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| Nota di contenuto | CONTENTS; 1. INTRODUCTION TO THE WHO/TDR HANDBOOK ON GLP; GENERAL INTRODUCTION; INTRODUCTION TO GLP AND ITS APPLICATION; 2. GOOD LABORATORY PRACTICE TRAINING; INTRODUCTION; THE FUNDAMENTAL POINTS OF GLP; RESOURCES; CHARACTERISATION; RULES FOR PERFORMING STUDIES; RESULTS - RAW DATA AND DATA COLLECTION; QUALITY ASSURANCE UNIT; 3. STEPWISE IMPLEMENTATION OF GLP; INTRODUCTION; IMPLEMENTATION AS A PROJECT; STEPWISE IMPLEMENTATION OF GLP REQUIREMENTS; ANNEXES: OECD SERIES ON PRINCIPLES OF GOOD LABORATORY PRACTICE AND COMPLIANCE MONITORING; I. OECD PRINCIPLES ON GOOD LABORATORY PRACTICE II. GUIDANCE FOR GLP MONITORING AUTHORITIES: REVISED GUIDES FOR COMPLIANCE MONITORING PROCEDURES FOR GOOD LABORATORY PRACTICEIII. GUIDANCE FOR GLP MONITORING AUTHORITIES: REVISED GUIDANCE FOR THE CONDUCT OF LABORATORY INSPECTIONS AND STUDY AUDITS; IV . QUALITY ASSURANCE AND GLP; V . COMPLIANCE OF LABORATORY SUPPLIERS WITH GLP PRINCIPLES; VI . THE APPLICATION OF THE GLP PRINCIPLES TO FIELD STUDIES; VII . THE APPLICATION OF |

THE GLP PRINCIPLES TO SHORT TERM STUDIES; VIII . THE ROLE AND RESPONSIBILITIES OF THE STUDY DIRECTOR IN GLP STUDIES
IX . GUIDANCE FOR GLP MONITORING AUTHORITIES: GUIDANCE FOR THE PREPARATION OF GLP INSPECTION REPORTS
X . THE APPLICATION OF THE PRINCIPLES OF GLP TO COMPUTERISED SYSTEMS; XI . THE ROLE AND RESPONSIBILITIES OF THE SPONSOR IN THE APPLICATION OF THE PRINCIPLES OF GLP; XII . REQUESTING AND CARRYING OUT INSPECTIONS AND STUDY AUDITS IN ANOTHER COUNTRY; XIII . THE APPLICATION OF THE OECD PRINCIPLES OF GLP TO THE ORGANISATION AND MANAGEMENT OF MULTI-SITE STUDIES; XIV . THE APPLICATION OF THE PRINCIPLES OF GLP TO IN-VITRO STUDIES
XV . ESTABLISHMENT AND CONTROL OF ARCHIVES THAT OPERATE IN COMPLIANCE WITH THE PRINCIPLES OF GLP

Sommario/riassunto

Good laboratory practices (GLP) are the recognized rules governing the conduct of non-clinical safety studies. They ensure the quality, integrity and reliability of the study data. This handbook is designed as an aid for those countries wishing to upgrade their laboratories to GLP status. Based on the Organisation for Economic Cooperation and Development (OECD) principles of GLP, the handbook provides laboratories and trainers in disease endemic countries with the necessary technical information for implementing GLP programs. The material in the handbook is presented in a clear and informative
