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Global Regulatory & Clinical Research Consultants

GOOD LABORATORY PRACTICES

GLP Self - Assessment / Audit Questionnaire

The purpose of this questionnaire is to help qualify potential GLP services related vendors

Vendor / GLP Facility Information

Vendor Name:	
Vendor Address:	
Vendor Contact Info:	
Project Name:	
Project Manager:	
Project Sponsor:	
Project Customer:	
Self Assessment Facilitator:	
Review Date:	

Item #	21 CFR Part 58	Item / Issue for GLP Assessment	Yes/No/NA	Comments
	Subpart A - General Provisions			
1.	§ 58.10	Has the sponsor, in utilizing the services of a consulting laboratory, contractor, or grantee to perform an analysis or other service, notified them that the service is part of a nonclinical laboratory study and must be conducted in compliance with the provisions of this part?	☐ Yes ☐ No ☐ NA	
2.	§ 58.15	Does the testing facility permit the FDA, at reasonable times and in a reasonable manner, to inspect the facility and all records and specimens required to be maintained?	☐ Yes ☐ No ☐ NA	
	Subpart B – Organization and Personnel			
3.	§ 58.29(a)	Does each individual engaged in the conduct of or supervision of the study have the education, training, and experience to perform the assignments?	☐ Yes ☐ No ☐ NA	
4.	§ 58.29(b)	Does the facility maintain a current summary of training, experience, and job descriptions for each person engaged in or supervising the study?	☐ Yes ☐ No ☐ NA	
5.	§ 58.29(c)	Are there sufficient personnel for the timely and proper conduct of the study according to the protocol?	☐ Yes ☐ No ☐ NA	
6.	§ 58.29(d)	Do personnel take sanitation and health precautions to avoid contamination of test and control articles and test systems?	☐ Yes ☐ No ☐ NA	

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7.	§ 58.29(e)	Do personnel engaged in the study wear appropriate clothing, changed at a frequency to prevent microbiological, radiological, or chemical contamination of test systems and test control articles?	☐ Yes ☐ No ☐ NA	
8.	§ 58.29(f)	Are personnel with an illness that may adversely affect the test systems, test or control article (TCA), and any other operation excluded from the study until corrected?	☐ Yes ☐ No ☐ NA	
9.	§ 58.29(f)	Are personnel instructed to report to their supervisor any health or medical conditions that may have an adverse effect on the study?	☐ Yes ☐ No ☐ NA	
10.	§ 58.31(a)	Does the testing facility management designate a study director before study initiation?	☐ Yes ☐ No ☐ NA	
11.	§ 58.31(b)	Does the testing facility management, if necessary replace the study director promptly?	☐ Yes ☐ No ☐ NA	
12.	§ 58.31(c)	Does the testing facility management assure there is a Quality Assurance Unit (QAU) established?	☐ Yes ☐ No ☐ NA	
13.	§ 58.31(d)	Does the testing facility management assure that test and control articles or mixtures are appropriately tested for identity, strength, purity, stability, and uniformity, as applicable?	☐ Yes ☐ No ☐ NA	
14.	§ 58.31(e)	Does the testing facility management assure that personnel, resources, facilities, equipment, materials, and methodologies are available as scheduled?	☐ Yes ☐ No ☐ NA	
15.	§ 58.31(f)	Does the testing facility management assure that personnel clearly understand the functions they are to perform?	☐ Yes ☐ No ☐ NA	
16.	§ 58.31(g)	Does the testing facility management assure that any deviations from these regulations reported by the QAU are communicated to the study director and corrective actions are taken and documented?	☐ Yes ☐ No ☐ NA	
17.	§ 58.33	Does the study director have appropriate education, training, and experience?	☐ Yes ☐ No ☐ NA	
18.	§ 58.33	Does the study director exercise overall responsibility for the technical conduct of the study, including analysis, interpretation, documentation, and reporting of results?	☐ Yes ☐ No ☐ NA	
20.	§ 58.33(a)	Does the study director assure that the protocol and changes are approved as provided by § 58.120 and followed?	☐ Yes ☐ No ☐ NA	

