Calibration and FDA Requirements

References: (a) 21CFR Part 210/211 Current Good Manufacturing Processes (cGMP)
(b) 21CFR Part 820 Quality System Regulation (QSR)
(c) 21CFR11 Electronic Records/Electronic Signatures

Background: Many of our customers work under the requirements of the Food and Drug Administration's regulatory requirements listed above as references a, b, and c.. We have reviewed these requirements and have included the applicable requirements into our quality system in order to serve our customers in these areas. We do not run our calibration lab as a pharmaceuticals laboratory; rather we have adopted practices, at the suggestion of our customers that meet the intent for a calibration lab supporting their businesses.

Above and beyond the requirements for ISO 900X and ISO/IEC 17025, these items include:

- Indoctrination of employees of CGMP/QSR requirements
- Upgraded training procedures and records to better reflect our training level (820.25)
- Calibration of IM&TE per 820.72 and 211.160.b.4
- Strict housekeeping requirements and lab monitoring
- Maintenance of automatic, mechanical and test equipment (211.68)

Companies typically under FDA regulation run very tight testing and calibration organizations. Many practices used in lab testing and trials have migrated into the calibration activity for no reason other than uniformity. Essco Calibration Laboratory will review your company specific calibration requirements and will provide feedback on the nature of service we can provide.

Kevin Pistey
Quality Manager