MALTA
MEDICINES
AUTHORITY

ACADEMY
FOR PATIENT CENTRED
EXCELLENCE AND INNOVATION
IN REGULATORY SCIENCES

Award in Basic Regulatory Sciences

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

A course spearheaded by the MMA Academy, intended to deliver a strong and comprehensive foundation in basic aspects of regulatory sciences. It is directed at personnel seeking to enhance their knowledgebase, skill set and competences in this dynamic sphere.

EQF/MQF Level: 4

ECTS: 1

Mode of Attendance and Duration: Part-time for a total of 25 hours, including lectures (23 hours), self-study (1 hour) and assessment (1 hour)

Dates: 4,5 and 6 September 2023

Venue: Malta Life Sciences Park, San Ġwann

Speakers:

Seasoned speakers with experience in the field of regulatory sciences and academia, including professionals from within the Malta Medicines Authority along with lecturers affiliated to the University of Malta.

Objective:

To provide a strong foundation in the basics of regulatory sciences, alongside a networking forum for dissemination of knowledge and best practices, supporting the delivery of pharmaceutical processes and services of excellence.

Learning outcomes:

Knowledge

The participant will be able to:

a) Understand what regulation is and define basic regulatory terms and abbreviations.
b) Detail the scope and history of medicinal product regulation and discuss key elements of risk within the pharmaceutical scenario.
c) Acknowledge the existence of diverse pharmaceutical regulated settings and outline essential skills required when working within such settings.
d) Gain awareness of existing national and European Directives, regulations, recognised standards and guidelines and grasp key principles and requirements emanating from them.
e) Outline the role and limitations of competent authorities including the structure of the Malta Medicines Authority (MMA) and appreciate the importance of collaborative practice.
f) Describe key aspects relating to quality management including what a Quality Management System (QMS) is and why it is needed, what an effective QMS looks like, common core principles, advantages of a robust QMS and consequences when a QMS is not followed, in accordance with ISO 9001:2015.
g) Describe the importance of the package leaflet, labelling and additional risk minimisation measures and understand what information they contain.
h) Understand basic principles of Good Manufacturing and Good Distribution Practices.
i) Discuss fundamental concepts and activities relating to pharmacovigilance.
j) Understand the basic rationale and principles of digitilisation within a rapidly evolving digital era.
k) Discuss the basics and essentials of medical devices and their regulation.
l) Grasp the concept of regulation as a science and describe the notion of person-centred regulation.
m) Understand the importance of abiding by set laws and regulations whilst avoiding potential victims of the system.
n) Describe how the approach towards regulation of pharmacy has evolved over the years from policing to compliance to adherence to concordance.

Skills

The learner will be able to:

a) Apply basic principles of regulation and use basic regulatory jargon in day-to-day activities.
b) Show awareness of risk within the pharmaceutical setting and refer to appropriate regulations, guidelines and any other corresponding sources when carrying out daily duties.
c) Operate within applicable rules, regulations, guidelines and standards and apply mastered essential skills when executing daily tasks.
d) Collaborate with peers across different practices.
e) Sustain a culture based on robust quality management systems.
f) Refer to package leaflets and labelling and infer information from such texts.

g) Apply basic principles of Good Manufacturing and Good Distribution Practice in daily operations.
h) Appreciate the significance of prevention, recognition, management and reporting of adverse drug reactions in ensuring patient drug safety.
i) Demonstrate the ability to differentiate between different digital tools and adopt digital principles within daily operations, where applicable, to ensure safe, effective and high-quality pharmaceutical processes and services.
j) Recognise the need for rigorous regulation to ensure market availability of medical devices that are of optimal quality, safety and efficacy.
k) Acknowledge the relevance and importance of science in regulation and the consequences of not considering or deviating from scientific principles and standards.
l) Practice with the premiss that the patient is at the fulcrum of all pharmaceutical activities.
m) Recognise the potential risk of creating victims of the system whilst striving to comply with set rules and regulations.
n) Appreciate how reaching concordance to regulation through positive cooperation and collaboration as distinct to forceful compliance may lead to enhanced motivation and continuous improvement.

Target Audience:

Individuals seeking to gain a strong foundation in the basics of regulatory sciences. Key personnel may include but are not limited to personal assistants, administrators, receptionists, operators, storekeepers and other support staff both in government agencies and industry.

Entry requirements:

Target audience must have minimum qualification(s) at MQF level 3 in at least one of the following subjects: English, Maltese, Biology, Chemistry, Physics, Maths or Computing.

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:

Formative feedback is provided throughout the course in response to effective questioning and engaging activities, emboldening dialogue and motivation, as well as knowledge recall, analytical thinking and evaluative skills. At the end of the course, participants shall complete a written summative assessment consisting of a set of multiple-choice questions.

Certification:

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

Course Fee:

€490

Registration:

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

Registrations may be submitted via the Online Registration Form by not later than 21 August 2023.

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

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