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21.	§ 58.33(b)	Does the study director assure that all experimental data, including observations of unanticipated responses to the test system, are accurately recorded and verified?	☐ Yes ☐ No ☐ NA	
22.	§ 58.33(c)	Does the study director assure that unforeseen circumstances that may affect the quality and integrity of the study are noted when they occur, and corrective action is taken and documented?	☐ Yes ☐ No ☐ NA	
23.	§ 58.33(d)	Does the study director assure that test systems are as specified in the protocol?	☐ Yes ☐ No ☐ NA	
24.	§ 58.33(e)	Does the study director assure that all applicable GLP regulations are followed?	☐ Yes ☐ No ☐ NA	
25.	§ 58.33(f)	Does the study director assure that all raw data, documentation, protocols, specimens, and final reports are transferred to the archives during or at the close of the study?	☐ Yes ☐ No ☐ NA	
26.	§ 58.35(a)	Is the QAU responsible for monitoring each study?	☐ Yes ☐ No ☐ NA	
27.	§ 58.35(a)	Does the QAU assure management that the facilities, equipment, personnel, methods, practices, records, and controls are in conformance with these regulations?	☐ Yes ☐ No ☐ NA	
28.	§ 58.35(a)	For any given study, is the QAU separate from and independent of the personnel engaged in the direction and conduct of that study?	☐ Yes ☐ No ☐ NA	
29.	§ 58.35(b)(1)	Does the QAU maintain a copy of a master schedule sheet of all nonclinical laboratory studies conducted at the testing facility indexed by test article and containing the test system, nature of study, date study was initiated, current status of each study, identity of the sponsor, and name of the study director?	☐ Yes ☐ No ☐ NA	
30.	§ 58.35(b)(2)	Does the QAU maintain copies of all protocols pertaining to all studies for which the QAU is responsible?	☐ Yes ☐ No ☐ NA	
31.	§ 58.35(b)(3)	Does the QAU inspect each nonclinical laboratory study at intervals adequate to assure the integrity of the study and maintain written and properly signed records of each periodic inspection showing the date of the inspection, the study inspected, the phase or segment of the study inspected, the person performing the inspection, findings and problems, action recommended and taken to resolve existing problems, and any scheduled	☐ Yes ☐ No ☐ NA	

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		date(s) for reinspection?		
32.	§ 58.35(b)(3)	Does the QAU immediately inform the study director and management of any significant problems that are likely to affect study integrity?	☐ Yes ☐ No ☐ NA	
33.	§ 58.35(b)(4)	Does the QAU periodically submit to management and the study director written status reports on each study, noting any problems and the corrective actions taken?	☐ Yes ☐ No ☐ NA	
34.	§ 58.35(b)(5)	Does the QAU determine that no deviations from approved protocols or standard operating procedures were made without proper authorization and documentation?	☐ Yes ☐ No ☐ NA	
35.	§ 58.35(b)(6)	Does the QAU review the final study report to assure that it accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the study?	☐ Yes ☐ No ☐ NA	
36.	§ 58.35(b)(7)	Does the QAU prepare and sign a statement to be included with the final study report that specifies the date(s) inspections were made and findings reported to management and to the study director?	☐ Yes ☐ No ☐ NA	
37.	§ 58.35(c)	Does the QAU maintain written documentation of the responsibilities and procedures applicable to the QAU, and the method of indexing such records?	☐ Yes ☐ No ☐ NA	
38.	§ 58.35(c)	Does the QAU maintain a record including inspection dates, the study inspected, and the phase and inspector for review by authorized regulatory personnel?	☐ Yes ☐ No ☐ NA	
39.	§ 58.35(d)	Does the QAU assure that inspections are being implemented, performed, documented, and followed up in accordance with GLP?	☐ Yes ☐ No ☐ NA	
40.	§ 58.35	Does the QAU maintain the QAU records in one location at the testing facility? **<u>If 'NO' is checked</u>**, list location(s) in comments section.	☐ Yes ☐ No ☐ NA	
	Subpart C - Facilities			
41.	§ 58.41	Is the testing facility of suitable size and construction to facilitate the proper conduct of the study?	☐ Yes ☐ No ☐ NA	
42.	§ 58.41	Is it designed to provide a degree of separation that will prevent any function or activity from having an adverse affect on the study?	☐ Yes ☐ No ☐ NA	
		Does the facility have a sufficient number of animal	☐ Yes	

