

Good Manufacturing Practices and GMP Inspections for Medicines and Healthcare Products

COURSE PROGRAMME

Introduction

Currently, there is a strong momentum for the strengthening of the local pharmaceutical sector in developing and emerging markets. Regional and national strategies to promote local pharmaceutical production in line with international standards are being developed. These include, for example, the Kenyan road map to Good Manufacturing Practice (Kenya GMP Roadmap), the "EAC Regional Pharmaceutical Manufacturing Plan of Action (RPMPOA)" and the "Pharmaceutical Manufacturing Plan for Africa".

While the rationale for local production is simple - including factors such as independence from donor programmes which may not run forever, more steady supply chains, and greater control to local regulators - there is still a long way to go and markets are tough... Local companies, especially in low and middle income countries, often face substantial hurdles.

One of the big challenges is the lack of a qualified human resources base in the manufacturing sector of medicines and other healthcare products. In particular, there is need for skilled personnel for quality units (quality assurance, quality control) and other GMP relevant areas. Costs for bringing in experts from abroad are high. Combined with other challenges, local manufacturers often struggle to compete and even survive. Not being in line with international quality standards, they are prevented from passing WHO prequalification, participating in international tenders, and entering international markets.

Moreover, the national medicines regulatory agencies (NMRAs) of these countries experience a shortage too of qualified staff in GMP, GMP inspection and dossier evaluation. This creates difficulties for the NMRAs to enforce internationally acceptable regulatory requirements (including GMP standards) thereby preventing the availability of affordable quality generics for the majority of their low income population groups.

This e-learning course introduces Good Manufacturing Practices and GMP inspections for medicines and healthcare products, focusing on WHO GMP standards and requirements as one of the major GMPs. Course participants will learn about GMP requirements, including procedural, organizational and infrastructural aspects, as well as about the GMP inspection process. They will be able to critically analyse and implement basic GMP requirements in their daily working routine in the manufacturing and regulatory environment. The participants will practice course contents in quizzes, assignments, and discussion forums. While the main focus is on medicines, an extra session of the course introduces the requirements for healthcare products, specifically for female condoms.

In the end, these capacity building measures in the area of GMP and GMP inspection will make participants from local manufacturers and national regulatory authorities better equipped for production and regulation of quality assured essential medicines and healthcare products, in line with national and international standards.

Course objectives

After having successfully completed the course, participants will be able to:

- Appreciate the importance and need for good manufacturing practices.
- Be familiar with the development of medicines regulation.
- Understand the main requirements in GMP, including procedural, organizational and infrastructural aspects.
- Have gained basic information on requirements for healthcare products such as female condoms, as a special focus.
- Critically analyse and implement basic GMP requirements in their daily working routine in the manufacturing and regulatory environment.
- Understand the need for, and the benefit of GMP inspections.
- Be familiar with different types of GMP inspections.

- Interpret and discuss the role of GMP inspectors.
- Understand the inspection process and structure of an inspection report.

What are the target participants?

The course is designed mainly for individuals and organisations in GMP-relevant areas and GMP inspectorates, both those with professional experience who want to deepen and update their knowledge, as well as young professionals who want to prepare intensively for their tasks.

Teaching and learning strategy

This online course requires the students to engage in self-directed learning and go through the course materials on the learning platform with the support of an online facilitator. Taking part in discussion forums, exchanging ideas with fellow participants and doing self-evaluation through online quizzes form a vital part of the learning experience.

In addition, there are several short assignments to guide the learning process of the participants, offering feedback on the submissions and an opportunity to interact with the facilitator. Assignment responses should be submitted within the respective due dates.

Assessment and grading

Participants will be graded based on their online participation and completion of activities. A certificate of completion and an e-badge will be awarded to all those who complete a minimum of 75% of all online activities (lessons, quizzes, discussion forums). The percentage of completion will be measured automatically online as the participant goes through the course.

In addition, participants need to obtain a passing mark of minimum 7/10 on the post-test.

Course duration

6 weeks

Level of effort: 4 hours per week