Peer Reviewed: A Historical View of 21 CFR Part 211.68

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The FDA 21 Code of Federal Regulations (CFR) Part 211.2(b) was the original section in the GMP regulation containing the requirements applicable to computer systems. Specifically, Section 211.2(b) put emphasis on the following: Computer backups Documentation Having hardcopy of master formulas Specifications Test records Master production and control records Batch production records (batch production and control records) Calculations. Section 211.2(b) was integrated in 1978 with 21 CFR 211.68, hereafter referred to as Section 211.68. As in the earlier Section...