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Typical Microbiology Concerns in an FDA Inspection – Part 3

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Abstract

One is always concerned with trying to understand how to look good during an FDA inspection. It can be difficult to predict what items will be of concern in the area of microbiology. Part 1 of this series discussed microbiological concerns in the quality systems-based inspection. Part 2 of the series discussed review of microbiology data and how FDA looks at the data. This part discusses some of the regulatory concerns associated with reviewing a microbiological out-of-specification result.

Background

Since the issuance of the Barr Decision (USA, 2993) the term out-of-specification became a “household word” in pharmaceutical companies. Prior to this time, FDA more often utilized the term Failure Investigation. (21CFR 211.192) Interpreting this decision for pharmaceutical analytical laboratories (Chemistry and Microbiology) was confusing for the immediate time following the decision’s issuance. Many different consultants, who did not participate in the lawsuit, opined on what this meant for microbiology. Quite a bit of conflicting information ensued. Since that time, FDA issued industry guidance on the investigation of out-of-specification test results. (FDA, 2016)