REDUCING RISK AND IMPROVING PROFITABILITY FOR MEDICAL DEVICE MANUFACTURERS

CALIBRATION WHITEPAPER

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With over 70 years of innovation in the test and measurement industry, Tektronix is your trusted source for integrated, web-based asset management solutions.

Introduction

Stringent regulatory requirements and increasingly cutthroat competition within the global marketplace have intensified the need for medical device manufacturers to adopt new and improved processes for managing their quality systems.

The regular calibration of sensitive instrumentation such as temperature sensors, pressure transducers and weighing instruments is considered mandatory by the U.S. Food and Drug Administration (FDA). The large quantities and tight tolerances of these types of instruments increase the risk associated with non-compliance.

Calibration management systems that provide real-time visibility and consistency should be standard operating procedure for medical device companies.

Using a manual or hybrid process for calibration management can lead to missed calibration cycles. Instruments that are left uncalibrated can offer less accurate data, resulting in compromised quality and product downtime. Companies found to be non-compliant with strict regulatory standards such as the FDA's 21 CFR Part 820, Quality System Regulations (QSR) and ISO 13485 can incur heavy penalties and lose consumer confidence.

Accidents caused by missed calibrations and incomplete, missing or poorly documented processes can lead to legal fees and judgments as well as time consuming corrective actions that can cause irreparable harm to an organization.

Calibration Management Essentials

There are five main areas of calibration management that must be attended to in order to maintain regulatory compliance and mitigate risk. These areas are:

- Documentation
- Planning and Decision Making
- Organization
- Execution
- Analytics and Reporting

Documentation is crucial throughout each step in the calibration process.

ISO 9001, ISO 13485 and the FDA all state that calibration records must be maintained and that process controls must be in place to provide fast, accurate reporting and historical trend data in the event of an audit.

Companies are required to have a document change control system in place to ensure any changes made to process methods are restricted to authorized personnel and tracked for future review. Inadequate documentation is cited as a leading cause for FDA "Form 483" observations. These observations result in the mandatory tracing and revalidation of all documentation before production lines can return to service. Inconsistencies within a company's calibration program are a red flag to regulatory bodies.

The work required to plan, schedule, document and track calibration intervals and procedures can add up to thousands of man hours per year depending upon the number of instruments a company has in service and the total number of periodic calibrations required. Organizations are increasingly turning to electronic management systems to increase the accuracy and visibility of their processes and to avoid the risk of missed calibrations, product delays and regulatory findings.

Calibration management systems can vary greatly, from manual 'pen and paper' or in-house legacy systems to modern, web-based applications. When choosing which system is right for you, it is important to carefully look at each method as it relates to the 5 main areas of calibration tasks and regulatory compliance.

Manual (Paper-Based) Systems

While smaller manufacturers may be drawn to the fact that a manual system requires little or no upfront investment, it is also time consuming, error prone and can lead to a wide range of costly issues associated with poorly organized processes and a lack of centralized reporting capabilities.

Manual systems do not provide the automation required to keep track of forms, documents, and assignment status from start to finish. If an issue arises with an instrument that is found to be out of tolerance, It is vital that documentation is available to determine the batches of product that instrument may have impacted.

Poorly documented processes can lead to business, research and regulatory risks that affect all aspects of an organization.

Utilizing a paper-based system to plan, execute and analyze calibration data can easily become more than a full time job, detracting from resources that can be better spent on core competencies. Employers, patients and hospitals are at risk when a streamlined process is not in place to manage complex calibration environments.

In-House Legacy Systems

Some companies employ a hybrid of a manual and legacy approach. The hybrid method involves noting calibration results by hand in the field and then transferring these results into spreadsheets at a later time. As companies grow, these systems become increasingly difficult (and eventually impossible) to manage. Field notes and other pieces of vital information may be misplaced or contain transcription errors. Spreadsheets do not provide for version control and traceability, nor do they provide the global visibility required for asset management within large international firms.

Using hybrid systems to produce the analytics and reporting required for FDA and ISO 13485 audits is nearly impossible.

