



Datastream 7i



COMPETITIVE ADVANTAGES:

- > Lower training and administration costs and streamline work processes through integrated EAM solution
- > Use historical data to perform reverse traceability and other key analyses
- > Capture electronic signatures to ensure accountability and security
- > Perform calibration checks via a mobile, handheld device

Calibration

To ensure consumer and workplace safety, manufacturing companies must closely monitor and regulate their equipment and processes. This is particularly important in industries such as pharmaceuticals, oil & gas, nuclear, energy, and consumer products where failure to meet regulatory requirements can not only delay getting products to market, but can also result in fines, plant closings, and lost revenue.

Calibration of the equipment, instruments, and processes used in manufacturing is essential in achieving the high-level of precision required by regulatory agencies like the Food and Drug Administration (FDA) and the International Organization for Standardization (ISO). The FDA's submission guidelines for pre-market notifications require companies to document how they perform, trace, and achieve consistency with equipment and instrument calibration. This documentation helps companies meet current good manufacturing practices (cGMP) for quality and safety.

Calibration Tools Unmatched in the Industry

Working with highly regulated industries such as pharmaceuticals, oil & gas, and others, Datastream has calibrations knowledge and experience in a variety of industries to help companies meet the stringent monitoring standards of regulatory agencies. In addition, Datastream has enhanced and extended the superior Web-based capabilities of Datastream 7i based on input from customers to provide a complete, compliant solution for calibration. Customers no longer have to maintain two separate systems—one for EAM and another for calibration—enabling them to save administrative and training costs.

The Calibration module fully supports the highest level of compliance requirements for calibration processes, reporting, and equipment. The module goes hand-in-hand with work management, preventive maintenance, and other functions, as well as fully supports the security of electronic records and signatures. The calibration module also offers the time-saving and convenience of mobile hand-held electronic devices. Datastream offers this all within one integrated enterprise asset management system. With easy-to-use screens and menus, the Datastream 7i Calibration module enables customers to:

> Become more efficient

- Use a single system for both EAM and calibration
- Schedule and execute calibrations for processes, systems, and instruments, including instrument loops
- Standardize and manage calibration information and procedures
- Maintain Original Equipment Manufacturer (OEM) supplier data, tolerance levels, and current specifications

> Increase flexibility

- Calibrate dual unit of measure devices
- Perform calibrations and log results remotely using handheld devices

> Anticipate, rather than react

- Enact remedial plans for out-of-tolerance equipment
- Integrate calibrations with asset, work management, and other enterprise systems



The Calibration module features unsurpassed capabilities, including:

Calibration Preventive Maintenance With Datastream 7i, each piece of equipment can be designated as a unique asset that resides within an organization. Calibration preventive maintenance (PM) can be established to generate calibration work orders for equipment. Each calibration PM contains instructions, approved procedures, OEM specifications, and process control limits for performing the calibration. Companies can set up calibration PM based on calendar days, accumulated usage determined by best practices, or

manufacturer recommendations. Datastream 7i also includes a calendar tool to aid in future maintenance work order planning and resource needs. The Datastream 7i Work Management module helps plan and organize employee work schedules.

Traceability Traceability is critical for best practices in calibration management. If a calibration standard is found to be incorrect, Datastream 7i allows users to quickly determine which instruments were mis-calibrated. Identifying the standard's last "good" calibration is critical to effectively segregating potentially affected products. The Datastream 7i Calibration module allows users to perform this reverse traceability.

Tracking Calibration Results Proper calibration procedures require tracking calibration results and variances between actual condition and standards established by the manufacturer, international standards, or internal best practices. Calibration records must show proper resolution or degree of accuracy for the results. Datastream

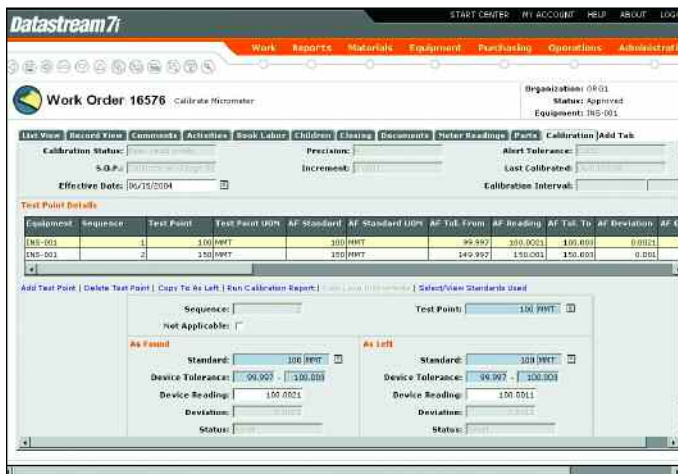
7i tracks results, including calibration sequences, test point data, tolerances, process control limits, "As Found" results, "As Left" results, action taken, and calibration status. The calibration work order is linked to a particular piece of equipment, allowing for easy cost roll-up and historical tracking of all equipment information based on parent equipment, department, or organization. Datastream 7i also tracks corrective action procedures and root-cause analysis related to out-of-tolerance work orders.

