Laboratory Compliance and Inspection Readiness

By Alice Krumenaker Jun 25, 2018 7:10 am PDT

Introduction

In an FDA regulated industry, routine inspections occur on a regular basis. Because of the important role quality control laboratories play in the testing and release of products, they are often an area of focus during FDA inspections. In many cases, companies do not receive notification prior to an inspection. Similar to the strategy used in sports, the best defense is a good offense. To translate this strategy to the regulated environment, the best plan is to maintain a state of inspection readiness at all times.

This article will provide some areas of focus to keep your laboratory ready for a regulatory inspection. Topics that will be addressed include:

- Training
- Procedures
- Instrument and data systems
- Electronic data and data acquisition systems

Training

A strong training program is a solid foundation for establishing a compliant laboratory. A good starting point for creating a training program is to set well defined requirements for training needs. In most cases, having some type of record verifying that training occurred and an assessment which shows training effectiveness will be sufficient documentation for any inspection. However, when it comes to training, it's time to look further than minimum requirements. To gain the maximum benefit from training, the program should be more than a documentation exercise, simply documenting that training was done. The goal of training should be to enable the trainee to understand the subject matter and to be able to use the knowledge to help improve performance, providing real value to the organization.

Laboratory training should be done on two levels. The first level is accomplished by training on procedures, which can be done either by reading or discussion, or a combination or both. The second level requires an actual demonstration of proficiency.

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