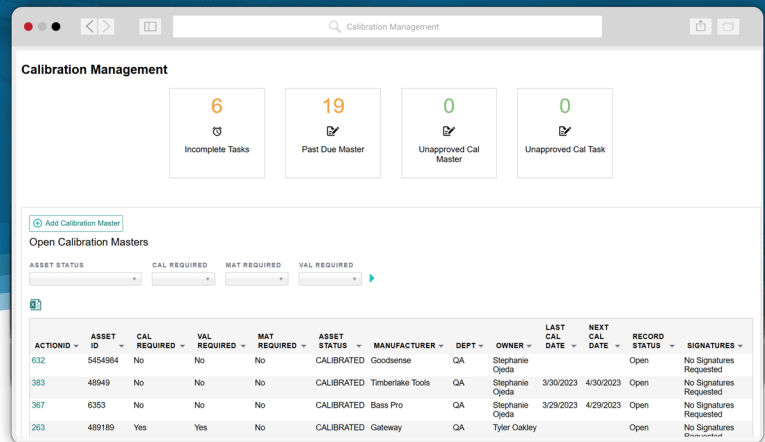


DATASHEET

Calibration Software Solution

AssurX Calibration 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.



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. Increase asset performance, extend lifespans, and ensure compliance.

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 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.

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|---------------------------------------|--|
| 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 | 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 | 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. |

Additional Benefits

REDUCE CALIBRATION CYCLE TIME: Eliminate 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: 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, and 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: Helps to minimize or eliminate problems from happening by controlling the process and creating a calibration frequency schedule. Continually improve equipment reliability, which results in lower costs. Increase or decrease calibration frequency by comparing actual reliability vs. target reliability over time.

REDUCE RISK AND IMPROVE QUALITY: 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. 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: Launch CAPAs and initiate change controls through integration with AssurX Change Management. Attach document records including SOPs. Initiate training tasks to maintain and demonstrate compliance with AssurX Document Management and Training Management solutions.

INTEGRATE WITH ENTERPRISE SYSTEMS: 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. Maintain the integrity of information while enhancing horizontal collaboration with others in the quality chain.