Typical Microbiology Concerns in an FDA Inspection – Part 2

By Jeanne Moldenhauer Nov 20, 2018 11:25 am PST

Abstract

This paper identifies additional areas of concern for FDA investigators during an inspection that apply to microbiology. This paper is an addition to Part 1 of the Typical Microbiological Concerns in a FDA Inspection. Like its predecessor, these concerns aid in preparing the microbiologist for the types of concern that may arise in an inspection. It also aids in verifying that your site has all the necessary documents in place.

Background

Issuance of CMPG 7356.002, "Drug Manufacturing Inspections" in 2002 and updated in 2017, provides the methodology used by FDA in inspections (FDA, 2017). In this guidance (CMPG 7356.002) FDA divides the typical pharmaceutical site into six systems: quality system, facilities and equipment system, materials system, production system, laboratory system and labeling and packaging system. Some of these concerns have been identified in the Pharmaceutical Microbiology Manual (PMM) (FDA, 2014) and Part 1 of this series of documents. The PMM provides additional guidance on the type of data reviewed by FDA investigators as well as microbiological concerns. Another source of identifying FDA concerns in inspections is information provided in FDA Warning Letters, which are available on the FDA's Website, in the Electronic Reading Room. This paper focuses on the concerns not directly related to the six-systems.

Sampling Data

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