TIPS FOR STAYING COMPLIANT WITH FDA REGULATIONS AND ISO STANDARDS IN THE MEDICAL DEVICE INDUSTRY

Tektronix®

UNDERSTANDING 21 CFR 820 AND ISO 13485 AND BEST PRACTICES FOR STAYING COMPLIANT

A recent meeting with a large medical device customer lead to an enlightening discussion on the differences between International Organization for Standardization (ISO) and US Food and Drug Administration (FDA) standards and regulations as they apply to medical device manufacturers. This is a short overview of a few of the key differences between the two standards and a quick guide to choosing a calibration provider that can help you build an ironclad calibration program.

Key Differences Between FDA Regulations and ISO Standards

For medical device manufacturers, the health and safety of patients is their top priority, and the accuracy and precision of the instruments they use in production is of the utmost importance. The medical device industry is regulated by strict standards such as the FDA's 21 CFR Parts 11 and 820, Quality System Regulation (QSR) and ISO 13485.

The goal of both FDA 21 CFR Part 820 and ISO 13485 is to provide a framework for compliance and ensure product quality and safety. 21 CFR Part 11 establishes technical and procedural controls that must be met if regulated records are maintained electronically. To create a quality management system (QMS) that meets quality and compliance requirements, it is important to understand the key differences in scope and application of both the ISO standard and FDA regulations.

Location

ISO 13485 is the internationally recognized standard that sets QMS requirements for medical device manufacturers, whereas FDA regulations apply to the manufacturers of all medical devices being sold commercially in the United States. Outside the United States, the ISO 13485 standard is often adopted and localized, as each country or region is governed by its own standards organization.

Conformity vs. Compliance

ISO 13485 certification is a voluntary quality standard which was designed to act as a framework on which to build compliance to various regulatory and customer requirements. 21 CFR Part 820 is a regulation that governs the methods, facilities and controls used for the design manufacture, packaging, labeling, storage, installation and servicing of all finished devices intended for human use. Compliance with 21 CFR 820 is mandatory for all medical device manufacturers and compliance with 21 CFR Part 11 is mandatory in regulated industries where electronic records are maintained.

Audit vs. Inspection

While an ISO registrar is auditing for conformity to a standard, a service that is voluntarily paid for, the FDA is inspecting for compliance to a regulation. During an FDA inspection, four major subsystems will be sampled, these subsystems are:

- Management controls
- Design controls
- Corrective and preventative action (CAPA)
- Production/process controls

If any subsystems are not compliant, proactive action should be taken to resolve any Form 483 observations. If these observations are not resolved properly, they can result in further enforcement actions including seizure, injunction, prosecution or civil penalties. Form 483 findings can be devastating to medical device manufacturers. Aside from legal penalties, inspection findings can halt production, lead to a product recall or do irreversible damage to your company's reputation.

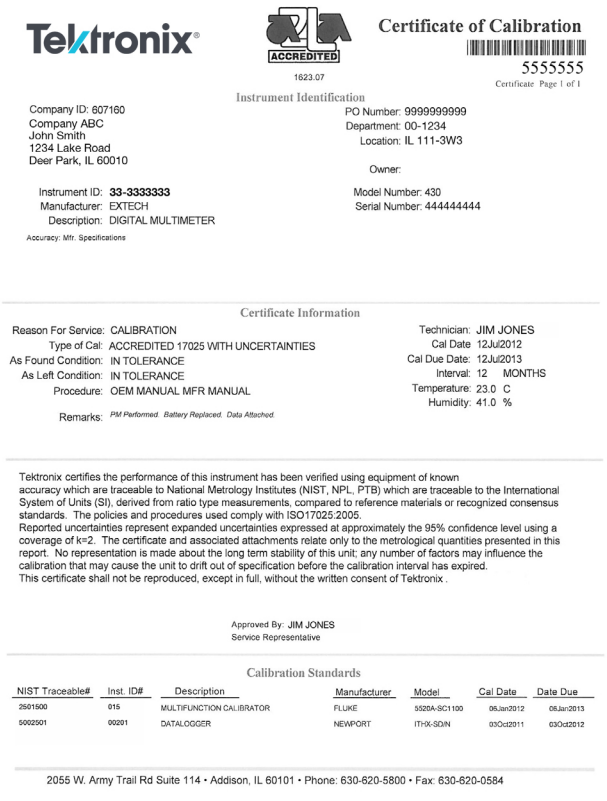
Documentation of issues by an ISO registrar on the other hand are rated by category and, during follow up visits, the auditor will return only to verify the corrective action in question. If appropriate actions are not taken, the registrar may choose to audit the entire quality system, potentially placing an organization's certification at risk. A loss of ISO 13485 certification impacts global regulatory licenses and the ability to conduct business in the specific international markets that require it.

Best Practices for Calibration Conformity and Compliance

For a calibration program to remain in compliance, it is essential to maintain a regular calibration schedule for test equipment. Missed calibration cycles can result in an out of tolerance condition, which can lead to compromised product quality, FDA findings, loss of ISO certification and a loss of stakeholder and consumer confidence.

