

Food and Drug Administration, HHS

§ 58.3

- 58.31 Testing facility management.
- 58.33 Study director.
- 58.35 Quality assurance unit.

Subpart C—Facilities

- 58.41 General.
- 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.

Subpart D—Equipment

- 58.61 Equipment design.
- 58.63 Maintenance and calibration of equipment.

Subpart E—Testing Facilities Operation

- 58.81 Standard operating procedures.
- 58.83 Reagents and solutions.
- 58.90 Animal care.

Subpart F—Test and Control Articles

- 58.105 Test and control article characterization.
- 58.107 Test and control article handling.
- 58.113 Mixture of articles with carriers.

Subpart G—Protocol for and Conduct of a Nonclinical Laboratory Study

- 58.120 Protocol.
- 58.130 Conduct of a nonclinical laboratory study.

Subparts H–I [Reserved]

Subpart J—Records and Reports

- 58.185 Reporting of nonclinical laboratory study results.
- 58.190 Storage and retrieval of records and data.
- 58.195 Retention of records.

Subpart K—Disqualification of Testing Facilities

- 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.

AUTHORITY: 21 U.S.C. 342, 346, 346a, 348, 351, 352, 353, 355, 360, 360b–360f, 360h–360j, 371, 379e, 381; 42 U.S.C. 216, 262, 263b–263n.

SOURCE: 43 FR 60013, Dec. 22, 1978, unless otherwise noted.

Subpart A—General Provisions

§ 58.1 Scope.

(a) This part prescribes good laboratory practices for conducting nonclinical laboratory studies that support or are intended to support applications for research or marketing permits for products regulated by the Food and Drug Administration, including food and color additives, animal food additives, human and animal drugs, medical devices for human use, biological products, and electronic products. Compliance with this part is intended to assure the quality and integrity of the safety data filed pursuant to sections 406, 408, 409, 502, 503, 505, 506, 510, 512–516, 518–520, 721, and 801 of the Federal Food, Drug, and Cosmetic Act and sections 351 and 354–360F of the Public Health Service Act.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

[43 FR 60013, Dec. 22, 1978, as amended at 52 FR 33779, Sept. 4, 1987; 64 FR 399, Jan. 5, 1999]

§ 58.3 Definitions.

As used in this part, the following terms shall have the meanings specified:

(a) *Act* means the Federal Food, Drug, and Cosmetic Act, as amended (secs. 201–902, 52 Stat. 1040 *et seq.*, as amended (21 U.S.C. 321–392)).

(b) *Test article* means any food additive, color additive, drug, biological product, electronic product, medical device for human use, or any other article subject to regulation under the act or under sections 351 and 354–360F of the Public Health Service Act.

(c) *Control article* means any food additive, color additive, drug, biological product, electronic product, medical device for human use, or any article other than a test article, feed, or water that is administered to the test system