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43.	§ 58.43(a)	rooms or areas, as needed, to assure proper separation of species or test systems?	☐ No ☐ NA	
44.	§ 58.43(a)	Does the facility have a sufficient number of animal rooms or areas, as needed, to assure proper isolation of individual projects?	☐ Yes ☐ No ☐ NA	
45.	§ 58.43(a)	Does the facility have a sufficient number of animal rooms or areas, as needed, to assure proper quarantine of animals?	☐ Yes ☐ No ☐ NA	
46.	§ 58.43(a)	Does the facility have a sufficient number of animal rooms or areas, as needed, to assure proper routine or specialized housing of animals?	☐ Yes ☐ No ☐ NA	
47.	§ 58.43(b)	Does the facility have a number of rooms separate from those above to ensure isolation of studies being done with test systems or test and control articles known to be biohazardous, including volatile substances, aerosols, radioactive materials, and infectious agents?	☐ Yes ☐ No ☐ NA	
48.	§ 58.43(c)	Are separate areas provided as appropriate for the diagnosis, treatment, and control of laboratory animal diseases?	☐ Yes ☐ No ☐ NA	
49.	§ 58.43(d)	Do the facilities provide for the collection and disposal of all animal waste and refuse or for safe sanitary storage of waste before removal from the facility?	☐ Yes ☐ No ☐ NA	
50.	§ 58.43(d)	Are the disposal facilities provided and operated as to minimize vermin infestation, odors, disease hazards, and environmental contamination?	☐ Yes ☐ No ☐ NA	
51.	§ 58.43(a)	Are the facilities designed, constructed, and located so as to minimize disturbances that interfere with the study?	☐ Yes ☐ No ☐ NA	
52.	§ 58.45	Are there storage areas, as needed, for feed, bedding, supplies, and equipment?	☐ Yes ☐ No ☐ NA	
53.	§ 58.45	Are the storage areas for feed and bedding separated from areas housing the test systems?	☐ Yes ☐ No ☐ NA	
54.	§ 58.45	Are these storage areas protected against infestation or contamination?	☐ Yes ☐ No ☐ NA	
55.	§ 58.45	Are perishable supplies preserved by appropriate means?	☐ Yes ☐ No ☐ NA	
56.	§ 58.47(a)(1)	As necessary, to prevent contamination, mix-ups, are there separate areas for receipt and storage of test and control articles?	☐ Yes ☐ No	

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			☐ NA	
57.	§ 58.47(a)(2)	As necessary, to prevent contamination, mix-ups, are there separate areas for mixing of the test and control articles with a carrier, e.g., feed?	☐ Yes ☐ No ☐ NA	
58.	§ 58.47(a)(3)	As necessary, to prevent contamination, mix-ups, are there separate areas for storage of the test and control article mixtures?	☐ Yes ☐ No ☐ NA	
59.	§ 58.47(b)	Are storage areas for the test and/or control article and test and control mixtures separate from areas housing the test systems?	☐ Yes ☐ No ☐ NA	
60.	§ 58.47(b)	Are they adequate to preserve the identity, strength, purity, and stability of the articles and mixtures?	☐ Yes ☐ No ☐ NA	
61.	§ 58.49	Is separate laboratory space provided for the performance of the routine and specialized procedures required by nonclinical laboratory studies?	☐ Yes ☐ No ☐ NA	
62.	§ 58.51	Is space provided for archives, limited to access by authorized personnel only, for the storage and retrieval of all raw data and specimens from completed studies?	☐ Yes ☐ No ☐ NA	
	Subpart D - Equipment			
63.	§ 58.61	Is equipment used in the generation, measurement, or assessment of data and equipment used for facility environmental control of appropriate design and adequate capacity to function according to the protocol?	☐ Yes ☐ No ☐ NA	
64.	§ 58.61	Is this equipment suitably located for operation, inspection, cleaning, and maintenance?	☐ Yes ☐ No ☐ NA	
65.	§ 58.63(a)	Is this equipment adequately inspected, cleaned, and maintained?	☐ Yes ☐ No ☐ NA	
66.	§ 58.63(a)	Is equipment used for the generation, measurement, or assessment of data adequately tested, calibrated, and/or standardized?	☐ Yes ☐ No ☐ NA	
67.	§ 58.63(b)	Do the Standard Operating Procedures (SOPs) required in § 58.81(b)(11) set forth in sufficient detail the methods, materials, and schedules to be used in the routine inspection, cleaning, maintenance, testing, calibration, and/or standardization of equipment?	☐ Yes ☐ No ☐ NA	
68.	§ 58.63(b)	Do these SOPs specify, when appropriate, the remedial action to be taken in the event of failure or	☐ Yes ☐ No	

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		malfunction of equipment?	☐ NA	
69.	§ 58.63(b)	Do these SOPs also designate the person responsible for the performance of each operation?	☐ Yes ☐ No ☐ NA	
70.	§ 58.63(c)	Are written records maintained of all inspection, maintenance, testing, calibration and/or standardizing operations?	☐ Yes ☐ No ☐ NA	
71.	§ 58.63(c)	Do these records, containing the date of operation, describe whether the maintenance operations were routine and followed the written SOPs?	☐ Yes ☐ No ☐ NA	
72.	§ 58.63(c)	Are written records kept of nonroutine repairs performed on equipment as a result of failure and malfunction?	☐ Yes ☐ No ☐ NA	
73.	§ 58.63(c)	Do these records document the nature of the defect, how and when the defect was discovered, and any remedial action taken in response to the defect?	☐ Yes ☐ No ☐ NA	
	Subpart E – Testing Facilities Operation			
74.	§ 58.81(a)	Are the SOPs in writing setting forth study methods adequate to insure the quality and integrity of the data generated in the course of a study?	☐ Yes ☐ No ☐ NA	
75.	§ 58.81(a)	Are all deviations in a study from SOPs authorized by the study director?	☐ Yes ☐ No ☐ NA	
76.	§ 58.81(a)	Are the deviations documented in the raw data?	☐ Yes ☐ No ☐ NA	
77.	§ 58.81(a)	Are significant changes in established SOPs properly authorized in writing by management?	☐ Yes ☐ No ☐ NA	
78.	§ 58.81(b)(1)	Are SOPs established for (but not limited to), animal room preparation?	☐ Yes ☐ No ☐ NA	
79.	§ 58.81(b)(2)	Are SOPs established for (but not limited to), animal care?	☐ Yes ☐ No ☐ NA	
80.	§ 58.81(b)(3)	Are SOPs established for (but not limited to), receipt, identification, storage, handling, mixing, and method of sampling of the test and control articles?	☐ Yes ☐ No ☐ NA	
81.	§ 58.81(b)(4)	Are SOPs established for (but not limited to), test system observations?	☐ Yes	

