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NoBoCap

About Community Contacts

NOBOCAP TRAINING PROGRAMS

Expand Your Expertise with NoBoCap Training Programs!

✅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 medical device regulations with confidence.

NOBOCAP TRAINING MODULES

Module 1: Implementing Regulatory Requirements for Medical Devices

📣 **Start Date: September 2025**

Understanding and applying regulatory requirements is essential for ensuring compliance and market access. This module is designed for professionals who are directly responsible for regulatory compliance, quality assurance, and risk management. Whether you work as a manufacturer, virtual manufacturer, distributor, importer, or authorized representative, this course will equip you with the tools needed to integrate medical device risk management into your quality and risk management systems.

Module 2: Generating Data for Technical Documentation – MDR

📣 **Start Date: May 2025**

One of the biggest challenges for manufacturers today is the preparation of robust Technical Documentation in line with MDR (EU 2017/745). This module provides in-depth guidance on two critical aspects:

✅Technical File preparation – Learn how to structure and compile the necessary documentation for regulatory submission.

✅ Clinical Evaluation Report (CER) – Understand the essential elements of clinical evaluation and how to meet the regulatory expectations of Notified Bodies.

Module 3: Generating Data for Technical Documentation – IVDR

📣**Start Date: April 14, 2025**

With IVDR (EU 2017/746) bringing stricter requirements for in vitro diagnostic (IVD) devices, ensuring compliance is more complex than ever. This course is specifically designed for IVD manufacturers, providing detailed insights into:

✅Technical File preparation - Learn how to structure a complete and compliant dossier.

✅ Performance Evaluation Report (PER) - Gain a deep understanding of performance evaluation requirements and the data necessary to support regulatory approval.

* Each of these modules 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, a valuable credential for professionals looking to solidify their regulatory expertise.

SHORT COURSES

Additional SHORT COURSES – Specialized Training for MedTech Professionals

C-level Management Training: MDR/IVDR Implementation and Resource Allocation

📣**May – June 2025**

This exclusive course is designed for C-level executives seeking to optimize regulatory compliance strategies within their organizations. Learn how to effectively allocate resources, manage compliance risks, and streamline dossier preparation for Notified Body submissions. This course is essential for decision-makers looking to strengthen their organization's regulatory preparedness and ensure a smooth transition under MDR/IVDR.

Performance Evaluation of AI as/in a Medical Device

📣**October 21–24, 2025**

Artificial intelligence is reshaping the MedTech industry, but navigating regulatory requirements for AI-supported medical devices presents unique challenges. This advanced short course provides:

✅ A deep dive into AI performance evaluation methodologies.

✅ Practical insights into regulatory expectations for AI-based medical technologies.

✅ A 3-day in-person training experience with industry experts.

Short Course: Training on MDR for Investors

📣 **June 4, 2025**

For investors interested in the MedTech and medical devices sector, understanding MDR is key to making informed decisions. This training session will provide an overview of key regulatory challenges, approval timelines, and compliance considerations that impact investment in medical technologies.

By joining these courses, you will gain practical knowledge, expert guidance, and a valuable certification that will empower you to excel in your regulatory role. Whether you are preparing your organization for MDR/IVDR compliance, seeking to strengthen your technical expertise, or investing in MedTech innovation, these programs are designed to support your professional growth and industry success.

