CONCEPT NOTE

Local production of quality and safe essential *in vitro* diagnostics and

WHO PQ, WHO EUL and ERPD processes

Background

Global initiatives to ensure harmonized regulation of *in vitro* diagnostics (IVDs) and other medical devices have resulted in changed regulatory requirements at national, regional and global levels, which may be difficult to interpret. In addition, for some manufacturers who intend to produce priority medical products for WHO Prequalification (PQ) of *in vitro* diagnostics, Emergency Use Listing (EUL), or Expert Review Panel for Diagnostics (ERPD), meeting WHO prequalification requirements can be challenging.

Correctly understanding and implementing WHO prequalification requirements given in WHO Technical Standards Series and WHO Technical Guidance Series documents and internationally based medical device quality management system and risk management standards has been a significant challenge for medical device manufacturers located in low- and middle-income countries (LMIC).

WHO's Local Production and Assistance Unit (LPA) supports Member States in strengthening local production to improve access to IVD devices by providing: (i) capacity building in, *inter alia*, quality assurance; and (ii) specialized technical assistance to IVD device manufacturers related to WHO PQ, EUL and ERPD by helping IVD manufacturers understand and implement WHO PQ requirements and international standards.

The aim of specialized technical assistance is twofold:

- to help recipients understand WHO PQ requirements by identify any major shortcomings in achieving compliance with WHO prequalification requirements; and
- to speed up the process of manufacturers achieving WHO PQ and EUL.

The *Local Production and Assistance* Unit with strong support from the *Prequalification IVD Assessment* team and the *Incidents and Substandard/Falsified Medical Products* team from the *Regulation and Prequalification Department* in WHO Headquarters is organizing a special workshop on local production of quality and safe essential in vitro diagnostics and WHO PQ, WHO EUL and ERPD processes. The workshop is intended for interested IVD manufacturers, medical device associations, Ministries of Health and National Regulatory Agencies located in low- and middle- income countries who wish to better understand the international medical device quality management system standard ISO 13485:2016, risk management standard ISO 14971:2019, and WHO guidance.

Goal

One goal of the workshop is to improve a manufacturer's and other interested parties' basic understanding of international medical device quality management system standard ISO 13485:2016, medical device risk management standard ISO 14971:2019, and WHO PQ, EUL and ERPD requirements. A second goal is to strengthen the capacity of LMIC manufacturers of essential *in vitro* diagnostic devices to consistently produce *in vitro* diagnostic devices that are safe and perform as intended.

Objectives

The specific objectives for the workshop are to:

1. Provide training and guidance to manufacturers and other stakeholders on the structure, requirements, and intent of ISO 13485:2016 *Medical Devices-Quality management systems-Requirements for regulatory purposes*

2. Provide training and guidance to manufacturers and other stakeholders on the structure, requirements and intent of ISO 14971:2019 *Medical devices – Application of risk management to medical devices.*
3. Provide training and guidance to manufacturers and other stakeholders on how to integrate the risk management standard into an ISO 13485 compliant quality management system.
4. Provide training and guidance to manufacturers and other stakeholders on the integration of ISO 13485:2016 and ISO 14971:2019 into WHO PQ, EUL and ERPD applications
5. Provide training and guidance to manufacturers on WHO significant change reporting, and WHO post-market surveillance and adverse event reporting.

Expected outcomes

The workshop is expected to deliver the following outcomes and outputs:

1. Capacity building of participants
2. Knowledge transfer to participants
3. Improvement in future PQ, EUL and ERPD applications and a reduction of application rejections because of deficient risk management and quality management systems

Workshop format

The workshop will be delivered virtually over two days for a total of approximately 7 hours using a suitable tool like Zoom.

The content of the workshop will include PowerPoint slide decks on the introduction to WHO PQ processes and guidance, ISO 13485 and ISO 14971. During the course of the ISO presentations mini quizzes will be used at strategic points to highlight important topics and to stimulate discussion during a question-and-answer session that follows the workshop.

Date

The workshop is planned for February 23 & 24, 2021, from 12 pm (CET Geneva) to 3:30 pm (CET Geneva)

Target Participants

The workshop is specifically designed for, and will be beneficial to, manufacturers of essential *in vitro* diagnostic devices medical device associations, Ministries of Health, and National Regulatory Agencies located and in low- and middle- income countries.

Workshop topics are designed for participants holding the following positions:

- Top management of an *in vitro* diagnostic manufacturer
- Quality managers
- Design engineers
- Production managers
- Internal auditors
- Product managers
- Regulatory Affairs & Quality Assurance
- Representatives of device industry associations
- Officials from Ministries of Health and National Regulatory Agencies

Reference

Local Production and Assistance Unit: https://www.who.int/phi/implementation/tech_transfer/en/

LPA Specialized Technical Assistance: https://extranet.who.int/pqweb/vitro-diagnostics/specialized-technical-assistance