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IN REGULATORY SCIENCES

# Award in
# Pharmaceutical Distribution Auditing

# Award in Pharmaceutical Distribution Auditing

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

The Award in Pharmaceutical Distribution Auditing is an in-depth course designed to equip participants with essential knowledge, practical skills, and competencies for conducting effective audits within regulated pharmaceutical distribution environments. Ideal for professionals involved in quality assurance and regulatory compliance, this program covers key areas including risk-based audit planning, conflict resolution, data integrity, and regulatory preparedness. Participants will gain the expertise needed to facilitate compliance with Good Distribution Practices (GDP), identify and address potential deficiencies, and manage audits of outsourced activities, ultimately supporting continuous improvement and the safe distribution of medical products.

**EQF/MQF Level:** 6

**ECTS:** 2

**Mode of Attendance and Duration:** Part-time for a total of 50 hours, including lectures, self-study and assessment

**Dates:** 14, 15 and 16 October 2025

**Venue:** Malta Life Sciences Park, San Ġwann

**Speakers:** Seasoned speakers with extensive experience related to Pharmaceutical Auditing and Good Distribution Practices

**Objective:**

To provide a thorough understanding of the principles of pharmaceutical distribution auditing, equipping participants to ensure compliance with Good Distribution Practices (GDP), minimise deficiencies, and strengthen regulatory preparedness. In tandem, it will serve as a networking platform for the exchange of knowledge and best practices, supporting continuous improvement in the safe distribution of medical products.

**Learning outcomes:**

***Knowledge***

At the end of the module/unit the learner will have acquired the following Knowledge:

a) Identify key aspects of conducting audits for outsourced activities such as storage and transportation and describe their importance in maintaining compliance.
b) Define the role of auditing in regulated pharmaceutical settings and recall its impact on quality assurance.
c) Describe the use of Aide Memoire and checklists for enhancing audit execution.
d) List the main steps in risk-based audit planning and explain how to evaluate distribution chains effectively.
e) Identify common GDP deficiencies, such as temperature mapping and cold chain management, and describe how to address these challenges.

***Skills***

At the end of the module/unit the learner will have acquired the following skills:

a) Apply risk-based audit planning techniques and demonstrate the use of audit tools to enhance audit execution and ensure compliance across distribution chains.
b) Plan and prepare comprehensive audits that align with regulatory standards.
c) Identify potential compliance issues, and apply corrective actions.
d) Demonstrate conflict resolution skills in communication related to the management of challenges and deviations during audits & create detailed audit reports.
e) Assemble documentation needed for regulatory inspections, ensuring recommendations for corrective and preventive actions are clearly defined.
f) Use anti-counterfeit protocols, audit computerized systems, and apply CAPA management strategies to prevent fraud and drive continuous improvement post-audit.
g) Operate within regulated environments to effectively conduct inspections.
h) Uphold data integrity and compliance.
i) Demonstrate understanding and application of standards, including ISO 9001 and ISO 13485, for quality assurance in pharmaceutical operations, also extending to medical devices.
j) Show critical reflection related to the management of activities and audits.

### *Competences*

At the end of the module/unit the learner will have acquired the responsibility and autonomy to:

a) Comply with the role and regulatory requirements of auditing in pharmaceutical environments.
b) Deal with human behaviour effectively during audits and manage communication challenges, ensuring conflict resolution.
c) Carry out risk-based evaluations of distribution chains and create audit plans accordingly.
d) Ensure readiness for regulatory inspections and be responsible for managing any deviations encountered.
e) Utilize audit tools such as Aide Memoire and checklists to carry out audits efficiently.
f) Monitor and supervise the documentation of audit findings, guide CAPA processes, and ensure continuous post-audit improvement.
g) Identify and deal with common GDP deficiencies, including issues in pest control, temperature mapping, and cold chain management.
h) Manage unexpected challenges and deviations during audits effectively.
i) Ensure compliance with data integrity protocols and legislative regulations.
j) Create and implement anti-counterfeit measures and manage computerized system audits.
k) Carry out comprehensive audits for outsourced activities, including storage and transportation processes.
l) Advise on and apply standards, such as ISO 9001 and ISO 13485, to maintain quality in pharmaceutical operations and medical device practices.

### Target Audience:

This course is designed for individuals who aim to establish a solid understanding of the fundamental principles in Pharmaceutical Distribution Auditing. It caters for a diverse range of stakeholders in the pharmaceutical sector, particularly those involved in quality assurance and regulatory compliance.

### Entry requirements:

Target audience must have minimum qualification(s) at MQF level 4 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 programme is delivered in the English Language. The Traditional/Face-to-Face learning approach ensures that 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 written summative assessment consisting of a set of multiple-choice questions.

### Certification:

Upon successful course completion, participants are granted an Award in Pharmaceutical Distribution Auditing 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 26 September 2025.

For further information or assistance, kindly contact the MMA Academy via academy.medicinesauthority@gov.mt or 23439168 / 23439200.

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