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Nota di contenuto	1. Introduction -- 2. General policy -- 3. Quality control--specifications and tests -- 4. Quality control--international reference materials -- 5. Quality control--national laboratories -- 6. Quality assurance--good manufacturing practices (GMP) -- 7. Quality assurance--inspection -- 8. Quality assurance--distribution and trade-related -- 9. Quality assurance--risk analysis -- 10. Quality assurance--drug supply -- 11. Quality assurance--storage -- 12. International Nonproprietary Names (INNs) Programme -- 13. Miscellaneous -- Annex 1. Recommendations on risk of transmitting animal spongiform encephalopathy agents via medicinal products -- Annex 2. The International Pharmacopoeia: revised concepts and future perspectives -- Annex 3. Guidelines on good manufacturing practices for radiopharmaceutical products -- Annex 4. Good manufacturing practices for pharmaceutical products: main principles -- Annex 5. Model certificate of good manufacturing practices -- Annex 6. Guidance on good manufacturing practices (GMP): inspection report -- Annex 7. Application of hazard analysis and critical control point (HACCP) method to pharmaceuticals -- Annex 8. Procedure for assessing the acceptability, in principle, of pharmaceutical products for

purchase by United Nations agencies -- Annex 9. Guide to good storage practices for pharmaceuticals.

Sommario/riassunto

This report presents the recommendations of an international group of experts convened by the World Health Organization to consider matters concerning the quality assurance of pharmaceuticals and specifications for drug substances and dosage forms. The report is complemented by a number of annexes. These include: a list of available international chemical reference substances and international infrared spectra; supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms; updated supplementary guideli