Confidential

CONCEPT NOTE

WEEK OF QUALITY 2023
On the Origin of Specifications:
Strengthening Quality for Manufacturing of Vaccines, Medicines, and In Vitro Diagnostics

Background

The production of medicines, vaccines, and in vitro diagnostics (IVDs) is governed by strict regulations and guidelines set by regulatory bodies such as the Food and Drug Administration (FDA), the European Medicines Agency (EMA), and the World Health Organization (WHO). These regulations and guidelines define the standards and requirements that manufacturers must meet to ensure the quality, safety, and efficacy or performance of their products.

The COVID-19 pandemic has had a significant impact on the production of medicines, vaccines, and in vitro diagnostic products, including their quality. A surge in demand for certain medicines, vaccines, and IVDs has put pressure on manufacturers to increase their production capacity and speed up the production process, which can increase the risk of quality issues if proper quality control measures are not maintained. The COVID-19 pandemic has introduced new challenges in maintaining the quality of medicines, vaccines, and IVDs. Manufacturers and regulators have had to adapt to the changing circumstances and implement new measures to ensure the quality, safety and efficacy or performance of these products[1].

Assessment time from submission of applications by manufacturers to approval by regulatory authorities greatly influences the timely access of health products. High-quality regulatory initial submissions reduce the number of quality related deficiencies and need for additional data generation, resulting in shorter clock stops and a reduced overall assessment time[2]. The *Week of Quality* is a special event, organized by the Local Production and Assistance (LPA) Unit, in WHO Headquarters, to serve as a yearly commemoration of the vital role that quality plays in the pharmaceutical and IVD industries. This workshop aims to enhance manufacturers' knowledge on quality data requirements and expectations for vaccines, medicines and IVDs as described in the guidelines of WHO and regulatory authorities for prequalification (PQ), emergency use listing (EUL) and licensing purposes.

The LPA Unit supports Member States in strengthening their sustainable local production and to undergo technology transfer to improve access to quality-assured health products. The LPA Unit works with manufacturers and regulators to enhance the understanding and promote best practices, particularly in low- and middle-income countries (LMICs), on quality requirements for vaccines, medicines and IVDs.

1. Impact of COVID-19 pandemic on pharmaceutical systems and supply chain – a phenomenological study, Explor Res Clin Soc Pharm. 2021 Jun;2:100037. doi: 10.1016/j.rcsop.2021.100037. Epub 2021 Jun 24. PMID: 34746915; PMCID: PMC8559533
2. Getting strategic about new-product submission in the pharma industry, McKinsey & Company, 2021 16 September

Goals

The main goal of the *Week of Quality* is to engage with manufacturers of essential medicines, vaccines and IVDs on a continuous, regular, and yearly delivery of guidance to raise awareness about the importance of quality in the pharma and diagnostics industries and inspire professionals to strive for excellence in their daily work. The first *Week of Quality*, in 2023, will deliver a series of lectures to share the guidelines of quality / Chemistry, Manufacturing, and Control (CMC) standard, risk management standard, and WHO PQ, ERPD and EUL requirements. This year the workshop focusses on the establishment of specifications to control the release of medical products that are safe, effective, and of high quality in the circumstances of a pandemic and beyond.

Objectives

The specific objectives for the *Week of Quality 2023:*

1. To provide guidance to manufacturers of essential medicines, vaccines and IVDs on the establishment of specifications to ensure the provision of medical products that are safe, effective, and of high-quality.
2. To provide guidance to manufacturers on how best to report the scientific and regulatory information related to the specifications, their acceptance criteria, and their justification in the product dossier to be submitted to the regulatory bodies.

Expected outcomes and outputs

The workshop is expected to deliver the following outcomes and outputs:
LMIC manufacturers of essential medicines, vaccines, and IVDs will have a better understanding of quality and CMC requirements, risk management standards, and WHO PQ, ERPD and EUL requirements, leading to an improvement in the quality of their products and applications.

Workshop format

The workshop will be delivered virtually (using the Zoom platform) over 5 days. A total of 2 to 2.5 hours sessions will be delivered per day. And interactive break will allow to roll polls/surveys to engage with the audience and collect valuable insights from the participants knowledge and needs.

Date

The workshop is planned for 12 to 13 June 2023, from 12:00 to 14:00, and for 14 to 16 June 2023, from 12 to 14:30 (CEST/UTC+2 Geneva Time).

Target Participants

The workshop is specifically designed for and will be mainly beneficial to manufacturers of medicines, vaccines and IVDs in LMICs, and with a special focus to technical personnel working in production, dossier preparation, quality control (QC), quality assurance (QA) and regulatory affairs. Member State authorities, such as Ministry of Health (MoH) and National Regulatory Authorities (NRA); from LMICs, and other countries having already an established local production, are welcome to participate.