NoBoCap

NOBOCAP TRAINING PROGRAMS

Expand Your Expertise with NoBoCap's Final Training Modules in 2025

✅ As the regulatory landscape for medical devices and *in vitro* diagnostic medical devices continues to evolve, staying ahead of the

latest requirements is more important than ever. With NoBoCap, we are committed to supporting professionals like you with high-quality training programs designed to enhance your regulatory expertise and ensure compliance with MDR (EU 2017/745) and IVDR (EU 2017/746).

✅ We are pleased to introduce a series of comprehensive, expert-led courses designed for professionals working in the MedTech sector, from manufacturers and regulatory specialists to C-level executives and investors. These programs provide practical insights, hands-on learning experiences, and recognized certifications to help you navigate the complexities of EU medical device regulations with confidence.

NOBOCAP TRAINING MODULES

Module 1: Implementing Regulatory Requirements for Medical Devices

📅 **Start Date: September, 2025**

This module is ideal for professionals responsible for regulatory compliance, quality assurance, and risk management. Whether you're a manufacturer, virtual manufacturer, distributor, importer, or authorized representative, you'll gain the tools to integrate MDR-compliant risk management into your organization's quality system.

Module 3: Generating Data for Technical Documentation(IVDR)

📅 **Start Date: 16 September, 2025. Registration deadline: 8 September, 2025**

With IVDR bringing stricter requirements for IVD devices, this module offers detailed guidance on preparing a compliant

Technical File and developing a robust Performance Evaluation Report (PER) – key pillars of IVDR conformity.

🎓 **Each module runs for 10 weeks** (including 8 weeks of course delivery and 2 weeks for assessment preparation), totaling 100 hours of structured learning. Upon completion, participants will receive a **5-credit EQF7 Certificate**, accredited by University of Medicine, Pharmacy, Sciences and Technology of Târgu Mureş.

SHORT COURSES

✅ PERFORMANCE EVALUATION OF AI AS/IN A MEDICAL DEVICE

📅Date: October 21–23, 2025

On-site: **Bucharest, Chamber of Commerce and Industry** *(as part of the BEHEALTH 2025 – International Hybrid Event in Healthcare)*

Artificial Intelligence is transforming the MedTech landscape – but navigating regulatory requirements for AI-supported medical devices comes with unique challenges.

This **Advanced Short Course**, delivered in person by top industry experts, offers:

- A deep dive into AI performance evaluation methodologies;
- Practical insights into regulatory expectations for AI-based medical technologies;
- A hands-on, 3-day training experience designed for professionals seeking clarity on AI as/in a Medical Device.

✅ C-LEVEL MANAGEMENT TRAINING

📅 **Date**: **November, 2025**

This exclusive course is designed for decision-makers and executives looking to optimize compliance strategies across their organizations.

Gain actionable insights into:

- Resource allocation in regulatory contexts;
- Managing MDR/IVDR-related risks;
- Dossier preparation for Notified Body submissions.

✅ MDR TRAINING FOR INVESTORS

📅 **Date: December 8–10, 2025**

On-site: TivoliVredenburg, Utrecht, Netherlands *(as part of the HealthTech Investor Summit – Connecting European HealthTech Entrepreneurs and Investors)*

For investors interested in the MedTech and medical devices sector, understanding MDR is key to making informed decisions. This course introduces relevant aspects of the EU regulatory landscape, to better understand the environment in which MedTech companies operate.

Don't miss this opportunity - Register now via the NoBoCap Portal and take the next step in your MedTech journey!

To apply in any of these courses, follow these simple steps:

👉 **How to Register**:

1. Visit https://portal.nobocap.eu

2. Create your account:

3. Navigate to the **NoBoCap Courses** section and check the next session start date and **register** for the course that best fits your needs:

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 pioneering 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:** https://nobocap.eu/community/

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

👉 **Application form:** https://eu4healthsolutions.formstack.com/forms/nobocap_community_application_clusters_hubs

NoBoCap Summit 2025 – New Edition Coming Soon !

📅 **Date: 15 – 16 October, 2025**

📍 **Brussels, Belgium**

🌐 Hybrid *format – onsite & online*

Bringing Europe together to Unlock the MDR/IVDR for Innovation in Europe

The Summit will bring together the **NoBoCap European Community of Innovation Hubs and Clusters**, alongside regulatory partners, Notified Bodies, National Competent Authorities, and representatives of the **Medical Device Coordination Group** and the **European Commission**.

Spin-offs, start-ups, scale-ups, investors, and key stakeholders from the MedTech ecosystem are invited to join this pivotal event on-site in Brussels.

📅 15 October – Pre-Summit Workshops

Join a series of practical sessions designed to offer valuable insights and hands-on experience with NoBoCap Services that support the unlocking of **MDR/IVDR and the AI Act** for innovation:

- Deep dives into the “valley of death” for innovators;
- Demonstrations of classification software, training tools, and matchmaking;
- Certification pathways for AI-supported technologies with Notified Bodies;
- Investor readiness and community-driven evaluations.

📅 16 October – Summit Day

The main day of the Summit features keynote presentations, expert panels, and interactive debates focusing on how to build a **more innovation-friendly regulatory system** in Europe.

Topics include the **impact of MDR/IVDR and the AI Act on innovation**, structured dialogue and scientific advice for early-stage innovators,

and practical approaches to integrating new technologies into health systems.

The event also highlights the role of the **NoBoCap Community in action**, with Innovation Hubs, SMEs, and partner organizations presenting initiatives that foster regulatory preparedness and accelerate market access.

👉**Explore the full programme and register here:**

https://ofcores.idloom.events/nobocap-summit

Next Event:

NoBoCap at BEHEALTH 2025 – Dedicated Panel on MDR/IVDR Implementation

📅 **October 20, 2025**
📍 **Romanian Government, Bucharest**
🌐 Hybrid *format – on-site & online*

As part of the BEHEALTH 2025 – International Hybrid Event in Healthcare, the **NoBoCap project will host a dedicated panel** on the impact of MDR and IVDR regulations across European healthcare systems.

Panel 1: Medical Devices Regulations (MDR and IVDR): Impacts on Healthcare Systems

⏰ **09:30–13:00** | 📍Room: TBC

This panel will explore the practical implications of EU regulations on medical devices, highlighting:

- Compliance challenges for healthcare providers and innovators;
- The evolving support role of Notified Bodies and community partners;
- The strategic importance of innovation for navigating complex requirements;
- Real-world needs from hospitals, SMEs, and regulators in the field.

EU4Health Objective: Developing and implementing European Union health legislation.

The BEHEALTH agenda will also feature additional sessions on **funding opportunities, international cooperation, and digital innovation in healthcare**.

👉Register: https://www.b2match.com/e/behealth-2025
