Quality Control, Documentation and Records Management

cGMP Testing vs. Standard Testing

The main differences between cGMP and Standard Testing are; much more control over the test documentation, how results are derived and interpreted and the documentation on the instrument being used. The instruments are checked out more thoroughly; all of the test instruments used to determine if a unit is working correctly are required to be NISTtraceable.

Organization and Personnel

Our Quality Manual defines our system, our organization, and the whole way we do business. The Quality Manual also covers each part of the system and gives a brief description.

Quality Assurance

An Internal Audit is performed once a quarter to go over procedures to make sure they are up to date with current testing practices (we do what we say we are doing in the procedures). We cover CA/PA forms which are filled out when there is a need for either a Preventive Action (we see a need for change), or a Corrective Action which may be due to an instrument failing and needing repair, or an action that needs to take place because of something found when we were audited by our customers. The Internal Audits are fully documented with who attends and what is covered.

Document Control

A very important part of the program is controlling all the documentation produced. Document Control assures that only the most current procedures and policies are being used. Each page of every document is sequentially numbered and has a unique part number and Revision Level assigned to it. Every form, procedure, data sheet, log book, etc is controlled and kept track of. Everything you do is documented or it didn't happen. Every sample tested, every calibration performed… everything is documented and secure and traceable.

Records Management

Quality System records are stored, kept secure, and archived for future reference. While we do archive data in a similar fashion for standard testing the security is much greater for cGMP.

Facility

Certain requirements are put forth through the program that require us to monitor the environmental conditions in the lab and document it conforms to our written specifications (we have a system that monitors Temperature, Humidity, Carbon Dioxide, Carbon Monoxide, as well as volatile organic compounds 24 hrs a day). We also provide documentation that assures a pest free work area, the quality of our gasses used, that we have enough space to perform the required testing, and that our employees were trained in safety (Right to Know Program).

Equipment

This is the largest difference in cGMP. The FDA is very specific on what needs to be done to instruments to make sure they are installed, operated, calibrated and used properly. Instrument s used for standard testing have critical parameters verified on a regular basis but it is no where close to the process of what takes place for cGMP. Before a customer sample can be tested on an instrument, that instrument must first complete the following steps:

1) Installation Qualification verifies proper installation.
2) Operation Qualification verifies proper operation of the instrument under "normal" use.
3) Performance Qualification verifies proper operation under a specific use.
4) Calibration and Maintenance verifies the instrument is meeting a specified set of operating parameters and properly calibrated. A calibration film in the expected range of the test sample is run just prior to customer testing. Every check and repair that is performed on the instrument is fully documented and stored within that instruments folder.

Analytical Methods

Every aspect of what we do when we perform a cGMP test is documented in a written procedure. All the analytical test methods we use for GMP are covered in step by step detail.

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General Laboratory Procedures

Samples are handled pretty much the same between standard testing and cGMP testing. Storage of these samples is different and cGMP requires we secure them in a locked cabinet for 1 year from the test date, versus holding them for one month in standard testing. Sample preparation is not recorded for standard testing but is for cGMP. Any deviations to established procedures are recorded for a cGMP test but not for standard testing. There are established ways to make corrections for cGMP that are not used in standard testing.

Data Review and Reporting

All data is peer reviewed by two people for cGMP.

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