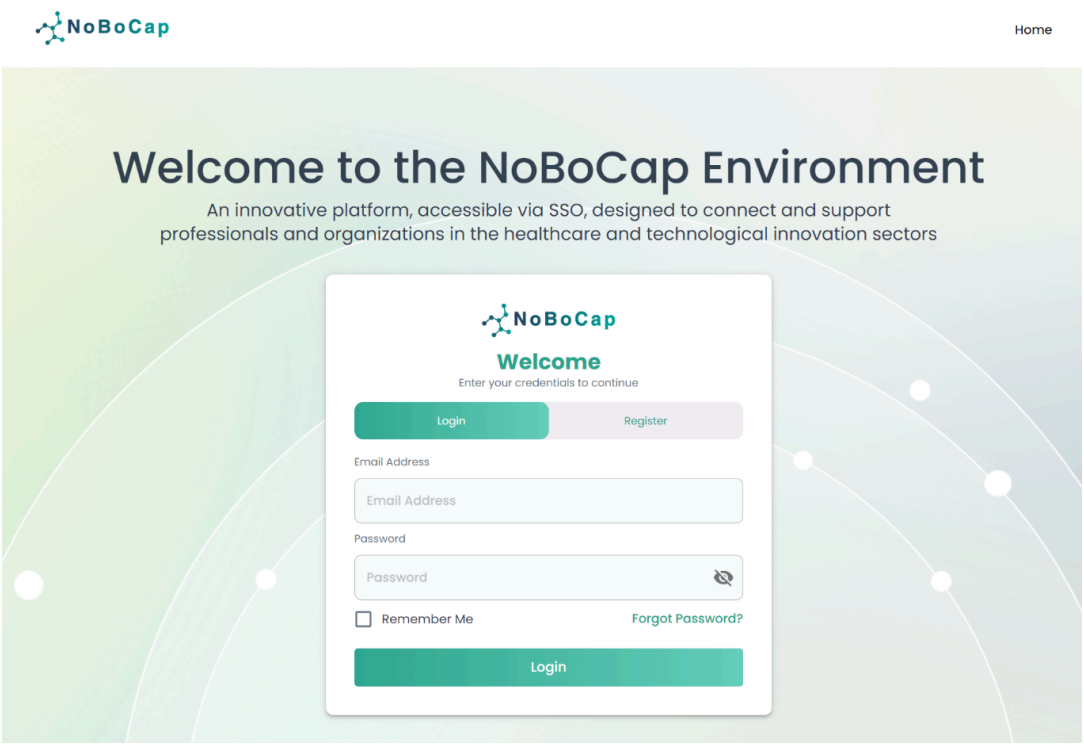
Don't miss this opportunity – register today and take the next step in your MedTech journey!

Secure Your Spot – Register Now!

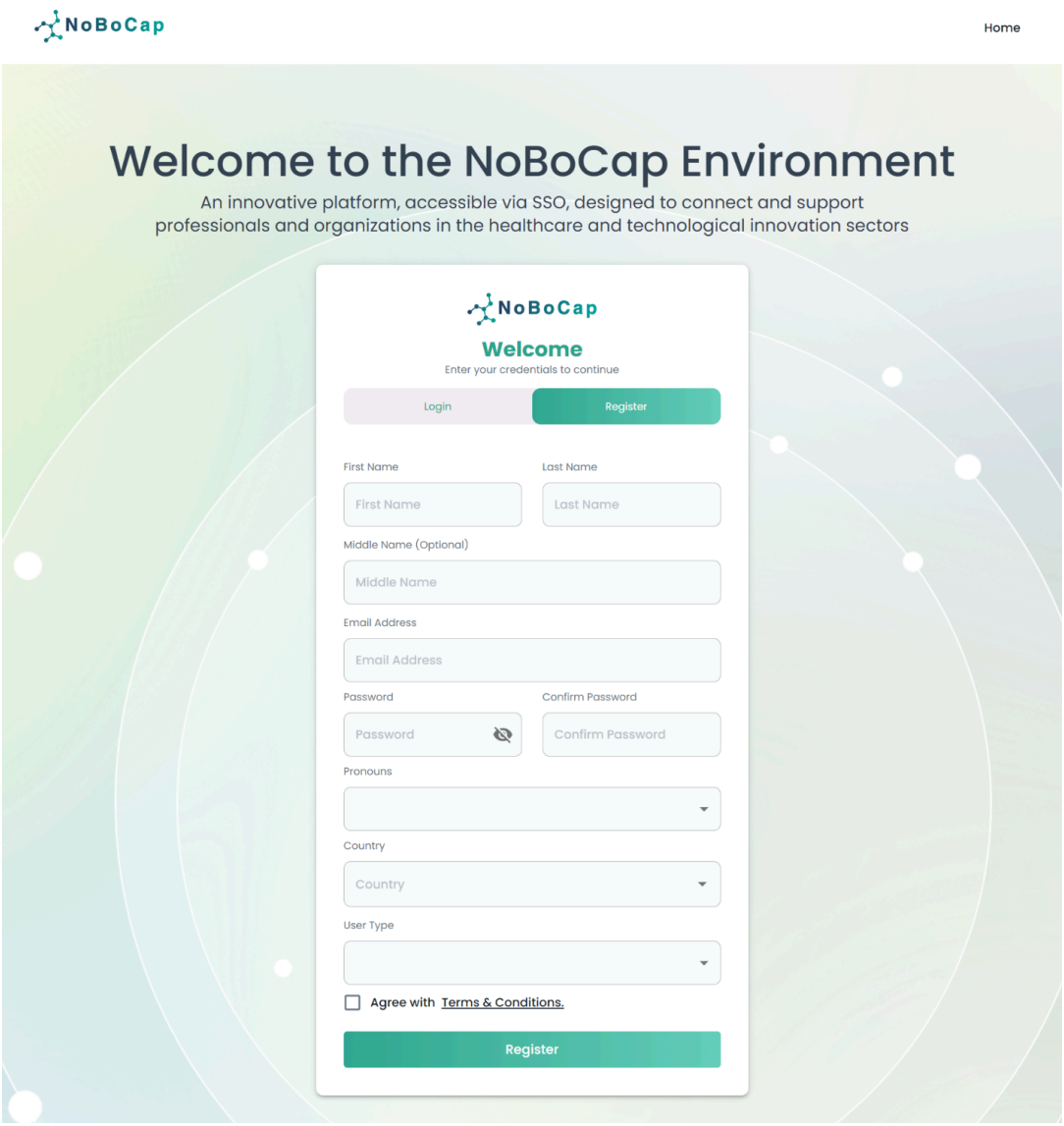
To apply in any of these courses, follow these simple steps:

