

MALTA

MEDICINES
AUTHORITY



ACADEMY
FOR PATIENT CENTRED
EXCELLENCE AND INNOVATION
IN REGULATORY SCIENCES

Award in Good Manufacturing Practice

Award in Good Manufacturing Practice

A course organised by the MMA Academy, intended to deliver the essentials of Good Manufacturing Practice (GMP) and offer a networking forum for the sharing of knowledge, national and international collaboration and advancement of individual aptitudes in the field of GMP.

MQF Level: 5

ECTS: 1

Dates: 5-7 July 2021 (full days for a total of 25 hours)

Venue: Malta Life Sciences Park, San Ġwann

Keynote speaker:

[Dr Ingrid Walther](#)

As GMP-compliance consultant, Dr Walther holds wide-ranging expertise and experience acquired over twenty years of professional activity within the regulated pharmaceutical environment, particularly in the fields of quality and research & development, alongside the management of strategic projects.

Objectives and learning outcomes:

A comprehensive overview of GMP, as applicable to products intended for medicinal and research purposes, alongside a networking environment, shall enable participants to:

- a) Appreciate the relevance, applicability and implementation of GMP.
- b) Demonstrate a critical understanding of quality risk management in manufacturing operations.
- c) Apply principles of good documentation practices in the light of data integrity requirements.
- d) Expand knowledge on qualification and process validation, construing regulatory expectations during inspections.
- e) Develop awareness of the latest GMP updates in sterile manufacturing as well as GMP aspects applicable to medicinal cannabis.
- f) Integrate key principles of GMP to operational roles and responsibilities, overcome challenges and continuously identify opportunities for improvement.

Target Audience:

Designed for all individuals involved in GMP, including quality assurance, quality control, validation, operations and manufacturing, regulatory affairs, and management.

Entry Requirements:

Applicants are required to be in possession of qualification(s) at MQF Level 4 or higher.

Delivery:

The face-to-face approach ensures that the speaker(s) and participants engage in discussions and debates, exchange ideas, and collectively analyze 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 Good Manufacturing Practice accredited and recognised by the Malta Further and Higher Education Authority.

Course fee: €1250

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 23 June 2021.

For further information or assistance, kindly contact the MMA Academy via academy.medicinesauthority@gov.mt or 23439167/88.

