

MEDICINES  
AUTHORITY



**ACADEMY**  
FOR PATIENT CENTRED  
EXCELLENCE AND INNOVATION  
IN REGULATORY SCIENCES

**Award in Pharmacovigilance**



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## Award in Pharmacovigilance

*A Higher Education Programme accredited by the Malta Further and Higher Education Authority*

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A course spearheaded by the MMA Academy, providing a comprehensive understanding on Pharmacovigilance aligned with the European Medicines Agency (EMA) guidelines on Good Pharmacovigilance Practices (GPV). It seeks to endow participants with the ability to evaluate and assess risks in a systematic and risk-based manner, empowering them to design and implement robust systems for managing Pharmacovigilance effectively, ensuring patient safety and regulatory compliance. The keynote speaker's vast experience within the dynamic sphere of Pharmacovigilance will provide participants with invaluable first-hand practical insights, bridging the gap between theory and practice.

**EQF/MQF Level:** 6

**ECTS:** 1

**Mode of Attendance and Duration:** Part-time for a total of 25 hours, including lectures (18 hours), self-study (6 hours) and assessment (1 hour)

**Status:** Open for enrolment **Dates:** To be announced

**Venue:** Malta Life Sciences Park, San Ġwann

### Keynote Speaker:

Dr Calin A. Lungu, a seasoned expert with over 30 years' experience in Drug Development, Clinical Research, Pharmacovigilance and Quality Assurance; Lead Eudravigilance (EV) and eXtended EudraVigilance Medicinal Product Dictionary (XEMPD) Trainer; expert Pharmacovigilance Auditor and Pharmacovigilance and Quality Assurance consultant.

### Objective:

This course shall provide participants with a thorough understanding of the key principles and requirements of Pharmacovigilance, consolidating their knowledge and skills within this field and ensuring that they are equipped to effectively implement and comply with EMA guidelines. In tandem it shall serve as a networking forum for the dissemination of knowledge and best practices.

### Learning outcomes:

#### Knowledge

The participant will be able to:

- Define Pharmacovigilance and its scope.
- Describe the regulations and guidelines covering Pharmacovigilance in the EU.
- Identify key Pharmacovigilance areas and describe systems for their management.
- List Pharmacovigilance obligations for Marketing Authorisation Holders (MAHs).

#### Skills

The learner will be able to:

- Apply multi-disciplinary knowledge for the comprehension of how medicinal product safety is handled.
- Communicate in appropriate technical language Pharmacovigilance requirements as described in the Good Pharmacovigilance Practice guidelines.
- Practice the ability to keep up to date on regulatory sciences requirements.
- Demonstrate critical appraisal skills in the review of emerging safety issues for medicinal products and take decisions on when medicinal product information updates are needed.
- Apply knowledge to create risk-based systems to manage Pharmacovigilance.

**Target Audience:**

Professionals working within or having an interest in Pharmacovigilance.

**Entry requirements:**

Prospective applicants must have minimum qualifications at MQF level 5 in a science related area or apply for consideration through the [Recognition of Prior Learning \(RPL\)](#).

For third country nationals, the link to Identity Malta's VISA requirement refers: <https://www.identitymalta.com/unit/central-visa-unit/>

**Delivery:**

This programme is delivered in the English Language. The Traditional/Face-to-Face learning approach ensures that the speaker(s) and participants engage in discussions and debates, exchange ideas, and collectively analyse evolving scenarios and prospective outcomes. In tandem, participants are encouraged to work on independent critical thinking and become proactive leaders in their own learning process.

**Assessment:**

At the end of the course, participants shall complete a 1-hour synoptic summative assessment, consistent with the intended learning outcomes. This shall consist of a set of multiple-choice questions which only have one correct answer.

**Certification:**

Upon successful course completion, participants are granted an Award in Pharmacovigilance, accredited and recognised by the Malta Further and Higher Education Authority.

**Course Fee:**

€950

Interested individuals are invited to read the [MMA Academy IQA Policy](#).

For further information or assistance, kindly contact the MMA Academy via [academy.medicinesauthority@gov.mt](mailto:academy.medicinesauthority@gov.mt) or 23439168/23439200

