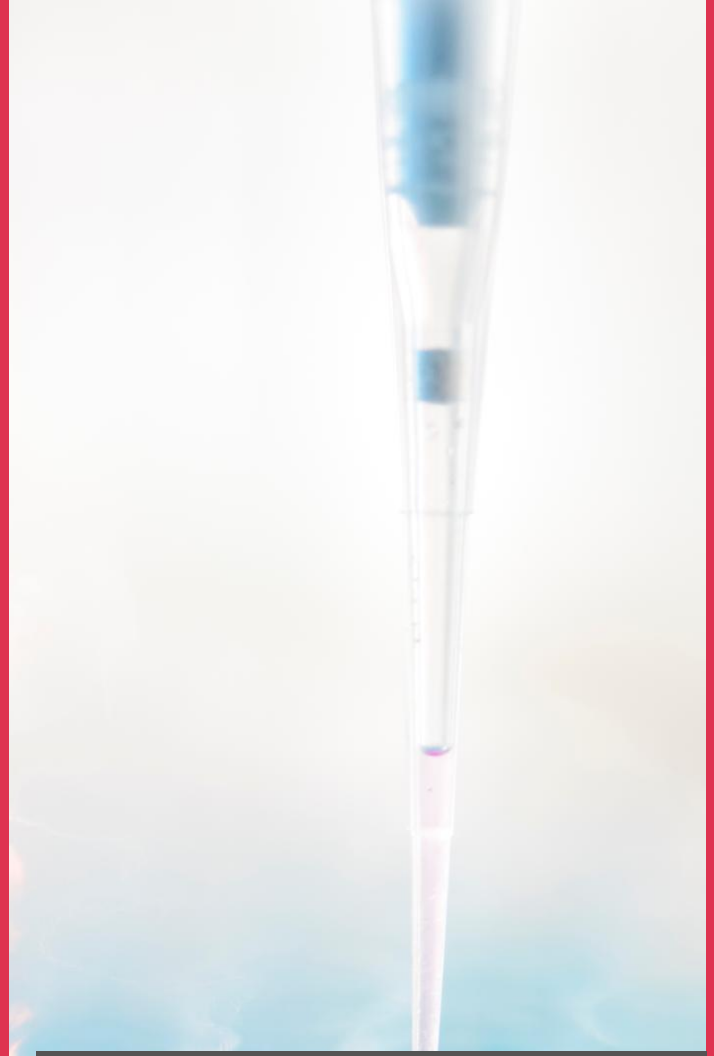
Bitesize sessions are delivered at set times meaning there is minimal disruption on your day to day function.

- **Cost-effectiveness & accessibility**

No travel or accommodation costs required for your team to attend training. The course can be studied from any location, all that you need is an internet connection.

- **Speed & flexibility**

Live online courses are fast to organise and deliver meaning your team cam be upskilled quickly. Revisit materials as often as you like for a month after the course, as everything is recorded and hosted on our virtual learning environment.



MEET THE TRAINER

RICHARD YOUNG

Richard Young has over 20 years' experience in the medical device industry with products such as class 3 implants to electromedical infusion systems. Richard has extensive experience in regulatory affairs, GMP (quality), GLP (laboratory testing) and clinical affairs. Richard has held various positions within industry such as QA/RA Manager and Director, Quality Assurance and Regulatory Compliance at various companies including Biomet, Plasma Surgical and Zimmer Limited.

Agenda: Session 1 - Regulatory basis of labelling

5 October 2020: 3pm - 5.30pm

Introduction and overview

- Examine the labelling requirements under the MDR

Labelling requirements under the new Regulations (MDR & IVDR)

Assess differences in labelling requirements between the new regulation and previous Directives.

- Understand the level of information instruction going on the label
- Understand the supporting information required for these changes
- Examine universally accepted, harmonised symbolsDiscuss the challenges with symbols and translation
- Review of labelling and packaging requirements at each stage of packaging
  - IFU, primary packaging, secondary packaging, tertiary packaging and pallet
  - Assess what is and is not required on each stage of packaging
- Examine electronic labelling
- Publishing labelling on your website
- How to print
- Examine the requirements in the US, highlighting key differences

Examine the requirements for specific cases

Assess differences in labelling requirements between the new regulation and previous Directives.

- Examine the impact of device class on the label
  - Understand the labelling requirements for: Single-use devices / Sterilisation / Implantable devices / Clinical investigation / Hazard warnings / Storage temperature / Economic operators

Agenda: Session 2 - Label design considerations

6 October 2020: 2pm - 4.30pm

Usability assessment and instructions for use (IFU)

Assess differences in labelling requirements between the new regulation and previous Directives.

- Review of the usability requirements compared those from the MDD
- Assess Instructions For Use (IFU) and how to ensure they meet usability requirements

Brexit

Some time will be spent on the impact of Brexit depending on the delegates attending. We appreciate it is a major issue for some but less so for others.

- What will the effect of Brexit have on labelling?
- Are we following same rules as the EU?
- If stock piling now, will the labels need to be changed at a later date?
- Will the CE mark need to be on the label?

Labelling linkages

Discover how labelling is linked to other process functions such as PMS, Risk Management and design development. You will learn how labelling impacts these key areas and vice versa.

- PMS and how labelling fits into this
- Design development
- Risk Management
- IFU need to print something to go with it
- Understand the electronic Instructions For Use eIFU

Agenda: Session 3 - Traceability and UDI

7 October 2020: 2pm - 4.30pm

Regulatory UDI requirements

UDI is linked to many regulatory areas making it important for organisations to engage with all relevant stakeholder to ensure MDR compliance.

- Definition of UDI and discuss the reasons for its introduction
- The regulatory ins and outs of UDI
- Strategies for achieving UDI success
  - Examine the timeframes
  - Review the information that must go into the UDI
  - Examine all the stakeholders involved in UDI
  - Making UDI fully integrated and comprehensive
- Identify the differences between existing US system and the new EU system
- Global UDI and database insights (GUDID)
- Learn how to register your UDI in target countries
- Consider the practical side of labelling systems and UDI printing

EUDAMED

- Examine how UDI is linked to the new EUDAMED database
- Examine the requirements in the US, highlighting key differences

Agenda: Session 4 - Practical Labelling considerations and MDR compliance

8 October 2020: 2pm - 4.30pm

Preparing for the MDR

- Strategies to get you labelling MDR compliant for the deadline
- Review strategies to be globally compliant such as the US and EU
- Examine how the conformity procedure route impacts labelling, basic UDI assignment, EUDAMED registration etc.
- How best to manage label design in the face of challenges:
  - NB designation
  - ISO updates standards for symbols
  - Brexit
- Best practice working with an overseas supply chain/ manufacturer

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For information or to book a course please contact our Training Consultants

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