WHO GUIDELINES ON QUALITY RISK MANAGEMENT (WHO TRS 981 – Annex 2)

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Overview

Good manufacturing practices (GMP), regulatory oversight, and supply chain controls help ensure the quality of medicines. However, gaps in control can expose patients to risks from substandard products. Quality risk management (QRM) offers a systematic approach to identifying and mitigating risks at various stages of production and distribution, enabling regulatory authorities to enhance oversight within resource constraints.

These guidelines support the implementation of effective QRM across the pharmaceutical life cycle, from research and development to distribution. While HACCP methodology has historically informed WHO's risk management guidance, recent international frameworks (that are referenced in the document) provide more tailored QRM guidance and approaches, fit for the pharmaceutical industry. These updated guidelines reflect evolving global standards, emphasizing risk-based decision-making to maintain medicine quality, safety, and efficacy.

Link to Document

TRS 981 - Annex 2: WHO guidelines on quality risk management