UNOPS | PROJECT QUALITY ASSURANCE PROGRAMME

UNOPS in Mexico, along with INSABI carries out the consolidated procurement of drugs, medical inputs, and devices at the best price and without neglecting quality.

According to the Procurement Manual (Annex 2), **UNOPS** has a programme in place that seeks to monitor and validate the processes in terms of **quality assurance** with the aim of guaranteeing the quality, efficacy, safety and expected use of the procured products. This **programme is independent** of the ultimate responsibility of ensuring and guaranteeing the quality of pharmaceutical products marketed in Mexico, which falls on **COFEPRIS**, as the regulatory entity and local authority for the protection of the Mexican population against health risks, and **providers**, as long as they comply with national regulations and follow the good practices of the pharmaceutical industry.

The two-phased program carried out by UNOPS is explained below:

1. Pre-contractual phase:

Carried out by UNOPS technical experts during the technical evaluation of the bids:

1 **Enabling Assessment**

At this stage, the offered product and the bidder's compliance to submit its bid are validated. That the product has a marketing authorization (Sanitary Registry) is validated and that it matches the description of the tendered code.

2 **Supplementary Evaluation**

It is guaranteed that the product offered complies with the aspects related to quality assurance, i.e., that the manufacturer has Good Manufacturing Practices in place and the licenses required for its operation, that the product complies with the labeling conditions and the special conditions for its commercialization, and that it complies with the acceptance parameters established based on the type of product (quality analysis).

2. Post-contractual phase

This phase is carried out once the contract with the supplier has been signed, by the UNOPS team of specialists; it established five aspects to ensure the quality, efficacy, safety and expected use of the products acquired within the procurement framework, which are carried out through 5 processes according to the requirements of each product:

Pharmacovigilance/ Technovigilance: Verification of health alerts / safety reports issued by regulatory agencies that are regional and global benchmarks, of the procured products.

Quality control analysis: Proof of the maintenance of the physicochemical and microbiological quality conditions required for their commercialization.

Inspection by attributes: Inspection of the procured products at the suppliers' warehouses.

Hosting quality events: Related to the procured products, such as the management of complaints and product recalls.

Quality audits: To processes of the Supplier Quality Management System.