How to Prepare Your QC Microbiology Laboratory for the Next FDA Inspection

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Introduction

The biopharmaceutical industry is a closely regulated industry subject to inspections by health regulatory authorities. A manufacturing facility or contract laboratory may receive several inspectors from different countries in a single year. As a result, a site must be ready for an inspection at all times. Inspections by the US Food and Drug Administration (FDA), in particular, require many resources and extensive preparation. The quality control (QC) laboratory is almost always scrutinized, as it is very involved in the release of raw materials, and performing in-process, release, and stability tests.

In order to prepare for a successful FDA inspection, QC management and analysts must know and understand the types of FDA inspections and their purpose, the Good Manufacturing Practice (GMP) regulations, FDA guidance documents and compliance manuals, and current expectations and inspection trends.

Types of FDA Inspections and Purpose

FDA inspections are generally classified into 3 primary categories: pre-approval (or pre-license for biologics), surveillance, and for-cause (1). Pre-approval (or pre-license for biologics) inspections are required for approval of a new drug application and subsequent supplements with significant changes (e.g., change in manufacturing site). Surveillance (or GMP) inspections are conducted following approval of a drug application. In the past, they used to be conducted every 2 years; however, recently, FDA has been making changes to the program to use risk-based rationale for planning inspections and this may change. For-cause inspections are initiated due to specific events such as complaints and adverse events and as follow up to verify corrective actions following regulatory actions such as warning letters.