Outdated methods of calibration management do not provide the visibility or level of centralized reporting required to maintain operational excellence.

In an attempt to reduce costs and/or avoid business downtime, many companies hold off on the transfer of asset data to contemporary technologies, relying instead on sometimes decades old legacy systems.

Companies that have been through mergers or acquisitions may be managing their compliance programs through a variety of legacy systems inherited from their predecessor organizations. These disparate solutions often result in perpetual inaccuracies, leaving the organization susceptible to a high degree of business, research and regulatory risks.

Using a web-based asset management application such as CalWeb from Tektronix, system administrators are able to customize program features to their company's unique needs, providing the real time visibility and scalability legacy systems lack. Bulk upload features allow companies to quickly and easily transfer existing data, eliminating the manual work associated with outdated transfer models. Increased plant efficiencies, streamlined collaboration and lowered risk thresholds are just a few of the many benefits of web-based calibration management.

CMMS (Computerized Maintenance Management System)

In moving towards more automated processes, some manufacturers have instituted computerized maintenance management systems (CMMS). While these systems can store and manage data efficiently in the plant's database, a great deal of time and resources are often required to train employees on using the system and transferring existing data can be an arduous task.

CMMS software is inflexible to new developments within an organization such as the introduction of additional products or revised policies and procedures.

These systems generally have a low level of automation, only providing a minimum functionality and are not guaranteed to meet the regulatory requirements for documentation and records retention.

Obstacles Associated with Traditional Calibration Management Models

- Slow data collection and transfer processes
- Lost or misplaced calibration documents
- Inaccurate tracking
- Lack of effective analysis
- Inaccurate scheduling/missed calibrations
- Lack of connectivity with external data Sources
- Transcription errors
- Lack of flexibility
- Insufficient security

Recognizing the pains and labor-intensive processes that highly regulated industries face while trying to remain competitive and compliant, the FDA implemented 21 CFR Part 11.

This regulation established the criteria for the use of electronic records and electronic signatures by organizations under the jurisdiction of the FDA. Part 11 codified the substantial need for improvement of those processes and justified corporate spending on electronic systems.

Companies that fail to provide necessary levels of visibility across the organization run the risk of being found non-compliant with FDA regulations, putting themselves in jeopardy of both direct and indirect consequences. Noncompliance is illegal and can leave a company vulnerable to government seizure. In recent investigations, a large pharmaceutical manufacturer was found to have compliance deficiencies which cost them $500 million and a global healthcare firm was similarly fined $100 million.

The more substantial cost of noncompliance however, may be found in the decline of stock value when customers leave and contracts are lost after an organization becomes a target of enforcement actions. Companies who have received consent decrees often have to spend millions of dollars on new employees and outside consultants hired to develop policies to bring the companies' systems into compliance with the terms of those decrees.[1]

Web-Based Calibration Management

With a high quality, integrated asset management application such as CalWeb from Tektronix, all aspects of running a calibration program are improved.

Users are provided with a centralized, accurate way to analyze calibration records and identify historical trends.

All instrument and calibration data is stored electronically, allowing for analysis, optimization of calibration frequency and effortless reporting. Certificates and labels can easily be printed and distributed. Barcodes can be generated for seamless communication and syncing of data with smart calibrators.

Customers who have already deployed a CMMS can easily integrate it with web-based applications using bulk upload features; built-in document control features ensure compliance with FDA and ISO regulations.

CalWeb by Tektronix

CalWeb offers our customers the following features and benefits:

Calibration Management - CalWeb provides automated document routing, approval and escalations, eliminating the risk of missed calibrations. Users can view Tektronix-managed and internally-managed inventory in real time with the ability to drill down by asset number, calibration due dates, inventory location or service status. Validation tools within CalWeb comply with ISO and FDA mandated Good Automated Manufacturing Practices (GAMP).

Document Storage - All points of the calibration process are documented in CalWeb including service history, loaner inventory, out of tolerance (OOT) and out of service instruments and calibration certificates. Document change controls ensure all documents and revisions are electronically tracked, signed and time/date stamped. CalWeb administrative tools allow system administrators to configure user rights and roles.