Calibrations should be performed in an accredited laboratory by experienced technicians, working equipment should be compared against appropriate standards and calibration certificates should include:

- Calibration test data report.
- Measurement uncertainties for each test point.
- Traceability to National Metrology Institutes or the International System of Units
- Accrediting body's logo.



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ACCREDITED
1623.07

Certificate of Calibration

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Instrument Identification

Company ID: 607160
Company ABC
John Smith
1234 Lake Road
Deer Park, IL 60010

PO Number: 9999999999
Department: 00-1234
Location: IL 111-3W3

Owner:

Instrument ID: **33-3333333**
Manufacturer: EXTECH
Description: DIGITAL MULTIMETER
Accuracy: Mfr. Specifications

Model Number: 430
Serial Number: 444444444

Certificate Information

Reason For Service: CALIBRATION
Type of Cal: ACCREDITED 17025 WITH UNCERTAINTIES
As Found Condition: IN TOLERANCE
As Left Condition: IN TOLERANCE
Procedure: OEM MANUAL MFR MANUAL
Remarks: *PM Performed. Battery Replaced. Data Attached.*

Technician: JIM JONES
Cal Date 12Jul2012
Cal Due Date: 12Jul2013
Interval: 12 MONTHS
Temperature: 23.0 C
Humidity: 41.0 %

Tektronix certifies the performance of this instrument has been verified using equipment of known accuracy which are traceable to National Metrology Institutes (NIST, NPL, PTB) which are traceable to the International System of Units (SI), derived from ratio type measurements, compared to reference materials or recognized consensus standards. The policies and procedures used comply with ISO17025:2005.
Reported uncertainties represent expanded uncertainties expressed at approximately the 95% confidence level using a coverage of k=2. The certificate and associated attachments relate only to the metrological quantities presented in this report. No representation is made about the long term stability of this unit; any number of factors may influence the calibration that may cause the unit to drift out of specification before the calibration interval has expired.
This certificate shall not be reproduced, except in full, without the written consent of Tektronix .

Approved By: JIM JONES
Service Representative

Calibration Standards

NIST Traceable#	Inst. ID#	Description	Manufacturer	Model	Cal Date	Date Due
2501500	015	MULTIFUNCTION CALIBRATOR	FLUKE	5520A-SC1100	05Jan2012	05Jan2013
5002501	00201	DATALOGGER	NEWPORT	ITHX-SD/N	03Oct2011	03Oct2012

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Choosing a Calibration Provider

When choosing a calibration provider, medical device companies should look for the following qualities:

- Robust quality program.
- Accredited facilities offering ISO 17025 accredited calibration.
- Experience with medical device manufacturers.
- Breadth of products serviced.
- Computerized records management.
- Traceability.

A calibration vendor that has a well-established history and a wealth of industry knowledge in managing complex calibration environments helps ensure your calibration program will remain compliant. Technicians should be experienced with servicing parts and products used in your specific industry and facilities where calibrations will be performed should be accredited. Calibration providers should offer services both onsite and at local or regional service centers.

Vendors should provide computerized records management that allows calibration certificates and service records to be kept online to easily demonstrate compliance and traceability. Records management systems should allow for electronic signatures and document controls, standard and custom reporting features, support out-of-tolerance investigations and should be validated against FDA regulations. Records management systems should also send automated calibration reminders that include the specific piece of equipment needing calibration and the calibration due date. Reminders should be customizable per customer specifications and should be issued well in advance of the due date, keeping sensitive equipment calibrated and compliant with all national and international standards.

Integrated Asset Management Solutions

For manufacturers with hundreds or thousands of instruments that need to be calibrated, a high-quality asset management solution should be in place to provide organizations with the ability to view the location of assets, optimize your processes with in-depth analytics, manage the distribution of assets and facilitate procurement of new assets or consumables. Advance exchange programs should be available for manufacturers with large numbers of field service technicians or multiple sites in order to reduce overhead and ensure continuous compliance. In advanced exchange programs, calibrated instruments are sent to technicians to replace pieces of equipment that are due for calibration, eliminating downtime. A vendor that offers this service will oversee and manage the inventory supply chain for equipment inventory

as specified by the customer. Calibration due dates can be level loaded, spreading out service orders to avoid equipment shortages.

Medical device manufacturing depends on precise, accurate testing results, from the initial design and development of a device to the shipment of a safe, effective product. To meet the many regulatory requirements of ISO and FDA standards, every detail of the asset management process must be simplified and harmonized.

Why Tektronix?

With ISO 9001 certification, over 1100 experienced technicians and more than 100 points of service nationwide, Tektronix offers an extensive global network of expert resources. Customizable asset management solutions such as CalWeb, advance replacement programs, the availability of both temporary and permanent onsite technicians and the ability to service equipment from over 9000 manufacturers makes Tektronix your trusted partner in innovation.

To learn how our unmatched suite of capabilities and services can keep you in compliance and help your business flourish, visit us at: tek.com/medical-equipment-calibration.

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For Further Information

Tektronix maintains a comprehensive, constantly expanding collection of application notes, technical briefs and other resources to help engineers working on the cutting edge of technology. Please visit **www.tektronix.com**

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