THIRD PARTY LABORATORY QUALIFICATION SELF-AUDIT

Third Party Laboratory
Address:
Contact:
Phone:
Email:
Date:

I. Basic Information

- Please list all analyses performed in the lab.
- For each analysis, please provide the following:
    - Instruments and methods
    - List of analytes
    - LOD, LOQ, Reporting Limits
    - How often are blank, standards, and spiked matrix samples analyzed?
    - How often are facilities tested for possible analyte contamination?

II. Documentation

Please provide copies of the following:

- Index of Standard Operating Procedures
- Company Organizational Chart
- Equipment List
- Accreditations and Certifications

III. Qualifications

For this section, please reference the location where the answer to each question may be found in the laboratory Quality Manual or other controlled document.

1. Has management defined, documented, and communicated its Quality Policy to its organization?
2. Has management appointed quality responsibility and authority to appropriate personnel?
3. Does the lab have a documented Quality System?
4. Does the management regularly review the Quality System at scheduled intervals?
5. Does the lab have a quality manual approved by management?
6. Are quality reports issued to management and used as a basis for continual improvement?
7. What accreditations does the laboratory maintain? Please list and attach copies.
8. Is there an SOP for sample submittal and receiving?
9. Is each sample assigned a unique laboratory identification number? How is it assigned?
10. Are samples stored securely and labeled with proper identity?
11. Is there a log of stored samples? For how long are samples stored?
12. Are temperature and humidity of sample storage area recorded?
13. Is a Certificate of Analysis (CofA) issued for each test performed?

14. Is all data on CofA's traceable to raw data stored by the laboratory?
15. How are CofA's for each customer stored? For how long?
16. Are clients notified of any method deviations taken during analysis? Is there a system for obtaining customer agreement to these changes?
17. Are there procedures to control, revise, and change documents?
18. Are all appropriate documents controlled and identified by revision level or date?
19. Do authorized personnel approve controlled documents prior to issue?
20. Are there SOP's available for handling reference standards and working standards?
21. Are CofAs and/or reference data for these standards available?
22. Are storage data and conditions available for these standards?
23. How often are standards re-analyzed or re-certified?
24. Do you have SOPs or guidelines on continual improvement?
25. Are SOPs and manuals available for handling all instruments?
26. Does the laboratory have a subcontractor list and approval system?
27. Does the laboratory conduct subcontractor audits? How often?
28. Are all reagents and chemicals sourced from approved suppliers?
29. Are reference standards certified (NIST or other)?
30. Are all reagents and chemicals marked with date of receipt, date opened, and expiration date? How are expiration dates assigned?
31. Does the laboratory have a documented calibration system?
32. Are there SOP's for calibration?
33. When calibration are performed by an outside contractor, does the laboratory require certifications and test data?
34. Are all calibrations traceable to NIST?
35. Are all analytical methods validated?
36. Are analytical method validation test data available?
37. Are all instruments currently certified to perform within the scope required for each analysis?
38. Are instruments calibrated? What is the calibration schedule?
39. Are weights used certified?
40. Is calibration data available for verification?
41. What are the procedures for re-testing a sample?
42. Are test results / chromatograms signed and dated by the analyst?
43. Is there a log for each instrument and piece of equipment? Is the log up to date?
44. Are laminar air flow stations validated for: velocity, filter integrity, linearity? How often?
45. Are records kept of temperature / pressure of each autoclave run?
46. Have you done heat distribution studies on the autoclave?
47. Are there SOP's for destruction of samples, media, and reagents?
48. Does the laboratory perform internal quality audits to verify that departmental personnel comply with established procedures?
49. Are follow-up audits performed in the case of any corrective action findings?
50. Are records of internal audits available?
51. Is there an SOP for observations that are outside of operating specifications?
52. Do you have an SOP for guidelines on Good Laboratory Practices (GLP)?
53. Are training records on each SOP available?
54. Is a training assessment of each analyst complete and certified?