Audit Support - CalWeb provides both standard and custom reporting features with automated conversion/ publishing capabilities. Electronically tracked and stored master lists, cycle times, revision history and certificates allow for proactive system management and provide accurate reporting and peace of mind when preparing for an audit or inspection.

Risk Management - CalWeb collects and stores all asset data, including preventative maintenance records, equipment downtime and historical trend analysis. These features allow companies to identify, assess and prioritize risk across product lines.

Calibration Management with CalWeb

CalWeb benefits medical device companies in each of the five major areas that are essential in managing a calibration program within a highly regulated environment.

Documentation

CalWeb is compliant with ISO and FDA regulations and features secure, sophisticated document and change controls including document lifecycle management, audit trail history, cross-linking and a centralized repository.

Business Benefits: These features increase productivity while eliminating the issues for which regulated companies are most often being cited. Document retrieval and reporting is virtually effortless when compared to traditional calibration record keeping.

Planning and Decision Making

All Tektronix and internally managed asset information, including instrument locations, calibration intervals and tolerance information can be defined and managed within the CalWeb application.

Business Benefits: Administrative costs are reduced when a system becomes paperless. Automated calibration results and tolerance history can easily be analyzed and may justify reduced calibration frequency for equipment that exceeds required process tolerances.

Organization

CalWeb provides a seamless way to streamline standard operating procedures. Permission levels can be assigned which will designate access based on the level of training each user has completed. Advanced analytics and reporting features allow for escalation of uncompleted tasks to the appropriate levels.

Business Benefits: Streamlined operating procedures improve company-wide efficiencies and result in reduced training time and costs. Calibration forms and assignment status are tracked electronically and provide automated version control.

Execution

Using CalWeb, calibration tasks are easily tracked and maintained throughout the organization. Automatic alerts can be set so that appropriate personnel are notified when calibrations are due. Service orders can be generated and tracked right from the user's console. Customer recalls for calibration and work-in-progress status updates can all be managed within CalWeb.

Business Benefits: Automated reminders, calibration cycle management and supply chain procurement features allow CalWeb customers to provide seamless and consistent service to their clients. The ability to view service status and inventory updates in real time leads to increased plant efficiencies and more proactive risk management.

Analysis

Inaccurate tracking and a lack of effective analysis can put an entire organization at risk. CalWeb from Tektronix offers a central and secure document repository, real time email notifications and advanced system reporting that provides for company-wide visibility regardless of physical location.

Business Benefits: In the case of an audit, CalWeb can facilitate both the preparation and the audit itself. Being able to simply and quickly validate organization-wide process controls reduces regulatory, scientific and business risks.

CalWeb from Tektronix aggregates data across multiple locations, offering real time analytics and fully customizable reporting for local, regional and global operations.

Summary

Every process plant, regardless of size, can benefit from using CalWeb by Tektronix to manage its calibration program. Multi-tiered solutions and pricing are built around workflows so the application can be uniquely tailored to each customer's needs. CalWeb's breadth of capabilities make it a natural fit for minimizing the time, cost and resources that go in to maintaining a complex calibration program.

Tektronix recognizes that medical device companies are making a real difference in people's lives. While compromised production quality in any industry can mean financial losses, we understand that in the healthcare sector it can even mean loss of life. With over 70 years in the test and measurement industry, no one knows calibration better than we do. It's your job to make life easier for others. It's ours to provide world-class resources that make life easier for you.

References

[1] 21 CFR Part 11: "How and Why to Comply," Medical Device and Diagnostic Industry, Sept. 1, 2002

ABOUT TEKTRONIX

Tektronix is the world's leading multi-brand service provider of calibration, repair and related services for test, measurement and control equipment. Tektronix provides:

- Services for equipment from 9,000-plus manufacturers — far more than just Tektronix!
- Extensive global service network — more than 100 points of service.
- 1,100-plus associates — highly-skilled technicians and sales representatives.
- Superior quality — accredited calibration at ISO/IEC 17025 accredited facilities.

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