BEAMEX eBOOK

CALIBRATION ESSENTIALS

SOFTWARE

2022 EDITION

beamex

CALIBRATION ESSENTIALS

SOFTWARE

This Calibration Essentials Software eBook will provide you with guidance and insights into how software can assist you in implementing best practices developed by your peers in the process industry.

THESE INSIGHTS have been gathered and communicated by Beamex professionals since our first calibration software was introduced in 1985. Implementing state-of-the-art calibration software improves your instrument reliability, supports compliance with regulations and internal policies, and streamlines your calibration process through automation.

IN MY OPINION, however, the most important reason to implement calibration software is to create reliable and connected calibration data. This ensures that your instrument management process is efficient, predictable, and complies with industry best practices that will improve your plant performance and uptime. In this way you will calibrate for yourself, not for your auditors.

I HOPE YOU ENJOY reading this eBook, and I encourage you to get in touch to discuss how Beamex can support you in your calibration journey.

Jan-Henrik Svensson CEO, Beamex Group

Calibration Essentials – Software *consists of multiple articles and resources for today's industry professionals:*

Contents

For more information about Beamex products and services:

▶ **CONTACT US**

WHY USE SOFTWARE FOR CALIBRATION MANAGEMENT?

BEAMEX WHITE PAPER

Save time, reduce risks, and quickly analyze data to help you make **better decisions.**

Most process plants have some sort of system in place for managing instrument calibration operations and data. However, the systems and processes can be very different – even within the same company across different plants. Methods often differ greatly in terms of cost, quality, efficiency, and data accuracy, as well as in the level of automation.

If you are writing results on paper or even manually entering data electronically, you're spending about half your time on paperwork. Using a documenting calibrator to automatically transfer test data to calibration software designed for the task can **decrease the amount of time spent on calibration – in many cases by up to 75%.**

If you're thinking about leaving the paper documentation lifestyle, using calibration software should be the ultimate goal. On your way there, you could store results in a spreadsheet or generic database. That will get you paperless, but it won't help you to realize all the benefits. The risk of human error and compromised data integrity will still be high and data entry will still be time consuming. It also won't automate updating calibration due dates like software designed for the job. *Here's a secret you may not know – many people still write down calibrations on paper.* They think that they are the only ones and are usually embarrassed at the thought and hesitant to reach out for help. If this is you, you are not alone. Start by reading this article and asking for help!

FROM A SEVEN-STEP TO A FOUR-STEP CALIBRATION PROCESS

Different calibration management systems

PAPER-BASED SYSTEMS

In traditional calibration, engineers and technicians use a pen and paper to record calibration results while out in the field. On returning to the shop, notes are tidied up or transferred to another paper document, after which they are archived as paper documents. Inherent in managing hundreds or even thousands of pieces of paper is the eventual misplaced, lost or damaged document.

While using a manual, paper-based system requires little or no investment, it is very labor-intensive and means that historical trend analysis becomes very difficult to carry out.

In addition, the calibration data is not easily accessible. The system is time consuming, soaks up a lot of resources, and typing errors are commonplace. Duplicated effort and re-keying of calibration data are also significant costs here.

> While using a manual, **paper-based** system requires little or no investment, it is very **labor-intensive.**”

IN-HOUSE LEGACY SYSTEMS (spreadsheets, databases, etc.)

Although certainly a step in the right direction, using an in-house legacy system to manage calibrations has its drawbacks. In these systems, calibration data is typically entered manually into a spreadsheet or database. The data is stored electronically, but the recording of calibration information is still time consuming and typing errors are common. Also, the calibration process itself cannot be automated. For example, automatic alarms cannot be set up on instruments that are due for calibration.

CALIBRATION MODULE OF MAINTENANCE MANAGEMENT SOFTWARE

Some use the calibration module of their maintenance management software for calibration management. Plant hierarchy and work orders can be stored, but the calibration cannot be automated because the system is not able to communicate with documenting calibrators.

Furthermore, this type of software is not optimized to manage calibrations and so often only provides the minimum calibration functionality, such as the scheduling of tasks and entry of calibration results. Although instrument data can be stored and managed efficiently in the plant’s database, the level of automation is still low. In addition, the system may not meet the regulatory requirements (e.g., FDA or EPA requirements) for managing calibration records.

