

PANEL: CHALLENGES FACING HEALTHCARE METROLOGY

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Abstract

With recent changes in FDA and European pharmaceutical and medical device laws, metrologists in the healthcare industry face greater challenges than ever before to assure not only the quality of their work but the adherence to regulatory requirements. This session will feature a panel of speakers in a number of areas: metrology software, computer validation, instrument qualification, regulatory compliance including QSIT and QSR, analytical instrumentation, and auditing. The panel will also discuss recent calibration, instrumentation, and computer system 483s issued by the FDA. This session will be the opportunity for attendees to raise and discuss issues of concern within their own work environment as regards to regulatory compliance.