MALTA
MEDICINES
AUTHORITY

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

## Award in
## Applied Good Manufacturing Practice
## and Pharmaceutical Quality

# Award in Applied Good Manufacturing Practice and Pharmaceutical Quality

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

This comprehensive course is designed to equip participants with the knowledge and confidence to navigate the Good Manufacturing Practice (GMP) landscape, understand current trends and appreciate the evolving roles and responsibilities within pharmaceutical quality, including that of the Qualified Person (QP). GMP principles are brought to life through dynamic, case-based sessions covering key areas such as sterile and non-sterile manufacturing, quality risk management, qualification and validation, data integrity and documentation practices. This approach enables learners to apply GMP effectively in daily operations while driving operational excellence and continuous improvement.

**EQF/MQF Level:** 7 **ECTS:** 2
**Mode of Attendance and Duration:** Part-time for a total of 50 hours, including lectures, self-study and assessment.

**Dates:** 24, 25 and 26 February 2026
**Venue:** Malta Life Sciences Park, San Ġwann

**Speakers:** Seasoned speakers with extensive experience related to applied Good Manufacturing Practice and Pharmaceutical Quality.

**Learning outcomes:**

By the end of this course participants will be able to:

a) Explore the landscape of GMP for operational compliance and regulatory readiness.
b) Describe the responsibilities of the QP in maintaining quality assurance systems.
c) Outline GMP requirements for specific environments, including sterile manufacturing, as per the current EU regulatory framework.
d) Recognise key principles of Quality Risk Management (QRM) as applicable to pharmaceutical manufacturing operations.
e) Identify qualification and process validation activities in the context of ensuring product quality and regulatory adherence.
f) Explain the principles of good documentation practices in relation to data integrity expectations in GMP environments.
g) Discuss data integrity risks and mitigation strategies as applied to GMP documentation and record-keeping systems.
h) Apply core GMP principles to operational roles and responsibilities within pharmaceutical settings.
i) Evaluate real-world case studies to explore how challenges in GMP operations can be transformed into opportunities for continuous improvement.

***Competences***

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

a) Carry out qualification and process validation activities in line with established protocols, ensuring alignment with regulatory and quality standards.
b) Collaborate with colleagues and stakeholders to analyse GMP inspection trends.
c) Incorporate compliance expectations into routine practice.
d) Supervise documentation procedures to ensure data integrity.
e) Take appropriate action in response to risks.
f) Guide operational teams in the application of GMP principles within sterile manufacturing settings.
g) Support a culture of continuous quality improvement.
h) Monitor the integration of QRM into daily pharmaceutical operations.
i) Addressing potential risks proactively.
j) Be responsible for evaluating real-world GMP challenges, using case-based reasoning to create practical solutions and support regulatory readiness.

***Knowledge***

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

a) Describe the role and responsibilities of the QP in maintaining GMP, pharmaceutical quality and regulatory compliance.
b) Identify current EU expectations for GMP in sterile manufacturing.
c) Describe how current EU expectations for GMP in sterile manufacturing impact operational procedures.
d) List key principles of QRM.
e) Explain QRM applications in pharmaceutical production scenarios.
f) Define qualification and process validation activities.
g) Describe the role of qualification and process validation in product lifecycle management.
h) Recognise principles of good documentation practices.
i) Describe how good documentation practices support data integrity within GMP frameworks.
j) Identify common data integrity risks.
k) Explain strategies to maintain accurate and reliable pharmaceutical records.

### *Skills*

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

a) Apply GMP principles to daily operational tasks in pharmaceutical environments to support compliance and product quality.
b) Demonstrate effective documentation practices that align with data integrity requirements and regulatory expectations.
c) Use QRM approaches to evaluate and mitigate risks in manufacturing operations.
d) Interpret GMP requirements for sterile manufacturing.
e) Integrate GMP requirements into relevant operational procedures.
f) Plan qualification and process validation activities in accordance with GMP guidelines.
g) Support lifecycle quality assurance.
h) Analyse inspection trends and regulatory updates.
i) Identify gaps and opportunities for continuous improvement.
j) Review QP responsibilities and contribute to quality assurance systems.
k) Support decision-making and documentation standards.
l) Evaluate real-world GMP case studies.
m) Propose solutions that transform challenges into operational improvements.

### Target Audience:

This course is designed for professionals seeking in-depth knowledge of GMP as applied to medicinal products and combination medical devices. It is ideal for those in Quality Assurance (QA), Quality Control (QC), manufacturing, validation, regulatory sciences and scientific management roles. Participants will critically engage with GMP principles, regulatory frameworks and real-world challenges.

### 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 Applied Good Manufacturing Practice and Pharmaceutical Quality* 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**.

Registrations may be submitted via the **Online Registration Form** by not later than 11 February 2026.

For further information or assistance, kindly contact the MMA Academy via academy.medicinesauthority@gov.mt or 23439188 / 2343 9280 / 23439200

The MMA Academy is licensed as a Further and Higher Education Institution by the MFHEA
Licence Number: 2021-004