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			☐ No ☐ NA	
82.	§ 58.81(b)(5)	Are SOPs established for (but not limited to), laboratory tests?	☐ Yes ☐ No ☐ NA	
83.	§ 58.81(b)(6)	Are SOPs established for (but not limited to), handling of animals found moribund or dead during study?	☐ Yes ☐ No ☐ NA	
84.	§ 58.81(b)(7)	Are SOPs established for (but not limited to), necropsy of animals or postmortem examination of animals?	☐ Yes ☐ No ☐ NA	
85.	§ 58.81(b)(8)	Are SOPs established for (but not limited to), collection and identification of specimens?	☐ Yes ☐ No ☐ NA	
86.	§ 58.81(b)(9)	Are SOPs established for (but not limited to), histopathology?	☐ Yes ☐ No ☐ NA	
87.	§ 58.81(b)(10)	Are SOPs established for (but not limited to), data handling, storage, and retrieval?	☐ Yes ☐ No ☐ NA	
88.	§ 58.81(b)(11)	Are SOPs established for (but not limited to), maintenance and calibration of equipment?	☐ Yes ☐ No ☐ NA	
89.	§ 58.81(b)(12)	Are SOPs established for (but not limited to), transfer, proper placement, and identification of animals?	☐ Yes ☐ No ☐ NA	
90.	§ 58.81(c)	Does each laboratory area have immediately available manuals and SOPs relative to the laboratory procedures being performed?	☐ Yes ☐ No ☐ NA	
91.	§ 58.81(c)	If published literature is used, is it used as a supplement to SOPs and not in lieu of SOPs?	☐ Yes ☐ No ☐ NA	
92.	§ 58.81(d)	Has an historical file been established and maintained of SOPs and all revisions, including the dates of such revisions?	☐ Yes ☐ No ☐ NA	
93.	§ 58.83	Are all reagents and solutions in the laboratory areas labeled to indicate identity, titer or concentration, storage requirements, and expiration date?	☐ Yes ☐ No ☐ NA	
94.	§ 58.83	Are deteriorated or outdated reagents and solutions not used?	☐ Yes ☐ No ☐ NA	

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95.	§ 58.90(a)	Is there an SOP for housing, feeding, handling, and care of animals?	☐ Yes ☐ No ☐ NA	
96.	§ 58.90(b)	Are all newly received animals from outside sources isolated and their health status evaluated in accordance with acceptable veterinary medical practice?	☐ Yes ☐ No ☐ NA	
97.	§ 58.90(b)	Are these evaluations in accordance with acceptable veterinary medical practice?	☐ Yes ☐ No ☐ NA	
98.	§ 58.90(c)	At the initiation of the study are the animals free of any disease or condition that might interfere with the purpose or conduct of the study?	☐ Yes ☐ No ☐ NA	
99.	§ 58.90(c)	In the course of a study are the animals that contract such a disease or condition isolated, if necessary?	☐ Yes ☐ No ☐ NA	
100.	§ 58.90(c)	If these animals are treated for the disease or signs of the disease, dose the treatment not interfere with the study?	☐ Yes ☐ No ☐ NA	
101.	§ 58.90(c)	Are the diagnosis, authorizations of treatment, and each date of treatment documented and retained?	☐ Yes ☐ No ☐ NA	
102.	§ 58.90(d)	Do warm blooded animals, excluding suckling rodents, used in laboratory procedures that require manipulations and observations over an extended period of time receive appropriate identification?	☐ Yes ☐ No ☐ NA	
103.	§ 58.90(d)	Do these aforementioned animals used in studies that require the animals to be removed from and returned to their home cages for any reason (e.g., cage cleaning, treatment) receive appropriate identification?	☐ Yes ☐ No ☐ NA	
104.	§ 58.90(d)	Does all information needed to specifically identify each animal within an animal-housing unit appear on the outside of that unit?	☐ Yes ☐ No ☐ NA	
105.	§ 58.90(e)	Are animals of different species housed in separate rooms when necessary?	☐ Yes ☐ No ☐ NA	
106.	§ 58.90(e)	Are animals of the same species, but used in different studies, not ordinarily housed in the same room when inadvertent exposure to control or test articles or animal mix-up could affect the outcome of the study?	☐ Yes ☐ No ☐ NA	
107.	§ 58.90(e)	If such mixed housing is necessary, is adequate differentiation by space and identification made?	☐ Yes ☐ No ☐ NA	

