Concept Note: Virtual cGMP Training Marathon

Background

Low- and Middle-Income Countries (LMICs) are becoming increasingly interested in strengthening the local production of quality-assured medical products. Many LMICs view strengthening local production as a strategic method to improve access to quality assured medical products, achieve universal health coverage, strengthen health security and reach the health-related targets and broader development goals of the SDGs. Most LMICs' need for medical products is dependent on importation that is characterized by lack of consistent supply of quality assured medical products. Therefore, promoting quality assured local production of medical products would be important to reduce the dependence on imports, curb shortages and stock-outs of medical products, combat substandard and falsified medical products and, in the long-run, build national health security and a knowledge-based economy.

Furthermore, COVID-19 has shown how susceptible medical product supply chains are when depend on a few manufacturers for raw materials and final products. This pandemic has shown disruption of supply chain even for shorter period of time which caused interruption of immunization in some LMICs and compromised access of essential medicine, too. Hence, the pandemic has underlined the need to encourage local production of essential medicine and health commodities. Local production is no more luxury and it is becoming a matter of ensuring health security.

However, local pharmaceutical manufacturers in many LMICs suffer from lack of proper facility design to poor implementation of quality management system and thus may not be able to fulfill the current regulatory requirements and may not be competitive. Various interventions are being employed to curb these challenges and achieve the goal of improved access of quality assured medical product in LMICs. Among the interventions, providing both basic and advanced GMP training to technical staff of local medical product manufacturers and National Medicine Regulatory Authority (NMRA) staff are tools to improve cGMP compliance quality management system of local medical product manufacturers.

Access to quality assured medical Products is a critical component of functioning health systems and fundamental for achieving universal health coverage. There is a big need for local manufacturers to build capacity in producing quality-assured medical products as many LMICs struggle to improve access to quality essential medical products and strengthen health security. In response to Member States' requests for support to address this need, the World Health Organization (WHO) Local Production and Assistance Unit (LPA) supports Member States, particularly LMICs, in strengthening local production using a holistic approach toward quality assurance and sustainability to improve access.

Therefore, LPA is organizing a Virtual cGMP Training Marathon to benefit:

1. Local manufacturers to increase their technical knowledge on cGMP to enable them produce quality assured medical products by improving cGMP compliance in their facility

2. NMRAs staff to increase their technical knowledge on cGMP so that they can apply it during regulatory inspection of local medical products manufacturer and reduce the risk of producing poor quality medical products

The training will be designed to be delivered virtually in marathon fashion starting from first week of September to last week of November. The training will be streamed live twice per week for half day each. The time of the training will accommodate the time differences of participants in all 6 WHO regions.

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General objective

To support and strengthen local medical product manufacturers to improve sustainable access of quality assured essential medical products in LMICs thereby contribute in the achievement of WHO triple billions goals embodied in the WHO GPW13.

Specific objectives

- Decrease the risk of producing poor quality Medical products by local medical product manufacturer that could be produced by lack of technical knowledge cGMP
- Support LMICs NMRA staff reducing the risk of poor quality medical product production in the market locally by increasing their technical knowledge cGMP
- Design and implement an innovative Virtual GMP training marathon that benefit larger number of LMICs countries in a cost effective manner
- Design an innovative Virtual GMP training marathon to combat COVID -19 pandemic and to get prepared for future pandemic

Course Organization and Content

This marathon virtual training course consists of 12 selected GMP topics. The topic includes Pharmaceutical quality management system, Quality risk Management and Quality Risk Management tool specifically FMEA , Process validation for oral solid dosage forms, Cleaning validation , Computerized system validation , Documentations required in medical product manufacturers ,HVAC, water system, etc.

Virtual Lectures & discussions with participants will be conducted. These approaches will make the trainees grasp the concept properly and help proper implementation GMP in their own set up. The trainees are expected to attend all the topics but they are free also to attend selectively.

Training program evaluation of the training will be conducted which will be used to continuously improve the marathon virtual training

Methods of the Virtual GMP Training Marathon

The training will be delivered virtually twice per week for half a day session for different participants in all 6 WHO regions. Power point presentations will be streamed live. Discussion with participants will be arranged.

Platform: Webex will be used to broadcast the training

Target Audiences

Manufacturers and regulators in all six of WHO regions are welcome to participate

Scope

Training is on finished pharmaceutical product cGMP requirements

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Outcome of the course

After completing this course, the participants will be able to;

- Explain the scientific background and practical implementation of GMP;
- Explain the new paradigm of GMP in terms of risk-based and quality system-based approach;
- Understand the principles behind the premise layout and design
- Understand on water for pharmaceutical use production treatment and distribution
- Understand on HVAC requirements, DQ,IQ ,OQ and PQ
- Understand and able to implement Process validation, Cleaning validation, Computer system validation etc
- Understand cGMP requirements on sterile product manufacturing and contamination prevention
- Develop and implement appropriate and efficient Corrective and Preventive Action plans;
- Build skills and confidence of local medical product manufacturers to handle both local and foreign regulatory inspection