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## **Course Outline for FDA-GLP Good Laboratory Practices 21CFR58**

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### **Course objective**

This training course has been designed for individuals involved in manufacturing of Finished Pharmaceuticals products. It offers in-depth training on the FDA's GLP requirements of

This course is also useful if you want to implement the Good Laboratory Practices for a Pharmaceuticals, Medical Devices, Human Food, Neutraceuticals, OR a non-regulated industry test or research laboratory,

### **Course length**

2-3 days (a few hours everyday) are required to complete the FDA-cGLP for Finished Pharmaceuticals Training.

### **Who should attend**

Anyone who do not have time to allocate a full day to take a LIVE class on FDA's GLP for finished pharmaceuticals, wants to quickly and efficiently understand what the pharmaceutical FDA's GLP requirements are, and implement the GLP without using a consulting firm

### **Title 21--Food and Drugs**

#### **CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES**

#### **GOOD LABORATORY PRACTICE FOR NONCLINICAL LABORATORY STUDIES**

58.1 Scope.

58.3 Definitions.

58.10 Applicability to studies performed under grants and contracts.

58.15 Inspection of a testing facility.

58.29 Personnel.

58.31 Testing facility management.

58.33 Study director.

58.35 Quality assurance unit.

58.41 General.

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- 58.43 Animal care facilities.
- 58.45 Animal supply facilities.
- 58.47 Facilities for handling test and control articles.
- 58.49 Laboratory operation areas.
- 58.51 Specimen and data storage facilities.
- 58.61 Equipment design.
- 58.63 Maintenance and calibration of equipment.
- 58.81 Standard operating procedures.
- 58.83 Reagents and solutions.
- 58.90 Animal care.
- 58.105 Test and control article characterization.
- 58.107 Test and control article handling.
- 58.113 Mixtures of articles with carriers.
- 58.120 Protocol.
- 58.130 Conduct of a nonclinical laboratory study.
- 58.185 Reporting of nonclinical laboratory study results.
- 58.190 Storage and retrieval of records and data.
- 58.195 Retention of records.
- 58.200 Purpose.
- 58.202 Grounds for disqualification.
- 58.204 Notice of and opportunity for hearing on proposed disqualification.
- 58.206 Final order on disqualification.
- 58.210 Actions upon disqualification.
- 58.213 Public disclosure of information regarding disqualification.

- 58.215 Alternative or additional actions to disqualification.
- 58.217 Suspension or termination of a testing facility by a sponsor.
- 58.219 Reinstatement of a disqualified testing facility

### **Worldwide Course Recognition:**

CALISO online training courses are recognized by all registrars and hiring companies as objective evidence of effective training on the particular standard and regulation. Since 1999, they have been the most popular and most widely used training courses in English, with over 15,000 trainees in the US and worldwide. The standards and regulations are provided online under licensing of the American National Standard Institute (ANSI), SAE International, or courtesy of the Federal Drug Administration (FDA).

### **Course requirements**

The training is optimized for Microsoft Internet explore 5.0 or higher and Netscape 4.5 or higher

### **Certificate requirements**

The course uses a continuous evaluation method with on-going quizzes to facilitate the information retention. If your final average is equal or greater to 70% you will be issued a **training certificate**. If your final average evaluation is less than 70%, you will have to take a final exam and score above 70% to be issued the training certificate.