Calibration History and Reports Each time a user performs a calibration, Datastream 7i automatically stores the data. Datastream 7i customers can search and view all calibration results for a selected piece of equipment by equipment class, department, or date range. Data can be directly exported to Microsoft Excel™ or the Discoverer reporting tool for ongoing analysis and reporting. Datastream 7i provides a wide array of standard calibration reports, including frequency, date of last calibration, and the next scheduled calibration. Calibration records and reports prove that a company maintains procedures for performing calibrations in a timely fashion. Regression analysis of results leads to a proactive approach to calibration, ensuring quality and consistency with critical business processes.

With the Calibration module, customers can:

- > **Maintain calibration** histories to trace changes as well as audit for compliance with strict quality guidelines set by the FDA, ISO and other agencies
- > **View and record calibration** results and generate a wide range of advanced reports, including reverse traceability, to assist in determining the calibration standards used and increase consistency and accuracy

Calibration Management



Manage calibration for instruments and loops, including planning and executing calibration activity and recording results.



“In a heavily regulated industry, we simply cannot tolerate any inaccuracy in our measurements. Having a fully integrated calibration module is the ideal solution to our incredibly demanding calibration requirements.”

Nick Crist,
Building Operations Manager,
Central Facilities Operations,
GlaxoSmithKline Pharmaceuticals R&D

- > **Eliminate complex, manual reviews** of paper calibration documentation and providing quicker access to data through standard reports and the ability to easily export data into Microsoft Excel
- > **Track changes** to calibration records and be prepared for internal and governmental audits
- > **Maintain electronic records and signatures** to track electronic updates and approvals

The Datastream 7i Calibration module includes the following reports:

- > **Calibration Analysis Report** Designed to perform analysis on calibration results, this report can search equipment calibration results for a specified number of work orders resulting in either a calibration “PASS” or “FAIL.” The user has the ability to choose whether to include work orders that passed but required re-calibration, passed but contained an “As Found” failure, or contained an incomplete calibration when the work order was completed. The output of the report helps determine whether calibration PM frequency should be adjusted and if calibrated equipment should be replaced.
- > **Calibration Due Report** This report helps manage calibration workload by scheduling calibration work orders in advance. The report displays open calibration work orders that are due by a specified date and allows users to omit backlogged calibration work orders when appropriate. Work orders, scheduled in Datastream 7i, appear on the report with calibration test point information ensuring that the right information is available at the time of calibration.
- > **Calibration Equipment Report** All equipment for which calibration applies is shown on this report, including equipment flagged as a Loop, Instrument, or Standard. The report also offers the option of including calibration specification data, calibration boilerplate data, and test point specifications associated with the equipment.
- > **Calibration History Report** This report shows calibration work order results for work orders meeting selection criteria. (Equipment ID, Department, System, Equipment Class and Category, Equipment Criticality, and Date Range.) The report provides a variety of information including maximum “As Found” deviation and maximum “As Left” deviation.
- > **Calibration Report** This paper version of the system’s calibration screen on a work order allows users to have a hard copy of the calibration requirements Device Readings as they are obtained. This allows a calibration operation without requiring the user to set up a computer for result entries. And with the Datastream 7i Mobile advanced module, users can import calibration work order information and enter calibration result entries from the field.
- > **Calibration Reverse Traceability Report** This report allows the user to retrieve work orders for equipment calibrated by a selected standard. This is necessary when a standard is calibrated and found to be out of tolerance or “suspect.” An investigation must be performed to determine which equipment was calibrated with a potentially out-of-tolerance standard and therefore may have erroneously placed equipment in an out-of-tolerance condition. This report can also retrieve work orders where calibration test points deviate from the standard.

Additional Information

Convenient, Time-Saving Mobile Capabilities Datastream 7i Mobile extends the functionality of Datastream 7i by allowing customers to enter calibration results directly into the Datastream 7i database from handheld devices. Using a Web services integration platform, customers can record, view, edit, and transfer calibration information to and from the Datastream 7i database without having to work from a fixed terminal. Datastream 7i Mobile allows users to view attachments such as CAD drawings, MSDS safety sheets, maps, and calibration procedures. Through the Datastream 7i Mobile advanced module, users can access Datastream 7i to complete calibration and other procedures while in the field or on the shop floor.

Outstanding Internal Quality Control Datastream's internal operations are audited by customers and prospective customers. In addition, Datastream initiates regular internal company audits conducted by its ASQ-certified auditors or by external contract auditors. These audits evaluate Datastream's development cycle, quality assurance program, employee training and education, and all records pertaining to these critical processes. Datastream's outstanding audit results are a key factor in customers' decisions to select Datastream.

With Datastream 7i companies successfully address calibration compliance requirements, increase the quality and reliability of manufacturing processes, and optimize and extend the useful life of calibrations equipment.



13560 Morris Rd.
Suite 4100
Alpharetta, GA 30004
1-800-260-2640



www.infor.com

Copyright © 2001-2006 Infor Global Solutions and/or its affiliates or licensors. All rights reserved. The Infor word and design marks are trademarks and/or registered trademarks of Infor Global Solutions or one of its affiliates. All rights reserved. All other trademarks listed herein are the property of their respective owners.

INFPB_DCLBGEENUS_0704-1