The World Health Organization (WHO)’s Sustainable Development Goals (SDG3) sets goals and targets to work towards and achieve by 2030. One of these goals is to achieve universal health coverage (UHC), meaning that all people have access to the health services they need, when and where they need them, without financial hardship. UHC can only be achieved where there is affordable access to safe, effective and quality-assured medicines, vaccines and other health products.

WHO’s 13th General Programme of Work (GPW13) sets the target to ensure one billion more people are benefitting from UHC by 2023. Closely aligned with GPW13, WHO’s work plan “Delivering Quality-assured Medical Products For All 2019-2023” prioritizes the work of the Regulation and Prequalification Department (RPQ). This plan aims to enhance access to affordable health products through four strategic priorities:

Strategic priority 1: Strengthen country and regional regulatory systems in line with the drive towards UHC
Strategic priority 2: Increase regulatory preparedness for public health emergencies
Strategic priority 3: Strengthen and expand WHO prequalification and product risk assessment processes
Strategic priority 4: Increase the scope and impact of WHO’s regulatory support activities

Working effectively towards each of these priorities requires RPQ to manage the quality of its processes and process outcomes through a quality management system (QMS).

Besides that, RPQ expects many of its stakeholders (such as National Regulatory Authorities and manufacturers) to operate under a QMS, resulting in an expectation for RPQ to operate under a QMS too.

RPQ has implemented a QMS that is based on the ISO 9001:2015 standard and is committed to further develop and implement its QMS in adherence with this standard.

The main objectives of RPQ’s QMS are:

- to promote and assure consistency of process outcomes across RPQ;
- to increase effectiveness, transparency and efficiency of RPQ processes;
- to improve cross-cutting processes between units and teams within RPQ;
- to strengthen collaboration and coordination with WHO entities outside RPQ.
The vision of RPQ management is that the QMS should facilitate the delivery of services that meet the needs and expectations of WHO Member States and other stakeholders while progressing to achieve the goals in WHO GPW13 and SDG3.

RPQ management, consisting of the RPQ Director, Unit Heads and Team Leads, commit to:

- support the implementation of the QMS, using a Plan – Do – Check – Act approach;
- support the continuous improvement of the QMS through internal audit, change management, quality management review and other mechanisms;
- support the further development of the QMS in adherence with relevant guidance documents, for example the relevant parts of the WHO guideline on the implementation of quality management systems for national regulatory authorities, Technical Report Series 1025 Annex 13;
- promote compliance with WHO and international regulatory standards, guidelines, guidance documents and related technical requirements;
- having competent, motivated and empowered personnel in adherence to WHO’s Human Resources (HR) polices;
- promote stakeholder focus throughout RPQ whilst considering risks and opportunities that may affect RPQ’s service delivery;
- engage with WHO Member States, implementing partners and other stakeholders in order to determine their needs and expectations that should be considered during the planning and determination of key performance indicators;
- consistently conduct quality management reviews with a view to benefit from the inputs of internal audit results, stakeholder satisfaction feedback and complaints handling related to the provided RPQ services for periods under review and help contribute towards continuous improvement of the QMS.