CALIBRATION SOFTWARE

With calibration software, users are provided with an easy-to-use interface. The software manages and stores all instrument and calibration data. This includes the planning and scheduling of calibration work; analysis and optimization of calibration frequency; production of reports, certificates, and labels; communication with documenting calibrators; and easy integration with maintenance management systems such as SAP and Maximo. The result is a streamlined, automated calibration process, which improves quality, plant productivity, safety, and efficiency.

Calibration software is the most advanced solution available to support and guide calibration management activities. In order to understand how software can help you better manage your process plant instrument calibrations, it is important to consider the typical calibration management tasks that companies undertake. There are five main areas here: planning and decision-making, organization, execution, documentation, and analysis.

> With **calibration software,** users are provided with an **easy-to-use** interface.”

The main areas of calibration management

PLANNING AND DECISION-MAKING

All plant instruments and measurement devices should be listed, then classified into 'critical' and 'non-critical' devices. Once these have been set up, the calibration ranges and required tolerances should be identified. Decisions then need to be made regarding the calibration interval for each instrument. The creation and approval of standard operating procedures (SOPs) for each device should be defined, followed by the selection of suitable calibration methods and tools for the execution of these methods. Finally, the current calibration status of every instrument across the plant should be identified.

ORGANIZATION

The next stage, organization, involves training the company's calibration staff – typically maintenance technicians, service engineers, process and quality engineers, and managers – in using the chosen tools and how to follow the approved SOPs. Resources should be made available and assigned to carry out the scheduled calibration tasks.

EXECUTION

The execution stage involves supervising the assigned calibration tasks. Staff carrying out these activities must follow the appropriate instructions before calibrating the device, including any associated safety procedures. The calibration is then executed according to the plan, although further instructions may need to be followed after calibration.

> **Based on the results,** analysis should be performed to determine if any **corrective action** needs to be taken."

The documentation and storage of calibration results typically involves electronically signing or approving all calibration records generated.

Based on the results, analysis should be performed to determine if any corrective action needs to be taken. The effectiveness of calibration needs to be reviewed and calibration intervals checked. These intervals may need to be adjusted based on archived calibration history. If, for example, a sensor drifts out of its specification range, the consequences could be disastrous for the plant, resulting in costly production downtime, a safety problem, or batches of inferior quality goods being produced which may then have to be scrapped.

DOCUMENTATION

Documentation is a very important part of a calibration management process. Many regulatory agencies and auditors require that records

are maintained and must be carried out according to written, approved procedures. Without implicit documentation proving traceability of measurement standards used, the result cannot be considered calibration.

An instrument engineer can spend as much as 50% of their time on documentation and paperwork – time that could be better spent on other value-adding activities. This paperwork typically involves preparing calibration instructions to help field engineers, making notes of calibration results in the field, and documenting and archiving calibration data.

> An **instrument engineer** can spend as much as 50% of their time on **documentation and paperwork.**"

Imagine how long and difficult a task this is if the plant has thousands of instruments that require calibrating on a six-monthly basis. The amount of manual documentation increases almost exponentially!

Any paper-based calibration system will be prone to human error. Noting down calibration results by hand in the field and then transferring these results into a spreadsheet back at the office may seem archaic, but many firms still do this. However, with regulatory agencies requiring data integrity procedures, many companies are going digital. Furthermore, analysis of paper-based systems and spreadsheets can be almost impossible, not to mention time consuming.

ANALYSIS

Using dedicated calibration management software enables faster, easier, and more accurate analysis of calibration records and identification of historical trends.

Plants can therefore reduce costs and optimize calibration intervals by reducing calibration frequency when this is possible, or by increasing the frequency where necessary.

For example, for improved safety, a process plant may find it necessary to increase the frequency of some sensors that are located in a hazardous, potentially explosive area of the manufacturing plant.

Conversely, rather than rely on the manufacturer's recommendation for calibration intervals, the plant may be able to extend the interval by looking closely at historical trends provided by calibration management software. For example, by analyzing the calibration history of a flow meter that is located in a 'non-critical' area of the plant, the company may be able to decrease the frequency of calibration, saving time and resources. Instrument drift can be monitored closely over a period of time and then decisions made confidently with respect to amending the calibration interval.

Benefits of using calibration software

> Calibration **instructions** are created using the software to **guide engineers** through the calibration process."

With software-based calibration management, planning and decision-making are improved. Procedures and calibration strategies can be planned and all calibration assets managed by the software. Instrument and calibrator databases are maintained, while automatic alerts for scheduled calibrations can be set up.

