MALTA
MEDICINES
AUTHORITY

ACADEMY
FOR PATIENT CENTRED EXCELLENCE AND INNOVATION IN REGULATORY SCIENCES

Award in
Medicinal Product Licensing
and Lifecycle Management

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

The Award in Medicinal Product Licensing and Lifecycle Management is an advanced programme on the European regulatory framework governing medicinal products. It focuses on the application of key regulatory principles in real-world contexts, covering marketing authorisation and licensing procedures, regulatory strategy and the management of medicinal products throughout their lifecycle, from development and authorisation to post-approval changes and pharmacovigilance. This course aims to develop an advanced understanding of the European regulatory framework governing medicinal products, strengthen knowledge of EU marketing authorisation and licensing procedures and enhance competence in the development and implementation of effective regulatory strategies. It also seeks to equip participants with the skills required to manage medicinal products throughout their lifecycle including post-authorisation activities and pharmacovigilance obligations, while promoting informed regulatory decision making to ensure compliance, product quality and efficacy and patient safety. Overall, the programme is designed to consolidate professional competence and support effective application of regulatory principles throughout the medicinal products' lifecycle.

EQF/MQF Level: 7 **ECTS:** 3

Mode of Attendance and Duration: Part-time for a total of 75 hours, including lectures, self-study and assessment.

Dates: 20, 21, 22 October 2026 **Venue:** Malta Life Sciences Park, San Ġwann

Speakers: Seasoned experts with extensive related experience.

Learning outcomes:

Competences

At the end of the course participants will have acquired the responsibility and autonomy to:

a) Manage regulatory activities, exercising professional judgement in decision-making.
b) Adapt to legislative and technological change, proactively updating practices in response to EU reforms and digital innovations.
c) Evaluate the essential components of regulatory dossiers and alignment with EU and national requirements.
d) Guide teams and stakeholders through evolving regulatory environments, ensuring alignment with regulatory expectations.
e) Collaborate effectively across disciplines, contributing to harmonized regulatory approaches.

Knowledge

At the end of the course participants will have been exposed to the following:

a) Discuss the overarching goals of regulatory policy, transparency, and governance, and how these contribute to safeguarding public health within the EU regulatory system.
b) Explain the structure and role of the European medicines regulatory system, including the key institutions, committees, and legal frameworks that underpin medicinal product licensing in the EU.
c) Describe the main marketing authorisation procedures—National Procedures, Mutual Recognition Procedure, Decentralised Procedure, and Centralised Procedure, indicating the regulatory contexts in which each procedure is applied.
d) Identify the purpose and regulatory basis of parallel importation and distribution, and key exceptional pathways, such as Article 20, Compassionate Use, Named Patient Supply, and other exemptions, describing when these mechanisms may be applied.
e) Outline the principles of lifecycle management, including renewals, variations (Type IA/IB/II), and post authorisation obligations at a high level.
f) Summarise the components and purpose of the Common Technical Document (CTD) and explain how it supports assessment and regulatory decision making across the EU network.
g) Explain the importance of pharmacovigilance and safety monitoring.
h) Recognise the principles of supply chain integrity, including the role of product information, public assessment reports, and measures for the prevention of falsified medicines.

Skills

At the end of the course participants will have acquired the following skills:

a) Evaluate and select appropriate regulatory pathways, balancing efficiency, compliance, and patient access.
b) Integrate data-driven oversight into regulatory planning.
c) Analyse emerging trends in regulatory digitalisation, including structured data initiatives [e.g. Identification of Medicinal Products (IDMP); Substance, Product, Organisation and Referentials (SPOR)] and their high-level impact on national competent authorities.
d) Apply risk-benefit methodologies, quality risk management principles, and regulatory decision-making tools.
e) Apply the principles of regulatory intelligence and horizon scanning, and their relevance to decision-making, planning, and maintaining regulatory readiness.

Target Audience:

This course is intended for individuals who wish to deepen their expertise in medicinal product licensing and lifecycle management within the EU regulatory framework. It is particularly targeted at pharmacists, scientists, and regulatory professionals involved in marketing authorisation procedures, post-authorisation changes, pharmacovigilance and the strategic management of medicinal products throughout their regulatory lifecycle.

Entry requirements:

Target audience must have minimum qualification(s) at MQF level 6 in a 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 course is delivered in the English Language. The Traditional/Face-to-Face learning approach in the form of classroom-based training will be adopted. The teaching process will be inclusive by recognizing the diverse backgrounds, learning styles, and needs of learners. Learning spaces will be physically accessible and materials will be provided in multiple accessible formats. Presentations and standard learning resources, alongside interactive discussions, group tasks, practical exercises and question and answer sessions will be incorporated. This mode of delivery ensures the speakers 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:

On completion of the course, participants shall complete a synoptic assessment consistent with the intended learning outcomes.

Certification:

Upon successful course completion, participants are granted an Award in Medicinal Product Licensing and Lifecycle Management, accredited and recognised by the Malta Further and Higher Education Authority.

Course Fee:

€950

Registration:

Interested individuals are invited to read the **MMA Academy IQA Policy.**

Prospective applicants are encouraged to register via the **Online Registration Form** by 11 September 2026.

For further information or assistance, kindly contact the MMA Academy via academy.medicinesauthority@gov.mt or 23439188 / 2343 9280

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