

MALTA

MEDICINES  
AUTHORITY



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

**Award in Good Distribution Practice**

## Award in Good Distribution Practice

A course organised by the MMA Academy, intended to convey solid grounding on core aspects of Good Distribution Practice (GDP), crucial for upholding quality and integrity of pharmaceutical products throughout the supply chain. It endeavours to provide a networking platform for the dissemination of scientific acumen and best practices, national and international collaboration and advancement of individual aptitudes in the field of GDP.

**MQF Level:** 5 **ECTS:** 1 **Dates:** 24 February, 3, 10, 17 March 2022 - Virtual-Live Sessions (full days for a total of 25 hours)

### Speakers:

**Ms Madeline Ault** - A pharmaceutical consultant and former MHRA senior GDP inspector who holds broad expertise and experience in the healthcare and pharmaceutical sectors, notably GDP, Quality Management Systems, Regulatory Requirements and Pharmaceuticals. A qualified teacher experienced in developing and delivering accredited training in associated areas.

**Ms Mariam Naqesh Bandi** - A pharmaceutical consultant and former MHRA GDP inspector, with a vast array of experience in pharmacy and wholesale pharmaceutical distribution.

**Dr Dylan Said** - Senior Head at the Malta Medicines Authority, having experience in Operations Management and International Affairs, alongside regulatory competence on EU rules against falsified medicines.

**Ms Stefanie Farrugia** - Head of the Inspectorate and Enforcement Directorate at the Malta Medicines Authority, managing the licensing, inspections and enforcement activities of wholesalers and manufacturers/importers.

### Objectives and learning outcomes:

A comprehensive overview of GDP, as applicable to pharmaceutical products shall enable participants to:

- Interpret the legislative framework for medicinal products and active pharmaceutical ingredients and relevant terminology.
- Understand quality management, identify key personnel, and acknowledge the importance of initial and continual training within the context of GDP.
- Discern storage requirements, implement methods to ensure the correct temperature range, and outline key principles about computerised systems and equipment.
- Expand knowledge on import and export of pharmaceuticals.
- Describe the importance of supplier and customer qualification in maintaining the integrity of the supply chain, respective challenges and due diligence.
- Fathom the importance of security throughout the pharmaceutical supply chain in tandem with risks associated with falsified medicines and anti-counterfeiting strategies.
- Gain insight on deviations, complaints, returns and recalls, alongside self-inspection practices and ways to maintain oversight and interactions with the license holder and regulator.

- Actively apply key GDP concepts, requirements, and roles/responsibilities in day-to-day practices.
- Convey concrete solutions to issues and formulate judgements in key areas of GDP, supporting the transformation of potential challenges into opportunities.

### Target Audience:

This course is directed at stakeholders who wish to gain extensive knowledge and understanding of Good Distribution Practice in the pharmaceutical industry.

### Entry Requirements:

Applicants are required to be in possession of qualification(s) at MQF Level 4 or higher. Mature students may be considered in line with the MMA Academy IQA Policy.

### Delivery:

The virtual learning approach ensures that participants and speakers engage in discussions and debates, exchange ideas and collectively analyse evolving scenarios and prospective outcomes. Participants are encouraged to think critically, collaborate, seek assistance through the appropriate channels and learn from peers, spearheading personal and professional growth and development in the 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 an online summative assessment consistent with the stated learning objectives.

### Certification:

Upon successful course completion, participants are granted an Award in Good Distribution Practice, 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 15 February 2022.

For further information or assistance, kindly contact the MMA Academy via [academy.medicinesauthority@gov.mt](mailto:academy.medicinesauthority@gov.mt) or 23439167/88.

