PAN-AFRICAN QUALITY INFRASTRUCTURE

E-Learning Course

Hygiene Concepts, Cross-Contamination Risks and Cleaning Validation (cGMP) for the pharmaceutical sector

Introduction

As a result of the Covid-19 pandemic, many manufacturing sites on the African continent had to scale down their pharmaceutical production due to lockdowns, supply shortages and stock-outs of imported active ingredients and other excipients. These supply shortages show once again the importance of **local production of medicines and medical devices** in accordance with international standards for the independence and sustainable development of African countries.

In order to resume and continue production - even in times of a pandemic - it is essential that manufacturers are able to comply with local hygiene regulations and provide adequate protection for their workers from the infection with the virus.

Current Good Manufacturing Practices (cGMP) is a system to ensure medicinal products are consistently produced and controlled according to quality standards. Moreover, it is a requirement for fulfilling regulatory requirements, being competitive, and entering international markets. Local manufacturers have highlighted the **prevention of cross-contamination and cleaning validation** as one of the big challenges in the area of compliance with international Good Manufacturing Practices (cGMP). There is a need for local manufacturers to build up human capacity to produce quality assured medical products and for regulators to strengthen regulatory oversight as many African countries struggle to improve access to high quality essential medical products and strengthen health security.

This training course is offered by PTB, the German National Metrology Institute, in the framework of our project "*Alliance for Product Quality in Africa*". PTB is commissioned by the German Federal Ministry of Economic Cooperation and Development (BMZ).

Goal

The purpose of this e-learning course is twofold:

1. In the context of ***COVID-19 pandemic preparedness for workplaces*** - to inform about possible transmission routes of the new corona virus SARS-CoV-2 in the professional context and to recommend hygiene concepts for pharmaceutical manufacturing sites.

The cGMP course is supported by

german cooperation
DEUTSCHE ZUSAMMENARBEIT

PTB
Physikalisch-Technische Bundesanstalt
Braunschweig und Berlin

2. In the area of current Good Manufacturing Practices (***cGMP***) – to provide practical information and in-depth knowledge about the ***risks of cross-contamination and cleaning validation*** for the manufacture of ***quality-assured medicines***.

The course focuses on the **cGMP standards and requirements of the WHO** as one of the most important GMPs. The new Health-Based Exposure Limits (**HBELs**) approach in cleaning validation is considered.

The course participants will be able to critically analyse the cGMP requirements for sanitation, hygiene and cleaning validation and to implement them in their daily work routine in the manufacturing and regulatory environment. The course contents are practiced interactively by the participants in quizzes, tasks and discussion forums.

These capacity building activities in the areas of **hygiene concepts, cross-contamination risks and cleaning validation** will ultimately prepare participants from pharmaceutical manufacturers and national regulatory authorities better for working in pandemic situations and will make them better equipped to produce and regulate quality assured essential medicines in accordance with national and international standards.

Course objectives

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

- Be familiar with the hygiene concepts for pharmaceutical manufacturing sites to protect workers from the infection with the new corona virus SARS-CoV-2.
- Appreciate the importance and need for good manufacturing practices (cGMP).
- Be familiar with identification & evaluation of potential cross-contamination risks.
- Know how to determine an appropriate cleaning procedure for different equipment.
- Be informed about development and validation of sampling and testing methods for the compounds to be cleaned.
- Be familiar with the evaluation of equipment surfaces.
- Know how to develop a cleaning validation risk assessment & protocol.
- Be familiar with the creation of a Cleaning Validation SOP.

Who are the targeted participants?

- Local manufacturers of pharmaceutical products, especially quality assurance and quality control department, as well as management level, to increase their technical knowledge on hygiene concepts (COVID-19), cross-contamination risks and cleaning validation (cGMP). This will enable them to prepare the workplace for working in pandemic situations and to improve cGMP compliance in their facility.
- Regulatory personnel to increase their technical knowledge on hygiene concepts (COVID-19), cross-contamination risks and cleaning validation (cGMP) so that they can apply it during regulatory inspection of local medical products manufacturers and in their own institutions (hygiene concepts).
- Participants need to be proficient in English, as the course will be conducted exclusively in English.

PTB will - partly - sponsor the participation of up to ***25 participants per course*** from Africa. Participants from the public sector / regulatory authorities will receive a full scholarship. Participants from the private sector / quality assurance staff from pharmaceutical manufacturing companies will receive a 50% scholarship (50% of 220 EUR).

Teaching and learning strategy

This e-course requires the participants to go through the course materials on the learning platform individually and with the support of two online facilitators to encourage self-directed learning. Taking part in discussion forums, exchanging ideas with fellow participants and completing online quizzes and assignments will form a vital part of the learning experience.

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 successfully 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, 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 facilitators. Assignment responses should be submitted within the respective due dates (one week after opening) as to the schedule below.

Course duration

3 weeks

Level of effort: approx. 4 hours per week

Timelines

- ***Virtual kick-off meeting:*** 11 June 2021, 11:00-13:00 EAT. Check-in: 10:30 EAT.
- ***3-week e-learning phase*** (individually from home with an internet-ready computer, ***flexible working hours***, around ***4 hours per week,*** 11th of June until 2nd of July 2021).
- ***Final closing meeting:*** 2 July 2021, 11:00-14:00 EAT. Check-in: 10:30 EAT.

Contact

Project Coordinator
Saida Bunk
Saida.Bunk@ptb.de

Project Assistant
Karin Vondeberg
Karin.Vondeberg@ptb.de