

GOOD MANUFACTURING PRACTICES: GUIDELINES ON VALIDATION (WHO TRS 1019 - Annex 3)

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Overview

The linked document, **WHO Technical Report Series No. 1019, Annex 3: Good manufacturing practices: guidelines on validation**, provides guidelines validation of Good Manufacturing Practices (GMP). Validation is an essential part of good practices, including good manufacturing practices (GMP) and good clinical practices (GCP). It is therefore an element of the pharmaceutical quality system.

Validation, as a concept, incorporates qualification and should be applied over the life-cycle of, for example, a product, process, method, system, equipment or utility. 1.2 These guidelines cover the general principles of qualification and validation. In addition to the main text, appendices on some validation and qualification activities (such as applied to heating, ventilation and air-conditioning systems, water systems, cleaning, analytical methods, computerized systems, and non-sterile processes) are included.

Link to Document

[TRS 1019 - ANNEX 3: GOOD MANUFACTURING PRACTICES: GUIDELINES ON VALIDATION](#)