

WHO Expert Committee on specifications for pharmaceutical preparations.

Abstract:

The Expert Committee on Specifications for Pharmaceutical Preparations works towards clear, independent and practical standards and guidelines for the quality assurance of medicines. Standards are developed by the Committee through worldwide consultation and an international consensus-building process. The following new guidelines were adopted and recommended for use: good practices for pharmaceutical quality control laboratories; supplementary guidelines for active pharmaceutical ingredients; good manufacturing practices for pharmaceutical products containing hazardous substances; good manufacturing practices for sterile pharmaceutical products; good distribution practices for pharmaceutical products; guidelines on the requalification of prequalified dossiers: and guidelines for the preparation of a contract research organization master file.