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108.	§ 58.90(f)	Are animal cages, racks, and accessory equipment cleaned and sanitized at appropriate intervals?	☐ Yes ☐ No ☐ NA	
109.	§ 58.90(g)	Are feed and water used for the animals analyzed periodically to ensure that contaminants known to be capable of interfering with the study and reasonably expected to be present in such feed or water are not present at levels above those specified in the protocol?	☐ Yes ☐ No ☐ NA	
110.	§ 58.90(g)	Are such analyses maintained as raw data?	☐ Yes ☐ No ☐ NA	
111.	§ 58.90(h)	Does the bedding used in the animal cages or pens not interfere with the purpose or conduct of the study?	☐ Yes ☐ No ☐ NA	
112.	§ 58.90(h)	Is the bedding changed as often as necessary to keep the animals dry and clean?	☐ Yes ☐ No ☐ NA	
113.	§ 58.90(i)	If pest control materials are used, is their use documented?	☐ Yes ☐ No ☐ NA	
114.	§ 58.90(i)	Are cleaning and pest control materials that interfere with the study not used?	☐ Yes ☐ No ☐ NA	
Subpart F – Test and Control Articles				
115.	§ 58.105(a)	Are the identity, strength, purity, and composition or other characteristics that will appropriately define the test or control article (TCA) determined and documented for each batch?	☐ Yes ☐ No ☐ NA	
116.	§ 58.105(a)	Are the methods of synthesis, fabrication, or derivation of the test and control articles documented by the sponsor or the testing facility?	☐ Yes ☐ No ☐ NA	
117.	§ 58.105(a)	Are marketed products used as control articles characterized by their labeling?	☐ Yes ☐ No ☐ NA	
118.	§ 58.105(b)	Is the stability of each TCA determined by the testing facility or by the sponsor, either before initiation of a study or concomitantly according to written SOPs, which provide for periodic analysis of each batch?	☐ Yes ☐ No ☐ NA	
119.	§ 58.105(c)	Is each storage container for a TCA labeled by name, chemical abstract number (or code number), batch number, expiration date (if any); and, where appropriate, storage conditions necessary to maintain the identity, strength, purity, and composition of the TCA?	☐ Yes ☐ No ☐ NA	

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120.	§ 58.105(c)	Are storage containers assigned to a particular test article for the duration of the study?	☐ Yes ☐ No ☐ NA	
121.	§ 58.105(d)	For studies lasting more than 4 weeks duration, are reserve samples from each batch of TCA retained for the period time provided in § 58.195?	☐ Yes ☐ No ☐ NA	
122.	§ 58.107(a)	Are procedures established for a system for the handling of the TCA articles to ensure that there is proper storage?	☐ Yes ☐ No ☐ NA	
123.	§ 58.107(b)	Are procedures established for a system for the handling of the TCA articles to ensure that distribution is made in a manner designed to preclude the possibility of contamination, deterioration, or damage?	☐ Yes ☐ No ☐ NA	
124.	§ 58.107(c)	Are procedures established for a system for the handling of the TCA articles to ensure that proper identification is maintained throughout the distribution process?	☐ Yes ☐ No ☐ NA	
125.	§ 58.107(d)	Are procedures established for a system for the handling of the TCA articles to ensure that the receipt and distribution of each batch is documented, including the date and quantity of each batch distributed or returned?	☐ Yes ☐ No ☐ NA	
126.	§ 58.113(a)(1)	For each TCA that is mixed with a carrier, are tests by appropriate analytical methods conducted to determine the uniformity of the mixture and to periodically determine, the concentration of the TCA in the mixture?	☐ Yes ☐ No ☐ NA	
127.	§ 58.113(a)(2)	For each TCA that is mixed with a carrier, are tests by appropriate analytical methods conducted to determine the stability of the TCA in the mixture?	☐ Yes ☐ No ☐ NA	
128.	§ 58.113(a)(2)	Is stability of the TCA in the mixture as required by the conditions of the study, determined either before initiation of the study, or concomitantly according to written SOPs that provide for periodic analysis of the TCA in the mixture?	☐ Yes ☐ No ☐ NA	
129.	§ 58.113(c)	Where any of the components of the TCA carrier mixture has an expiration date, is that date clearly shown on the container?	☐ Yes ☐ No ☐ NA	
130.	§ 58.113(c)	If more than one component has an expiration date, is the earliest date show?	☐ Yes ☐ No ☐ NA	
Subpart G - Protocol for and Conduct of a Nonclinical Laboratory Study				
131.	§ 58.120(a)	Does each study have an approved written protocol that clearly indicates the objectives and all methods for the conduct of the study?	☐ Yes ☐ No	