Organization also improves. The system no longer requires pens and paper. Calibration instructions are created using the software to guide engineers through the calibration process. These instructions can also be downloaded to a technician's handheld documenting calibrator while he is in the field.

Execution is more efficient, and errors are eliminated. Using software-based calibration management systems in conjunction with documenting calibrators means that calibration results can be stored in the calibrator's memory then automatically uploaded back to the calibration software. There is no re-keying of calibration results from a notebook to a database or spreadsheet. Human error is minimized and engineers are freed up to perform more strategic analysis or other important activities.

Documentation is easier. The software generates reports automatically and all calibration data is stored in one database rather than across multiple disparate systems. Calibration certificates, reports, and labels can all be printed out or sent in electronic format.

Analysis becomes easier too, enabling engineers to optimize calibration intervals using the software's trending function. Also, when a plant is being audited, calibration software can facilitate both the preparation process and the audit itself. Locating records and verifying that the system works is effortless when compared to traditional calibration record keeping. Regulatory organizations and standards such as those set out by the FDA and EPA place demanding requirements on the recording of calibration data. Calibration software has many functions that help in meeting these requirements, such as change management, audit trail, and electronic signature functions.

> **Analysis** becomes easier too, enabling engineers to **optimize calibration** intervals using the software's trending function."

BUSINESS BENEFITS

For the business, implementing software-based calibration management means overall costs are reduced. These savings come from fully digitized calibration procedures, which are paperless with no manual documentation. Engineers can analyze calibration results to see whether the calibration intervals on plant instruments can be optimized. For example, those instruments that perform better than expected may well justify a reduction in their calibration frequency.

Plant efficiencies should also improve, as the entire calibration process is now streamlined and automated. Manual procedures are replaced with automated, validated processes, which is particularly beneficial if the company is automating a lot of labor-intensive calibration activities. Costly production downtime will also be reduced.

Even if a plant has already implemented maintenance management software, calibration management software can be easily integrated into the system. If the plant's instruments are already defined in a database, the calibration management software can utilize the records available in the system database.

Integration saves time, reduces costs, and increases productivity by preventing unnecessary double effort and re-keying of work orders into multiple systems. It also enables the plant to extend automated data acquisition to their ERP system with documenting calibrators, which is not possible with a standalone system.

Beamex solutions

Beamex's suite of calibration management software can benefit process plants of all sizes. For relatively small plants where calibration data is only needed for one location, only a few instruments require calibrating, and regulatory compliance needs are minimal, Beamex LOGiCAL Calibration Management Software is an ideal solution.

Companies that have a medium to large number of instruments and calibrations, or those operating in industries where regulatory compliance is essential, Beamex CMX Calibration Management Software is ideal. It fulfills the requirements of 21 CFR Part 11 and other relevant regulations that are applicable to electronic records, electronic signatures, and data integrity. It also offers Beamex Mobile Security Plus, which provides enhanced functionality with compatible offline mobile devices, such as the Beamex MC6 family of Advanced Field Calibrators and Communicators, and tablets or smartphones with the Beamex bMobile Calibration Application. This enhancement further lowers the risk of ALCOA violations by identifying those using offline mobile devices by their electronic signature and by protecting offline data against tampering.

Along with CMX, the Beamex bMobile Calibration Application allows for paperless execution and documentation of inspection activities in the field. It works offline as well, which is ideal where reliable network connections are not available. The Beamex bMobile Calibration Application also supports Beamex Mobile Security Plus, which ensures the integrity of calibration data throughout the entire process.

Beamex's multi-site solution, CMX Enterprise, is suitable for process manufacturers with multiple sites, multilingual users, and a large number of instruments that require calibration. Here, a central calibration management database is often implemented and used by multiple plants.

> "Beamex's suite of **calibration management** software can benefit **process plants** of all sizes."

SUMMARY

Every process plant, regardless of industry sector, can benefit from using calibration management software. Compared to traditional, paper-based systems, in-house legacy calibration systems, or calibration modules of maintenance management systems, using dedicated calibration management software results in improved quality, increased productivity, and reduced costs.

For more information visit the Calibration Software section of the Beamex website.

