

# Exciting Developments in Long-Term Educational Programs!

We are thrilled to bring you the latest updates on our range of long-term courses designed to enhance your skills and knowledge in MDR and iVDR. Let's dive into the details:

#### Module 1: Implementing Regulatory Requirements for Medical Devices

This dynamic module *will start on May 6th, 2024,* and will teach participants the essential skills required to audit against the Medical Device Regulation (MDR). The participants will gain a comprehensive understanding of MDR requirements, whether aspiring to become internal auditors, full-time auditors, or product assessors.

### Module 2: Generating Data for Technical Documentation (MDR)

The first session of this comprehensive Module 2 began on March 4th, 2024, focusing on delving into the intricacies of constructing Technical Documentation and Clinical Evaluation Reports. Participants will deepen their understanding of MDR compliance, building upon the foundational knowledge gained in Module 1. Mark your calendars because the next cohort of Module 2 is approaching!

### Module 3: Generating Data for Technical Documentation (IVDR)

Prepare yourself for the specialized world of In Vitro Diagnostic Regulation (IVDR) in Module 3 of our Postgraduate Certificate series. This module delves into the construction of Technical Documentation and Clinical Evaluation Reports under the IVDR framework, building upon the foundational knowledge from Module 1.

Applications for Module 3 *will open on July 11th, 2024*. Stay tuned for updates and mark your calendars for the application opening date.

Each module offers a 10-week program delivered entirely online, with a combination of virtual classroom sessions and online assessments. Upon completion, you'll receive a Postgraduate CPD certificate worth 5 credits, accredited by Technological University Dublin (TU Dublin).

Don't miss this opportunity to enhance your expertise in medical device regulations and advance your career! Follow us to stay up-to-date with the latest updates.

There's still time to **register for Module 1** on the following link:

Register Now



# Short-Term Courses and Interventions Update

In addition to our long-term courses, we're also excited to share updates on our short-term courses and interventions:

Short Course on Training for C-level Management of Market Operators on MDR/IVDR Implementation and Resource Allocation

Explore strategies for Success in the European Medical Device Industry:

- Learn to market your MedTech product effectively in Europe's regulatory landscape;
- Discover essential investments needed for regulatory compliance;
- Master the process of selecting the right Notified Body for your product;
- Develop and implement effective quality management systems;
- Gain insights from a startup investment timing case study;
- Engage in interactive discussions on regulatory challenges and opportunities.

Join us for an exclusive Short Course designed for C-level management professionals!

Sessions:

- 17 May 2024 Face to Face Session
- 🧰 24 May 2024 Webinar
- 🚃 31 May 2024 Webinar
- 🧾 7 June 2024 Webinar
- 📕 14 June 2024 Webinar
- 21 June 2024 Face to Face Session

Don't miss this unique opportunity to equip yourself with the knowledge and strategies necessary to navigate the complex European regulatory environment.

Register

## **NOBOCAP COMMUNITY**

# Calling All Innovators!

# Join NoBoCap Community



EU regulatory challenges, innovative solutions and initiatives toward strengthening the MedTech industry by enhancing the efficiency of Notified Bodies and Market Operators is more important than ever before.

We are calling Innovators to join the NoBoCap Community and become a part of our network driving change to Qualify to Certify! This could be the beginning of an unbelievable journey.

At NoBoCap Community, our pioneeristic and agile spirit keeps us interconnected with EU Regulatory challenges trying to increase knowledge and preparedness of Market Operators (MOs) in the application of MDR and IVDR.

NoBoCap Community allows you to be part of an innovation ecosystem designed to Unlock the EU regulation. Be one of those striving to bring innovation into healthcare and join the NoBoCap Community today!

Be innovative, bring unexpected ideas, push the boundaries, and contribute to solving complex challenges!

Visit our page

# If interest to join the community, please visit the What to Offer page and complete the application form.

Application form

## **NEWS**



# **NoBoCap Community Webinars**

It's never too early to.. Save the Date! The next exclusive webinar for the NoBoCap Community is set to commence in **June 2024.** 

The NoBoCap Community witnessed a momentous occasion with the exclusive webinar titled "**Welcome to the NoBoCap Community**" on March 21. The event, tailored specifically for NoBoCap members and partners, was a success and marked a significant milestone in our journey. The webinar delved into the main topic of unlocking EU regulations for innovation. With a focus on facilitating access to the regulatory framework, the discussions were enlightening and forward-thinking. Participants engaged in insightful conversations aimed at ensuring innovators can seamlessly navigate the complexities of the European market.

A central point of the presentation was the NoBoCap ecosystem. From Clusters & Hubs to Knowledge & Know-how partners, and Supporting Partners, the diversity and strength of our community were on full display.

Stay tuned for updates on the upcoming June webinar and other community initiatives, and be a part of shaping the future of innovation in Europe with NoBoCap.



### Stay informed! European Commission's website

In the realm of Medical Devices and In Vitro Diagnostics, staying informed of regulatory updates is essential for manufacturers, healthcare professionals, and patients.

The European Commission's Directorate-General for Health and Food Safety (DG SANTE) release regularly updates and reports that provides valuable insights into the status of certifications and applications under the MDR and IVDR Regulations. Visit the European Union's Health Website because it serves as an important resource for accessing the latest information and insights regarding the Medical Device Regulations (MDR) and the In Vitro Diagnostic Regulations (IVDR).

Visit website



### **Online Market Operators Survey**

We have designed an anonymous survey aimed at understanding the training needs of medical device market operators across the European Union. Your participation will provide important insights that can shape future training programs and improve industry standards.

Your cooperation in completing this survey is highly appreciated. Your input will help us better serve the needs of online market operators in the medical device industry.

Thank you in advance for your participation and support! Let's work together to enhance the effectiveness and efficiency of medical device markets in the EU.

Start the survey

#### NoBoCap

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