WHO GUIDELINES ON VARIATIONS TO A PREQUALIFIED PRODUCT (WHO TRS 981 - Annex 3)

Publisher: WHO

Overview

This document summarizes the guidelines for managing variations to WHO prequalified pharmaceutical products. It is designed to assist manufacturers in handling changes to a prequalified finished pharmaceutical product and provides information on how to present an application for such changes or variations.

The guidelines emphasize that the applicant is responsible for the safety, efficacy, and quality of a product throughout its lifecycle, and change management forms a critical component during manufacturing to ensure the same. Please note that these guidelines do not outline the actual procedure for submitting variations to a prequalified product. Applicants are advised to consult updated information on the WHO website when considering a variation application.

Link to Document

TRS 981 - ANNEX 3: WHO GUIDELINES ON VARIATIONS TO A PREQUALIFIED PRODUCT