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			☐ NA	
132.	§ 58.120(a)(1)	Does the protocol contain (as applicable), a descriptive title and statement of the purpose of the study?	☐ Yes ☐ No ☐ NA	
133.	§ 58.120(a)(2)	Does the protocol contain (as applicable), identification of the TCA by name, chemical abstracts number, or code number?	☐ Yes ☐ No ☐ NA	
134.	§ 58.120(a)(3)	Does the protocol contain (as applicable), the name of the sponsor and the name and address of the testing facility at which the study is being conducted?	☐ Yes ☐ No ☐ NA	
135.	§ 58.120(a)(4)	Does the protocol contain (as applicable), the number, body weight, range, sex, source of supply, species, strain, substrain, and age of the test system?	☐ Yes ☐ No ☐ NA	
136.	§ 58.120(a)(5)	Does the protocol contain (as applicable), the procedure for identification of the test system?	☐ Yes ☐ No ☐ NA	
137.	§ 58.120(a)(6)	Does the protocol contain (as applicable), a description of the experimental design, including the methods for control of bias?	☐ Yes ☐ No ☐ NA	
138.	§ 58.120(a)(7)	Does the protocol contain (as applicable), a description and/or identification of diet used in the study as well as solvent, emulsifiers, and/or other materials used to solubilize or suspend the TCA before mixing with the carrier?	☐ Yes ☐ No ☐ NA	
139.	§ 58.120(a)(7)	Does the protocol contain (as applicable), a description including specifications for acceptable levels of contaminants that are reasonably expected to be present in the dietary materials; and are known to be capable of interfering with the purpose or conduct of the study if present at levels greater than established by the specifications?	☐ Yes ☐ No ☐ NA	
140.	§ 58.120(a)(8)	Does the protocol contain (as applicable), the reason for route-of-administration choice?	☐ Yes ☐ No ☐ NA	
141.	§ 58.120(a)(8)	Does the protocol contain (as applicable), each dosage level, expressed in milligrams per kilogram of body weight (or other appropriate units), of the TCA to be administered and the method and frequency of administration?	☐ Yes ☐ No ☐ NA	
142.	§ 58.120(a)(9)	Does the protocol contain (as applicable), the type and frequency of tests, analyses, and measurements to be made?	☐ Yes ☐ No ☐ NA	

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143.	§ 58.120(a)(10)	Does the protocol contain (as applicable), the records to be maintained?	☐ Yes ☐ No ☐ NA	
144.	§ 58.120(a)(11)	Does the protocol contain (as applicable), The date of approval of the protocol by the sponsor and the dated signature of the study director?	☐ Yes ☐ No ☐ NA	
145.	§ 58.120(a)(12)	Does the protocol contain (as applicable), a statement of the proposed statistical methods to be used?	☐ Yes ☐ No ☐ NA	
146.	§ 58.120(b)	Are all the changes in or revision of an approved protocol and the reasons documented, signed by the study director, dated, and maintained with the protocol?	☐ Yes ☐ No ☐ NA	
147.	§ 58.130(a)	Is the nonclinical laboratory study conducted in accordance with the protocol?	☐ Yes ☐ No ☐ NA	
148.	§ 58.130(b)	Is the test system monitored in conformity with the protocol?	☐ Yes ☐ No ☐ NA	
149.	§ 58.130(c)	Are specimens identified by test system, study, nature, and date of collection?	☐ Yes ☐ No ☐ NA	
150.	§ 58.130(c)	Is this (ID) information located on the specimen container or does it accompany the specimen in a manner that precludes error in the recording and storage of data?	☐ Yes ☐ No ☐ NA	
151.	§ 58.130(d)	Are records of gross findings for a specimen from postmortem observations available to a pathologist when examining that specimen hisopathologically?	☐ Yes ☐ No ☐ NA	
152.	§ 58.130(e)	Are all data generated during the conduct of a nonclinical laboratory study, except those that are generated by automated data collection systems, recorded directly, promptly, and legibly, in ink?	☐ Yes ☐ No ☐ NA	
153.	§ 58.130(e)	Are all data entries dated on the date of entry and signed or initiated by the person entering the data?	☐ Yes ☐ No ☐ NA	
154.	§ 58.130(e)	Is any change in entries made so as not to obscure the original entry, indicate the reason for such change, and is dated and signed or identified at the time of the change?	☐ Yes ☐ No ☐ NA	
155.	§ 58.130(e)	In automated data collection systems, is the individual responsible for direct data input identified at the time of data input?	☐ Yes ☐ No ☐ NA	

