Improving Microbiological Control Of Non-Sterile Pharmaceuticals: Unlocking The FDA Guidance

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The document is the first time that the FDA has pieced together a compliance framework for non-sterile medicines, and, in some ways, the document stands as a companion piece to the Aseptic Processing Guidance (issued in 2004, although in clear need of an update). The trigger for the non-sterile document was based on the pattern of non-sterile product recalls involving microbial contamination, based on the period 2014 to 2017 when 197 bacterial and fungal contamination events, associated with either the manufacture, packaging, shipping, or storage of the drug, were recorded. The FDA considers the...