

AUDITING AND INSPECTING PRECLINICAL RESEARCH AND COMPLIANCE WITH GOOD LABORATORY PRACTICE (GLP)

N.J. DENT

Country Consultancy Ltd., Copper Beeches, Milton Malsor, United Kingdom

Contents

- 1 Introduction
- 2 Objective of the Guidelines
- 3 Who Does It Affect?
- 4 Why Have It?
- 5 How Is It Enforced?
- 6 What Is GLP?
 - 6.1 Responsibilities
 - 6.2 Training and Recording: Confirmation of Suitability
 - 6.3 Quality Assurance
 - 6.4 Standard Operating Procedures (SOPs)
 - 6.5 Study Plans and Reports
 - 6.6 Data
 - 6.7 Equipment
 - 6.8 Computers
 - 6.9 Test Systems
 - 6.10 Test Substance
 - 6.11 Archives
- 7 How Can Compliance Be Maintained Within a Facility?
- 8 Pitfalls and Benefits
- References