Form Group: Facility Inspection
Packet ID: FI-
Location:
Date:
Closed:

A. Facilities

Yes, No, N/A

1. Facility is of suitable size:
2. Adequate working areas:
3. Facility appears clean/well maintained:
4. Satisfactory facilities for sanitation:

B. Test Control and Reference Substance

Yes, No, N/A

5. Are there separate areas for:
a. receipt and storage of test/control/reference substances?
b. storage of test/control/reference substances mixtures?
c. test substance mixing?
6. Receipt and usage:
a. receipt and condition upon receipt documented:
b. bulk inventory log maintained:
c. adequate usage/accountability documentation:
d. SOP followed:
7. Storage:
a. limited access:
b. environmentally controlled if necessary:
c. Is temperature continuously monitored?
d. calibration of temperature monitoring device per SOP:
e. temperature range adequate for compound integrity:
f. storage area adequately ventilated:
8. Test/control/reference substances properly labeled :
a. name, CAS or code number:
b. batch number:
c. expiration date:
d. storage conditions:
9. Test/control/reference substance storage neat and organized:

C. Equipment

Yes, No, N/A

10. Equipment cleaned as per SOP:
11. Equipment designed as per SOP:
12. Equipment located as per SOP:

13. Equipment appears to be in good repair:

14. Equipment adequately stored when not in use:

15. Maintenance logs on equipment up-to-date:

a. contains standardization/calibration records:

b. specifies routine and non-routine maintenance:

c. specifies whether or not SOP was followed for routine maintenance:

d. specifies nature of defect or routine maintenance:

e. specifies how and when defect was discovered:

f. specifies remedial action taken in response to defect:

16. Maintenance/calibration/standardization/cleaning per SOP:

17. Owner's manual easily accessible:

18. Maintenance logs easily accessible:

D. Test System Sample Storage
Yes, No, N/A

19. Separate from test/control/reference standard storage area:

20. Clean, organized free from contamination:

21. Limited access:

22. Tracking/accountability system in place and adequate:

23. control/treated adequately separated:

24. Temperature continuously recorded:

25. Recording devices adequately calibrated/standardized:

26. Maintenance logs on freezers up to date:

a. Specifies routine and non-routine maintenance:

b. Specifies whether or not SOP was followed for routine maintenance:

c. Specifies nature of defect for non-routine maintenance:

d. specifies how and when defect was discovered:

e. specifies remedial action taken in response to defect:

27. Maintenance log readily available:

E. General Laboratory
Yes, No, N/A

28. Work area neat, clean, uncluttered:

29. Proper storage of clean glassware:

30. SOP book available in work areas:

31. Appropriate dress procedures are followed:

32. All reagents/solutions properly labeled:

a. identity:

b. titer/concentration:

c. storage conditions:

d. expiration date:

33. No reagents/solutions out of date:

34. Proper storage maintained for all reagents/solutions:

35. Have SOPs addressing safety issues been followed?

F. Standard Operating Procedures
Yes, No, N/A

36. Have SOPs been approved by management according to IR-4 Operational Handbook (IR-4 Regional Management)?

37. . Is there an effective date for each SOP?

a. Did CRO TFM review SOP?

38. . Is there a revision number?

39. . Are SOPs appropriately retained after revision?

40. Are there procedures in place for replacing revised SOPs and ensuring that old SOPs are not available for use?

41. Are required SOPs in place (160.81)?

a. test system area preparation:

b. test system care:

c. receipt, ID, storage, handling, mixing & method of sampling test/control/reference substances:

d. test system observations:

e. laboratory or other tests:

f. handling of test system found dead during study:

g. necropsy:

h. collection and ID of specimens:

i. histopathology:

j. data handling, storage & retrieval:

k. maintenance & calibration of equipment:

l. transfer, proper placement & ID of test systems:

42. Do SOPs accurately reflect current procedure?:

43. a. Are there procedures in place for periodic review of SOPs to maintain accuracy?

b. Are SOP review intervals being followed?

44. . Is there an index for the SOPs?

45. SOP available on each piece of equipment:

a. routine inspection/maintenance intervals specified:

b. calibration/standardization procedures specified:

c. remedial action to be taken in case of malfunction or power failure specified:

d. person responsible for performance of each operation:

46. SOPs readily available:

G. Personnel Records

Yes, No, N/A

47. Training Records:

a. are current:

b. are being reviewed periodically as per SOP:

c. document recent GLP training:

d. document procedural training as per SOP:

48. CV's:

a. provide adequate detail of past experience:

b. provide adequate detail of education:

c. provide adequate detail of formalized training/meetings:

d. have been updated according to SOP:

49. Current job descriptions available for all personnel:

50. GLP personnel files maintained after departure:

H. Management of Facility

Yes, No, N/A

51. Had an EPA/FDA inspection:

52. Have all deficiencies been corrected?

53. Is organization chart available?

54. Does organization chart adequately describe reporting structure?

55. Is a floor plan available?

56. Is the facility adequately staffed?

I. Archives

Yes, No, N/A

57. Are the archives adequate?

a. limited access:

b. neat and orderly:

c. environmentally controlled:

58. Have precautions to prevent deterioration of the raw data been addressed?

59. Are procedures in place for logging data in and out?

60. Is the material indexed to expedite retrieval?

61. Is there a designated archivist?

62. Is a backup archivist designated?

63. How long are raw data maintained?

J. Quality Assurance

Yes, No, N/A

64. Is there an independent QA unit reporting directly to management?

65. Does the QA conduct periodic facility inspections?

66. How often?

67. Does QA inspect critical phases of each study?

68. Does QA audit all reports?

69. How much of a data check is done (comment)?	
70. Are Study Directors and testing facility management allowed to see all QA findings?	
71. Does the QA maintain a copy of the Master Schedule?	
72. Is the status of each study adequately documented?	
73. Are all required elements on the Master Schedule?	
a. indexed by test substance:	
b. test substance identified:	
c. nature of the study:	
d. date study was initiated:	
e. current status:	
f. identity of sponsor:	
g. name of study director:	
74. Are all QA records easily accessible and properly indexed?	
75. Is the QA statement included in the report?	
76. Are QA SOPs adequate?	
78. Is the QA adequately staffed?	
77. Does the QA offer periodic GLP training?	
79. Does the QA appear to have management support?	
81. Does the QA have a copy of the final regulation?	
80.Does the QA maintain a copy of all signed approved protocols?	