👉 **How to Register**:

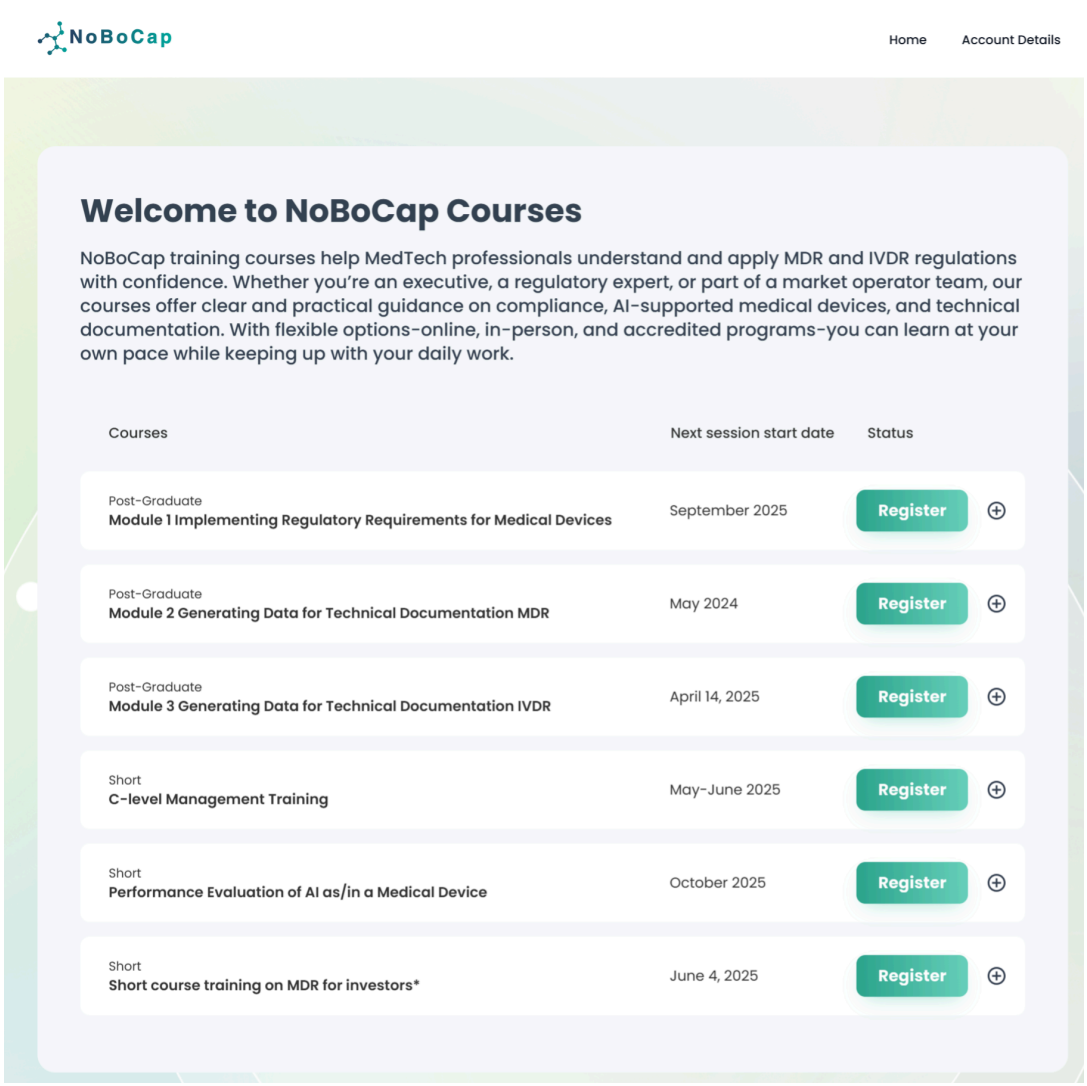
1. Visit https://portal.nobocap.eu



2. Create your account:

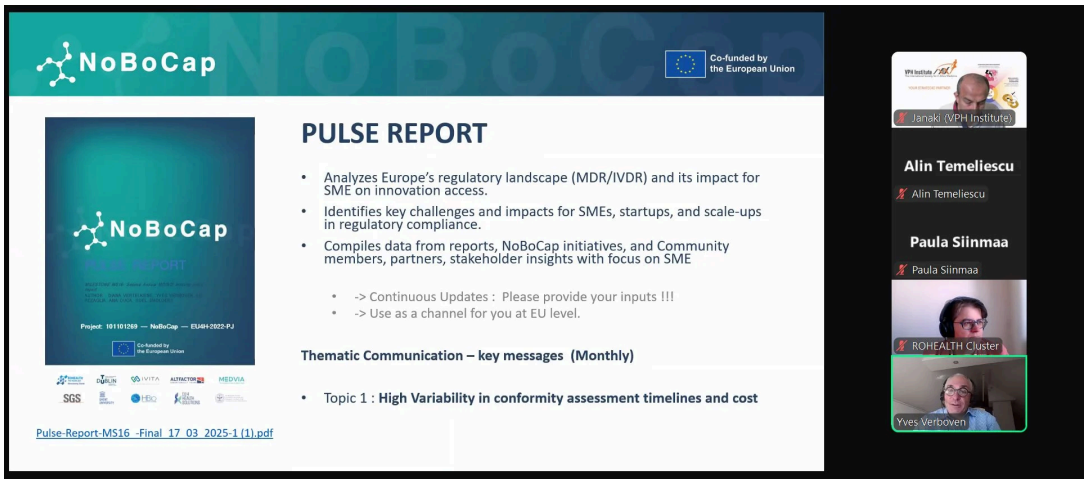


3. Navigate to the **NoBoCap Courses** section and check the next session start date and **register** for the course that best fits your needs:



NOBOCAP COMMUNITY

NoBoCap Community Online Webinar – Driving Innovation Through MDR/IVDR!



On March 20th, the NoBoCap Community of Innovation Hubs, Clusters, and Partners gathered for another insightful webinar, continuing our mission to *Unlock MDR/IVDR Regulation for Innovation.*

Webinar Highlights:

✅ **Welcome & Future Plans**: Yves Verboven (EU4HealthSolutions) introduced new members, emphasized the value of our monthly e-webinars, and announced the NoBoCap Summit on October 15-16, 2025.

✅ **Community Channel & Pulse Report**: The NoBoCap Community Channel was spotlighted as a space for exchange, featuring the Pulse Report on MDR/IVDR's impact on innovation and regulatory challenges.

✅ **European Commission Evaluation**: A reminder about the ongoing *Call for Evidence* and Public Consultations on the *Have Your Say* portal, closing March 21, 2025.

✅ **Regulatory Expertise**: Alec Macknight (SGS) shared University Accredited Level 7 Modules, designed to enhance regulatory knowledge and navigate medical device regulations.

✅ **Classification Software Insights**: Ruth Beckers (Qualix Belgium) discussed digital classification software, addressing high-risk classification issues and evolving compliance requirements.

✅ **MedTech Innovation**: Maika Sabido Siller (BASQUE HEALTH CLUSTER) provided insights into regional MedTech innovation, emphasizing the importance of collaboration between industry and regulators to enhance market access.

Next Webinar:

📅 **April 17, 2025**

Let’s Stay Connected and Exchange – Join Forces!

Stay tuned for more details on how we can continue to collaborate and innovate in the MedTech space.

NoBoCap

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