

### Standards-Driven Management of Equipment Calibration Activities

Reduce manufacturing costs and quality failures with higher calibration accuracy.



AssurX Calibration Management software enables regulated and ISO-compliant manufacturers to quantify, control, and demonstrate acceptable device measurements. The solution aligns with the ISO 9001 Standard for Quality Management Systems and NIST calibration standards for the US.

The core methodology of AssurX Calibration Management is consistent across industries and can be used by Life Sciences (Medical Device, Diagnostics, Pharmaceutical, Biotech), Food & Beverage, and any other manufacturing enterprise (High-Tech, Consumer, Industrial).

*AssurX Calibration Management enables you to:*

- Identify assets that require calibration, asset characteristics, capabilities, functions and features (serial number, type/makes, tolerance data, setup date, and current status).
- Define a calibration schedule for each asset based upon pre-defined time intervals.
- Capture all details of instrument adjustments.
- Launch ad-hoc calibration tasks when required.
- Request and capture signatures required for the proper closure of calibration tasks.
- Integrate with additional processes including CAPA, deviation management, document management, training management, and change management for a turnkey quality system.

#### FEATURES AND FUNCTIONALITY

AssurX software captures all required data for calibration measurements (safety, quality, and environmental). Extensive configurability with **no custom coding** allows your organizations to design a calibration process unique to your requirements.

The AssurX Calibration Management Solution enables your organization to have control over your hardware and provide accurate outcomes that increase asset performance, extend lifespans, and ensure compliance.

**Activities by authorization:** Only authorized users can perform activities in the calibration system based on granted permissions. All AssurX solutions provide role-based security and a full audit trail.

**Importing records:** AssurX can import equipment details from Microsoft® Excel™ files or any other structured data sources.

**File attachments:** Attach virtually any size or type of file(s) to equipment records.

**Advanced tolerance:** Acceptable tolerance limits can be specified for a set of values. Any deviation found during calibration is automatically flagged and routed through the appropriate workflow for investigation.

**Custom fields:** In addition to standard fields provided by AssurX, authorized users can add equipment fields that can also be found using advanced search features.

**Intuitive advanced queries:** Users can filter out equipment and calibration records or add multiple search conditions simultaneously to the level needed.

**Tools for efficient operations:** Dashboards, notifications and escalations keep calibration management on pace by driving time-sensitive actions and collaboration.

#### REDUCE CALIBRATION CYCLE TIME

Automating calibration management eliminates siloed and manual work by facilitating the identification and correction of any out of specification (OOS) equipment.

Facilitate action plans through an automated process that can integrate with AssurX Corrective and Preventive Action (CAPA).

#### INCREASE EFFICIENCY

The AssurX platform is designed to simplify data storage by retaining all electronic information in a centralized location. Users can track and manage calibrations from testing through re-calibration, corrective actions, even through decommissioning. All records become connected and accessible in the AssurX system.

## IN-DEPTH ROOT CAUSE ANALYSIS

Conduct a process-driven, step-by-step failure mode and effects analysis (FMEA). Measurements and trend analysis turn data into actionable information to identify impending quality events and drive informed decisions based on concrete data.

## REDUCE CALIBRATION COSTS

Failures can be very expensive. If the problem continues, it will further impact production and expenses. AssurX helps you stop problems from happening “too often” by controlling the process and creating a calibration frequency schedule.

AssurX allows you to continually improve equipment reliability, which results in lower costs. By comparing actual reliability vs. target reliability over time, you can increase or decrease calibration frequency for equipment that may prove more or less reliable than targeted.

## REDUCE RISK AND IMPROVE QUALITY

Establish a consistent approach to calibration management, from tracking and investigation through remediation, corrective actions and preventive actions, and any resulting changes. Assign risk levels to equipment to make sure higher-risk equipment is investigated first.

AssurX supports cross-functional approvals which promotes awareness and aligns agreement of your decision makers. Data collected during the process serves as a facilitator for continuous quality improvement.

## INTEGRATE ASSURX QUALITY PROCESSES FOR GREATER CONTROL AND EFFICIENCY

Configurable, best practices workflows capture all information. Launch CAPAs and initiate change controls through integration with AssurX Change Management. Attach document records including SOPs and initiate training tasks to maintain and demonstrate audit-ready compliance with AssurX Document Management and Training Management solutions.

## INTEGRATE WITH ENTERPRISE SYSTEMS

Maintain the integrity of information while enhancing horizontal collaboration with others in the quality chain.

Integrate with external enterprise applications including ERP, MES, CRM, and other systems with a robust, open interface. Exchange information bi-directionally with other functional areas where calibrations require input from other business units and equipment vendors.

## BENEFITS AT A GLANCE:

- Demonstrate compliance by providing auditors with demonstrable and objective evidence of measurement traceability and electronic, time-stamped approvals.
- Minimize risk and uncertainty by establishing a proactive calibration schedule to maximize equipment reliability and keep measurements within specification limits.
- Build trust and confidence in the reliability of your measurements and your commitment to quality.
- Better manage risk by routing calibrations by criticality or when a reliability target isn't being met.
- Increase visibility with dashboards and reports that display the status of open tasks.
- Increase enterprise-wide accountability through a clear workflow of tasks, reminders, and escalations.
- Integrate with other systems for full cycle visibility and collaboration.
- Cross-functional approvals promote awareness and facilitate continuous quality improvement.

Want to learn more?

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