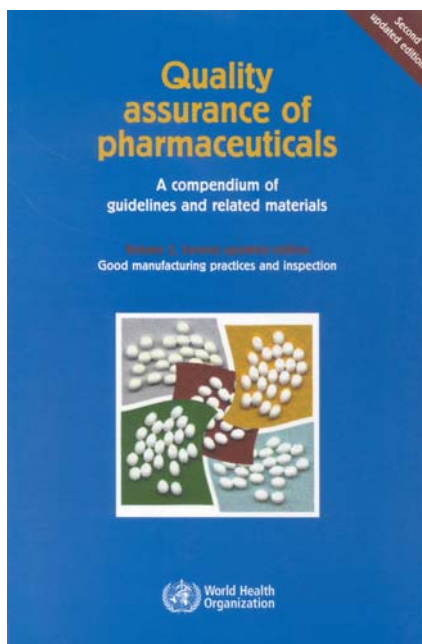

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World Health Organization

Quality Assurance of Pharmaceuticals A Compendium of Guidelines and Related Materials Volume 2. Second updated edition Good Manufacturing Practices and Inspection



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Quality assurance of pharmaceutical products is a continuing concern of WHO. Despite efforts made around the world to ensure a supply of quality and effective medicines, substandard, spurious and counterfeit products still compromise health care delivery in many countries.

To respond to the global need for adequate quality assurance of pharmaceuticals, WHO's Expert Committee on Specifications for Pharmaceutical Preparations has over the years made numerous recommendations to establish standards and guidelines and to promote the effective functioning of national regulatory and control systems and the implementation of internationally agreed standards by trained personnel. Many of the relevant documents endorsed by the Committee are reproduced in this volume, providing guidance covering all aspects of good manufacturing practices (GMP). Important texts on inspection are also included.

Most of the material has been published separately in the Expert Committee's reports. This compendium brings it together to make it more accessible and of greater practical value to those working in faculties of pharmacy, in medicines regulation and control, and in the pharmaceutical industry.

This is the second updated edition of the compendium and includes texts published in 2005 and 2006 in the WHO Technical Report Series.

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