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156.	§ 58.130(e)	Is any changed in automated data entries made so as not to obscure the original entry, indicate the reasons for change, and is dated and the responsible individual identified?	☐ Yes ☐ No ☐ NA	
	Subpart J – Records and Reports			
157.	§ 58.185(a)	Has a final report been prepared for each nonclinical laboratory study?	☐ Yes ☐ No ☐ NA	
158.	§ 58.185(a)(1)	Does the final report include (but not limited to) the name and address of the facility performing the study?	☐ Yes ☐ No ☐ NA	
159.	§ 58. 185(a)(1)	Does the final report include (but not limited to) the dates on which the study was initiated and completed?	☐ Yes ☐ No ☐ NA	
160.	§ 58. 185(a)(2)	Does the final report include (but not limited to) the objectives and procedures stated in the approved protocol, including any changes in the original protocol?	☐ Yes ☐ No ☐ NA	
161.	§ 58. 185(a)(3)	Does the final report include (but not limited to) the statistical methods employed for analyzing the data?	☐ Yes ☐ No ☐ NA	
162.	§ 58. 185(a)(4)	Does the final report include (but not limited to) the TCA identified by name, chemical abstracts number (or code number), strength, purity, and composition or appropriate characteristics?	☐ Yes ☐ No ☐ NA	
163.	§ 58. 185(a)(5)	Does the final report include (but not limited to) the stability of the TCA under conditions of administration?	☐ Yes ☐ No ☐ NA	
164.	§ 58. 185(a)(6)	Does the final report include (but not limited to) a description of the methods used?	☐ Yes ☐ No ☐ NA	
165.	§ 58. 185(a)(7)	Does the final report include (but not limited to) a description of the test system used?	☐ Yes ☐ No ☐ NA	
166.	§ 58. 185(a)(7)	Does the final report include (but not limited to), where applicable, the number of animals used, sex, body weight range, source of supply, species, strain & substrain, age?	☐ Yes ☐ No ☐ NA	
167.	§ 58. 185(a)(7)	Does the final report include (but not limited to) the procedure used for animal identification?	☐ Yes ☐ No ☐ NA	
168.	§ 58. 185(a)(8)	Does the final report include (but not necessarily limited to) a description of the dosage, dosage regimen, route of administration, and duration?	☐ Yes ☐ No ☐ NA	
		Does the final report include (but not necessarily	☐ Yes	

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169.	§ 58. 185(a)(9)	limited to) a description of all circumstances that may have affected the quality or integrity of the study?	☐ No ☐ NA	
170.	§ 58. 185(a)(10)	Does the final report include (but not necessarily limited to) the name of the study director, the names of other scientists or professionals, and the names of all supervisory personnel involved in the study?	☐ Yes ☐ No ☐ NA	
171.	§ 58. 185(a)(11)	Does the final report include (but not necessarily limited to) a description of the transformations, calculations or operations performed on the data?	☐ Yes ☐ No ☐ NA	
172.	§ 58. 185(a)(11)	Does the final report include (but not necessarily limited to) a summary and analysis of the data and a statement of the conclusions drawn from the analysis?	☐ Yes ☐ No ☐ NA	
173.	§ 58. 185(a)(12)	Does the final report include (but not necessarily limited to) the signed and dated reports of each of the individual scientists or other professionals involved in the study?	☐ Yes ☐ No ☐ NA	
174.	§ 58. 185(a)(13)	Does the final report include (but not necessarily limited to) the locations where all specimens, raw data, and the final report are to be stored?	☐ Yes ☐ No ☐ NA	
175.	§ 58. 185(a)(14)	Does the final report include (but not necessarily limited to) the statement prepared and signed by the QAU as described in § 58.35?	☐ Yes ☐ No ☐ NA	
176.	§ 58.185(b)	Is the final report signed and dated by the study director?	☐ Yes ☐ No ☐ NA	
177.	§ 58.185(c)	Are corrections or additions to a final report in the form of an amendment by the study director?	☐ Yes ☐ No ☐ NA	
178.	§ 58.185(c)	Does the amendment clearly identify that part of the final report that is being added to or corrected and the reasons for the correction or addition?	☐ Yes ☐ No ☐ NA	
179.	§ 58.185(c)	Is the amendment signed and dated by the person responsible?	☐ Yes ☐ No ☐ NA	
180.	§ 58.190(a)	Are all raw data, documentation, protocols, final reports, and specimens (except those specimens obtained from mutagenicity tests and wet specimens of blood, urine, feces, and biological fluids) generated as a result of a nonclinical laboratory study retained?	☐ Yes ☐ No ☐ NA	
181.	§ 58.190(b)	Is there an archive for orderly storage and expedient retrieval of all raw data, documentation, protocols, specimens, and interim and final reports?	☐ Yes ☐ No ☐ NA	

