cGMP Maintenance Program Considerations

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ABSTRACT Facilities governed by current good manufacturing practices (cGMPs) must remain in a validated state. The site preventive maintenance program is a critical part of this effort. Requirements for equipment are stated in 21 Code of Federal Regulations (CFR) 211.67. All facility, process, utility, and laboratory equipment used in the manufacturing, processing, packing, holding, or testing of drug products, biological products, or medical devices must be characterized as GMP or non-GMP. This article provides general elements of a site preventive maintenance program including record-keeping...