WEBINAR

Local Production of quality and safe essential *in vitro* diagnostics and WHO PQ, WHO EUL and ERPD processes

SAVE THE DATE

February 23 & 24, 2021
from 12h to 15h30 (CET Geneva)

Register Here

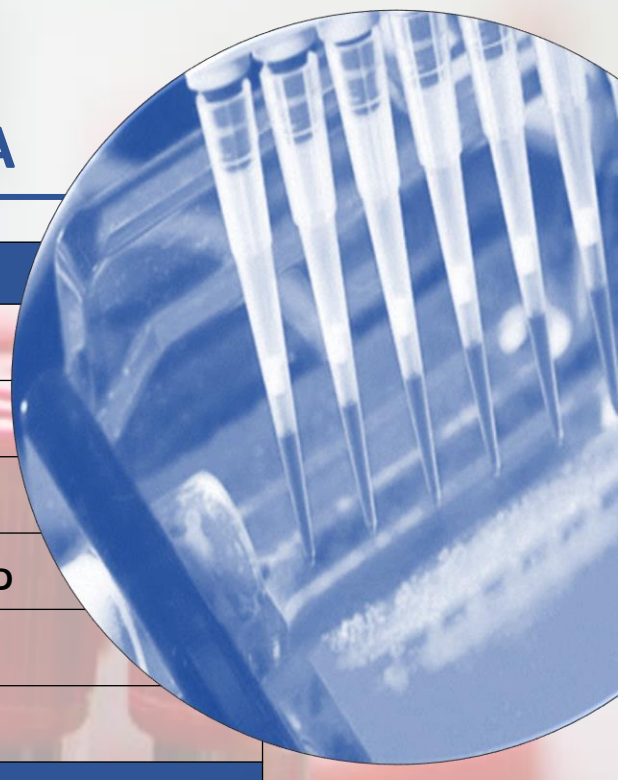
BACKGROUND

The Local Production and Assistance Unit (LPA) Unit with strong support from the Prequalification (PQ) Assessment team and the Incidence, Substandard and Falsified Medical Products team from the Regulation and Prequalification Department in WHO Headquarters is organizing a special workshop that is intended for interested IVD manufacturers located in low- and middle- Income countries (LMIC) 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.

For some manufacturers who intend to produce priority medical products for WHO PQ of *in vitro* diagnostics, Emergency Use Listing (EUL) (e.g. COVID-19 devices), or Expert Review Panel for Diagnostics (ERPD), meeting WHO PQ requirements can be challenging. In addition, 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.

WHO's LPA supports LMIC manufacturers by providing capacity building and special technical assistance. The LPA works with medical device manufacturers to help them understand and implement WHO PQ requirements and international standards by providing public workshops on PQ related topics and one-on-one assessment of a manufacturer's organizational structure and procedures. This training is intended for IVD manufacturers, medical device associations, Ministries of Health and National Regulatory Agencies' officials.

AGENDA



DAY 1	TOPIC
Opening Session	Welcome Remarks
Session 1	Overview of WHO PQ, EUL and ERPD programs
Session 2	ISO 13485 QMS requirements and PQ, EUL and ERPD programs
Session 3	ISO 14971:2019 risk management process and PQ, EUL and ERPD
Q & A Session	All participants will be invited to share comments & questions
Closing Session	Closing remarks on day 1
DAY 2	**TOPIC**
Opening Session	Welcome Remarks
Session 4	LPA unit specialised technical assistance process
Session 5	CAPA process related to LPA assistance
Session 6	WHO PQ IVD product dossier
Session 7	WHO significant change reporting
Session 8	WHO post-market reporting requirements
Experience sharing	Invited global device manufacturer
Session 9	A global device manufacturer's experience and observations on the manufacture of PPEs and low risk devices
Q & A Session	All participants will be invited to share comments & questions
Closing Session	Closing remarks on day 2

World Health Organization

Local Production & Assistance Unit (LPA)
Regulation and Prequalification Department (RPQ)
Access to Medicines and Health Products Division (MHP), HQ