

1. Record Nr.	UNINA9910785666403321
Titolo	Quality practices for regulated non-clinical research and development [[electronic resource] /] / UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases
Pubbl/distr/stampa	Geneva, : WHO on behalf of the Special Programme for Research and Training in Tropical Diseases, c2009
ISBN	1-282-76077-7 9786612760778 92-4-068530-8
Edizione	[2nd ed.]
Descrizione fisica	1 online resource (327 p.)
Disciplina	344.7304
Soggetti	Laboratories - Standards Laboratories - Technique
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Note generali	Handbook : Good Laboratory Practice (GLP).
Nota di bibliografia	Includes bibliographical references.
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 PRACTICE III. 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

---