21 CFR PART 11 COMPLIANCE IN HEALTHCARE CALIBRATION SYSTEMS

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Abstract

21 CFR Part 11 prescribes the application of electronic records and signatures in healthcare manufacturing and quality systems. The regulation, promulgated in 1997, is currently being implemented by companies and subsequently inspected against by FDA. This presentation describes current practices in inventorying, remediating and developing systems used by metrology groups under this regulation. Two primary categories of software, management systems and instrumentation control, will be discussed. Important issues specific to these categories will be presented. Due to the rapidly evolving nature of this subject, a portion of the presentation will be an open forum for audience participation in sharing critical and timely information on this subject.