

01 JUL 2026

03 JUL 2026

# MEDICINES AND MEDICAL DEVICES

## Safety and Risk Management in the Real World Clinical Practice

5<sup>th</sup> Edition

**ADVANCED  
EDUCATION**

NOVA MEDICAL SCHOOL



## **COURSE PRESENTATION**

Health technologies with a significant impact on longevity are mainly medicines and medical devices, with notable progress reflected in advanced and combination therapies that incorporate clinical, economic and regulatory challenges.

Healthcare professionals, patients, the pharmaceutical industry and regulators are key stakeholders, as they ensure the rational, appropriate and safe use of health technologies. Within the complex European regulatory system for Risk Management and Pharmacovigilance, it is essential to understand the regulatory requirements that all actors in the value chain must comply with in order to guarantee patient safety.

A detailed analysis of the Risk Monitoring System in the area of medicines and medical devices, and its management through risk minimisation and risk communication plans, in accordance with Good Pharmacovigilance Practices, is becoming increasingly important for healthcare professionals operating within the health ecosystem.

The acquisition of knowledge in risk quantification methodologies and signal detection, critical discussion of periodic safety reports, and a thorough understanding of the spontaneous reporting system and causality assessment models are, among other topics, areas that should be learned through interactive and multidisciplinary discussion, based on real cases and supported by experts in the clinical and regulatory fields of medicines and medical devices.

An important part of the evidence currently and in the future generated within this value ecosystem lies in the use of epidemiological and statistical methodologies applied to real-world data, where Big Data and the Internet of Things will undoubtedly play a particularly significant role. Pharmacoepidemiology and its methods make important contributions to understanding the safety profile of medicines in clinical use and support the measurement of health gains and the effectiveness of risk management measures, thereby ensuring the optimisation of healthcare resources.

**5TH EDITION**

**1,5 ECTS**

**24 HOURS**

Application deadline: **JUNE 1, 2026**

## LEARNING OBJECTIVES

1. To understand and correctly interpret the critical aspects of European legislation on Risk Management and Pharmacovigilance for medicines and medical devices.
2. To acquire knowledge of the European regulatory framework for the application of signal detection methodologies and the development of risk management plans, recognising their importance in ensuring patient safety.
3. To equip participants with an understanding of the mechanisms of action of adverse drug reactions (ADRs), addressing the pharmacovigilance of therapeutic classes of particular relevance due to the frequency and severity of adverse reactions, and the prevention of avoidable ADRs.
4. To gain in-depth knowledge of Spontaneous Reporting Systems, from case reporting and management through to their integration into European information systems and the preparation of safety reports.
5. To further develop participants' knowledge of epidemiological methodologies applied to the post-authorisation phase of medicines and medical devices, for the monitoring of their safety profile in clinical practice, and for the analysis and interpretation of meta-analytical studies that generate evidence with an impact on medicines safety.

## COORDINATION



**Maria Teresa Herdeiro, PharmD,  
MScPharma, MSc, PhD**

## FACULTY

**Ana Sofia Martins, PharmD, MSc**  
**Carla Santos, PhD**  
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**Rui Marques, PharmD, PhD**  
**Rui Pombal, MD**

# PROGRAM

IN-PERSON

NOVA Medical School | Campus Carcavelos

24H

DAY 1 | 01/07/2026

09h00 – 18h00

## REGULATIONS IN PHARMACOVIGILANCE AND RISK MANAGEMENT IN EUROPE. DRUGS AND MEDICAL DEVICES

European regulatory framework for drugs and medical devices  
European pharmacovigilance legislation & good pharmacovigilance practices  
Periodic safety update reports  
Risk management plan & risk minimization activities  
Signal detection  
Causality assessment in pharmacovigilance- Methods

DAY 2 | 02/07/2026

09h00 – 18h00

## RISK-BENEFIT ASSESSEMENTS IN PHARMACOVIGILANCE & RISK MANAGEMENT

Regulatory framework for medical devices  
Safety of medical devices: The Regulators Perspective  
Drug Safety During Clinical Trials  
Mechanisms of adverse drug reactions, cardiovascular, neurological, renal and hepatic  
Spontaneous reporting system & Eudravigilance

DAY 3 | 03/07/2026

09h00 – 18h00

ONLINE

## REAL WORLD EVIDENCE APPLIED TO SAFETY AND RISK MANAGEMENT OF DRUGS AND MEDICAL DEVICES

Responsibilities of the MAH with regard to pharmacovigilance  
Post-authorization safety studies  
ADRS monitoring in hospital pharmacy  
Submission of the Technical Documentation to the Notified Bodies, with a Focus on the  
Clinical Evaluation  
Innovative methods for safety and effectiveness assessment and prevention in health care  
Assessment

Este curso conta com o apoio de

### **COURSE FEE: 750€**

Application fee: **50€**  
Tuition fee (incl. insurance + coffee-breaks): **700€**

### **APPLICATION REQUIREMENTS**

Healthcare professionals,  
Pharmacovigilance and Risk Management  
Technical Managers in the pharmaceutical  
industry, Pharmacovigilance Units,  
Pharmacists and Nurses

CV

### **ADMISSION CRITERIA**

When applying for a course, the applicant agrees to subject personal and professional data. This data will be verified and assessed to check that the applicant meets the admission criteria for the specific programme.

Applications are accepted on a rolling basis during the application window unless there is a priority in the target audience. This may result in applications closing once the limit for number of participants has been reached.

**MAX. PARTICIPANTS: 16**

### **ATTENDANCE REQUIREMENTS**

For attendance certification as well as awarding ECTS credits and/or CME certification it is mandatory to complete:

- 90% attendance
- Evaluation

### **LANGUAGE**

Portuguese  
English

### **PROGRAM MANAGER**



**EDUARDO PARREIRA**

### **ADDITIONAL INFORMATION**

**For more details, please contact the Program Manager:**

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