EUPATI Open Classroom

# MODULE 2. REGULATORY AFFAIRS

EUPATI

## Introduction and summary

The importance of patient involvement in medicines R&D is commonly acknowledged and offers benefits for all involved parties. Patients should have access to knowledge and experiences that enable effective participation. EUPATI training responds to the need for educated patients in the current medicines R&D system and allows patients to develop their capacity to collaborate and engage with other stakeholders as equal partners.

This module corresponds to the EUPATI Open Classroom Regulatory Affairs module

The purpose of the **Regulatory Affairs module** is to provide an overview of medicines regulation, including the different marketing authorization procedures, benefit-risk assessment, pharmacovigilance, pharmacoepidemiology as well as the role that patients can play in these processes.

## Learning and Assessment

The objective of EUPATI is to provide appropriate academic and rigorous training, yet presented in a way that enables concrete and applicable learning outcomes for the patient community, leading to measurable impact in medicines development.
Each on-demand training unit has a short multiple choice assessment that is available to learners wanting to receive a certificate for the training unit.

**Training** is delivered through the **EUPATI Open Classroom**, a Moodle workplace learning management system that includes instructional text content, infographics, videos and case studies. The learner has also access to an online **toolbox and glossary.**

The **Toolbox** is an online library on the A-Z of medicines research and development (R&D) and patient involvement. The purpose of the Toolbox is to provide access to well-structured, comprehensive, scientifically reliable, and user-friendly educational materials for patients on a variety of topics in these areas. The information is not medicine- or disease-specific, but is applicable to the majority of diseases and/or medicines.

The **Glossary** is integrated into the content and allows learners to read keyword descriptions as they go through the learning process.

Learning is **modular, flexible and on-demand**, supported by the EUPATI team. The Trainees can access learning materials at their own pace and convenience. Once they finish a course or module, the certificates is generated automatically after successfully completed assessment.

The **assessments** are made for each course and are problem-based multiple-choice questions. Assessments are used to determine the competency of the established learning outcomes for each course in the module.

During the course learners are encouraged to:

- Make connections between what they have learned and their personal and professional situation.
- Think of opportunities to apply the training in their personal and professional life.

## Learning and assessment strategies

EUPATI Open Classroom uses the following learning strategies to effectively deliver educational content to trainees in a digital environment:

- **Asynchronous Learning**: Trainees can access learning materials at their own pace and convenience. They can read course materials including lectures and infographics, watch videos, listen to audios and complete assignments without being constrained by a specific schedule.

- **Microlearning**: Breaking down complex content on medicines R&D into small, easily digestible units allows trainees to absorb information more effectively. The content is separated into different pages with short text lessons that are combined with images, infographics, and videos.

- **Gamification**: Open Classroom uses badges after the completion of each module. Learners get rewards for completing their profile or finishing modules which can boost their engagement and progress. They can also share these badges on LinkedIn and get public recognition of their learning.

- **Self-assessment and feedback**: The online modules include self-assessment quizzes at the end of each course. This module includes 6 courses, therefore, to obtain the certificate for this module it is necessary to complete 6 quizzes. Along the lines of microlearning, Open Classroom encourages frequent, small-quantity assessments that help learners calibrate their understanding of the material. Immediate feedback on their performance helps learners identify areas for improvement and reinforces their understanding of the content.

- **Multimedia integration**: The modules offer multimedia elements, such as videos, images, infographics, to enhance the presentation of content and meet different learning styles. User-friendly content is available on different devices such as desktops, tablets and cell phones.

- **Real-world application**: Incorporating real-world examples and case studies as part of the content helps learners understand how the knowledge they acquire can be applied in practical life situations.

- **Accessibility and Inclusion**: The content meets the accessibility features to ensure that learners with disabilities can fully participate in the learning process.

## Curriculum

The module of Regulatory Affairs in Open Classroom is composed of 5 courses

Completion of all **5 courses** is mandatory to obtain the **Regulatory Affairs module**

| Courses | Hours* |
|---|---|
| Introduction to Regulatory Affairs | 10 |
| Epidemiology and Pharmacoepidemiology | 8 |
| Pharmacovigilance - Risk management | 8 |
| Product information and information to the public | 8 |
| Regulatory procedures- Marketing-Authorisations and their lifecycle management | 8 |
| **Total** | **42 hours** |

*This is an estimate based on the volume of content, although the actual hours required vary on an individual basis.

## Learning Outcomes per course

The learning outcomes of the different courses of this module are:

| COURSES | LEARNING OUTCOMES |
|---|---|
| **Introduction to Regulatory Affairs** | • Outline the principles of medicines regulation<br>• Describe the legislative framework for medicines regulation<br>• Describe the purpose and function of the International Council of Harmonisation and outcomes of its work<br>• Explain the reasoning behind the implementation of the Common Technical Document<br>• Understand the current EU regulatory requirements (pre and post-authorisation) for a medicinal product<br>• Explain the concept of benefit and cost-effectiveness<br>• Describe the various roles patients can play in approval and benefit-risk evaluation pre- and post-approval of medicines<br>• Explain the role of modern pharmacopoeias<br>• Describe the roles of the European Directorate for the<br>• Quality of Medicines (EDQM)<br>• Understand and describe the key principles of GoodxPractice<br>• Describe the key elements of GxPs most relevant in pharmaceutical medicine |
| **Epidemiology and Pharmacoepidemiology** | • Illustrate the basic concepts of epidemiology<br>• Describe the application of epidemiological research<br>• Explain the concepts of prevalence and incidence in epidemiology<br>• Describe the principles of pharmacoepidemiology, its study types and data sources and their application in research |
| **Pharmacovigilance - Risk management** | • Outline the principles of pharmacovigilance<br>• Explain the major steps in pharmacovigilance signal management<br>• List the key stakeholders in pharmacovigilance and their roles<br>• Compare Post Authorisation Safety Studies (PASS) and Post Authorisation Efficacy Studies (PAES)<br>• Outline the organisation of public hearings<br>• Explain the concept and structure of EudraVigilance<br>• Outline the principles of risk management for medicinal products in the European Union (EU) including the risk management plan<br>• Explain the EU specific measures for additional monitoring<br>• Outline the concept of safety communication<br>• Relate the 'Direct to health care professionals communication' to the overall principles of safety communication |

| COURSES | LEARNING OUTCOMES |
| --- | --- |
| **Product information and information to the public** | • Describe the components of product information and access to information they contain<br>• Outline the legal mandate and review process of product information<br>• Explain the difference between advertising and promotion of medicines to the general public and healthcare professionals with reference to the legal framework<br>• Explain the relation between different levels of Codes of Conduct and their differentiation to Codes of Ethics<br>• Relate the EFPIA Code of Practice to the underlying EU Directive 2001/83 |
| **Regulatory procedures-Marketing-Authorisations and their lifecycle management** | • Understand the basics of regulatory affairs functions in pharmaceutical companies<br>• Understand and explain the principal EU regulatory legal framework and procedures for authorising a medicine<br>• Understand and describe the main special cases in marketing authorisations and their particular conditions<br>• Explain the non-standard procedures for marketing authorisations and their differences<br>• Describe the main variation types of a marketing authorisation<br>• Describe and discuss the regulatory steps in a marketing authorisation application (MAA) for a medicine, including the different types of MAAs and their legal basis<br>• Describe the EU provisions for early access and use of medicines outside of or without a marketing authorisation |