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182.	§ 58.190(b)	Do the conditions of storage minimize deterioration of the documents or specimens in accordance with the requirements for the time period of their retention and the nature of the documents or specimens?	☐ Yes ☐ No ☐ NA	
183.	§ 58.190(b)	If the facility has contracted with a commercial archive to provide a repository for all material to be retained, has specific reference been made in the archive to those other locations?	☐ Yes ☐ No ☐ NA	
184.	§ 58.190(c)	Is an individual identified as responsible for the archives?	☐ Yes ☐ No ☐ NA	
185.	§ 58.190(d)	Do only authorized personnel enter the archive?	☐ Yes ☐ No ☐ NA	
186.	§ 58.190(e)	Is material retained or referred to in the archives indexed to permit expedient retrieval?	☐ Yes ☐ No ☐ NA	
187.	§ 58.195(b)(1)	Except for wet specimens, samples of TCA, and specially prepared materials (e.g., histochemical, electron microscopic, blood mounts, teratological preparation, & uteri from dominant lethal mutagenesis tests): Are documentation records, raw data, and specimens pertaining to a nonclinical laboratory study (and required to be made by this part); retained in the archive(s) for a period of at least 2 years following the date on which an application for a research or marketing permit, in support of which the results of the nonclinical laboratory study were submitted, is approved by the FDA?	☐ Yes ☐ No ☐ NA	
188.	§ 58.195(b)(2)	Except for wet specimens, samples of TCA, and specially prepared materials (e.g., histochemical, electron microscopic, blood mounts, teratological preparation, & uteri from dominant lethal mutagenesis tests): Are documentation records, raw data, and specimens pertaining to a nonclinical laboratory study (and required to be made by this part); retained in the archive(s) for a period of at least 5 years following the date on which the results of the nonclinical laboratory study are submitted to the FDA in support of an application for a research or marketing permit?	☐ Yes ☐ No ☐ NA	

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189.	§ 58.195(b)(3)	Except for wet specimens, samples of TCA, and specially prepared materials (e.g., histochemical, electron microscopic, blood mounts, teratological preparation, & uteri from dominant lethal mutagenesis tests): In other situations (e.g., where the nonclinical laboratory study does not result in the submission of the study in support of an application for a research or marketing permit); are documentation records, raw data, and specimens pertaining to a nonclinical laboratory study (and required to be made by this part); retained in the archive(s) for a period of at least 2 years following the date on which the study is completed, terminated, or discontinued?	☐ Yes ☐ No ☐ NA	
190.	§ 58.195(c)	Are wet specimens (except those specimens obtained from mutagenicity tests and wet specimens of blood, urine, feces, and biological fluids), samples of test or control articles, and specially prepared materials (which are relatively fragile and differ markedly in stability and quality during storage), retained only as long as the quality of the preparation affords evaluation?	☐ Yes ☐ No ☐ NA	
191.	§ 58.195(d)	Are the master schedule sheet, copies of the protocols, and records of quality assurance inspections (as required by § 58.35), maintained by the QAU as an easily accessible system of records for the period of time specified previously (#s 187 - 189 above), as appropriate?	☐ Yes ☐ No ☐ NA	
192.	§ 58.195(e)	Are summaries of training and experience and job descriptions (required to be maintained by § 58.29) retained along with all other testing facility employment records for the length of time specified previously (#s 187 - 189 above), as appropriate?	☐ Yes ☐ No ☐ NA	
193.	§ 58.195(f)	Are records and reports of the maintenance, calibration, and inspection of equipment (as required by § 58.63), retained for the length of time specified previously (#s 187 - 189 above), as appropriate?	☐ Yes ☐ No ☐ NA	
194.	§ 58.195(g)	Are records required by the part retained either as original records or as true copies such as photocopies, microfilm, microfiche, or other accurate reproduction of the original records?	☐ Yes ☐ No ☐ NA	
195.	§ 58.195(h)	If a facility conducting nonclinical testing goes out of business, are all raw data, documentation, and other material specified previously transferred to the archives of the sponsor of the study?	☐ Yes ☐ No ☐ NA	
196.	§ 58.195(h)	If the above transfer occurs, is the FDA notified in writing?	☐ Yes ☐ No ☐ NA	

General Observations:
Comments:

After you have entered the necessary information to complete this questionnaire, print and distribute it to collect the signatures and dates that you need for approval.

Please provide Signed Document to:

Signatures for Approval

Vendor Project Manager _____ Date: ____ / ____ / ____

Vendor Quality /QAU Manager _____Date: ____ / ____ / _____

MDRS, LLC RA//CA/QA _____ Date: ____ / ____ / ____