Calibration Software improves calibration management tasks in all these areas

- Better planning and decision-making
- Easier organization
- Faster execution
- Automated documentation
- Analysis capabilities

The Business Benefits of using software for Calibration Management

- Reduced costs
- Improved quality
- Increased efficiency

THE EVOLUTION OF

CALIBRATION DOCUMENTATION

BEAMEX WHITE PAPER

Our **modern history** is defined by the advent of writing

Writing is humankind's principal technology for collecting, manipulating, storing, retrieving, communicating, and disseminating information. Before we learned to write, we lived in an era referred to as pre-history, or prehistoric times. As humans evolved, began cultivating land, and started living a less nomadic existence, the documentation of events became more sophisticated. Cave drawings gave way to hieroglyphics; stone tablets evolved into scrolls and then into bound books; the invention of typeset documents gave more and more people access to the written word. Today, we can send emails, text messages, and a variety of other digital communication around the world in a matter of seconds. Humans have evolved and documentation has evolved, and with it the way in which we manage calibration.

In the beginning, there was no way to document calibration findings other than with a pen and paper. This information was brought back from the field, entered into a form, and filed away. Just as in the *Library of Alexandria* (one of the largest and most significant libraries in the ancient world) with its thousands of papyrus scrolls, managing hundreds or even thousands of paper calibration documents comes with the inherent risk of misplaced, lost, or damaged documents – in the case of the Alexandria library, caused by a fire allegedly started by **Julius Caesar**. Additionally, a paper and pen system is labor-intensive, time-consuming, prone to errors, and provides little to no opportunity to analyze historical trends.

Digital systems enter the scene

DATABASES

As we progress through time, more digitalized systems of calibration management have emerged including the use of spreadsheets and databases. While certainly a step in the right direction, this method of documentation still has its drawbacks. Similar to the pen and paper method, this form of recording calibration data is still time-

consuming and error prone. It also lacks automation in that reminders and tasks cannot be set up on instruments that are due for calibration.

Read the blog post: Manual Data Entry Errors

> The use of **software** to manage calibration reports was the next **giant leap.**"

SOFTWARE SYSTEMS

The use of software to manage calibration reports was the next giant leap. The calibration module within some maintenance management software allows instrument data to be stored and managed efficiently in a plant's database. But again, this method falls short due to lack of automation, limited functionality, and often non-compliance with regulatory requirements (for example, FDA or EPA requirements) for managing calibration records.

DEDICATED CALIBRATION SOLUTIONS

Advances in technology seem to come faster and faster. Today, dedicated calibration software is the most advanced solution available to support and guide calibration management activities. With calibration software, users are provided with an easy-to-use Windows Explorer-like interface. The software manages and stores all instrument and calibration data. This includes the planning and scheduling of calibration work; analysis and optimization of calibration frequency; production of reports, certificates, and labels; communication with smart calibrators; and easy integration with maintenance management systems such as SAP and Maximo. The result is a streamlined, automated calibration process that improves quality, plant productivity, safety, and efficiency.

In order to understand how this type of software can help better manage process plant instrument calibrations, it is important to consider the typical calibration management tasks that companies undertake. There are five main areas here: planning and decision-making, organization, execution, documentation, and analysis.

> **Instruments** and **measurement devices** should be listed and classified into **'critical'** and **'non-critical'** devices."

PLANNING AND DECISION-MAKING

Instruments and measurement devices should be listed and classified into 'critical' and 'non-critical' devices, with calibration ranges and required tolerances identified for each individual device. The calibration interval, creation, and approval of standard operating procedures (SOPs), and selection of suitable calibration methods and tools should also be defined. Finally, the current calibration status for every instrument should be identified.

ORGANIZATION

Organization involves training the company's calibration staff in using the chosen tools and how to follow the approved SOPs. Resources should be made available and assigned to carry out the scheduled calibration tasks.

EXECUTION

The execution stage involves staff carrying out assigned calibration activities and following the appropriate instructions before calibrating a device, including any associated safety procedures.

DOCUMENTATION

Unlike many of the more archaic methods, calibration software generates reports automatically, and all calibration data is stored in one database rather than multiple disparate systems. Calibration certificates, reports, and labels can all be printed out on paper or sent in electronic format.

The documentation and storage of calibration results typically involve electronically signing or approving all calibration records generated.

ANALYSIS

Improvements in documentation lead to improvements in analysis. Using specialized calibration management software enables faster, easier, and more accurate analysis of calibration records and identification of

historical trends. Also, when a plant is being audited, calibration software can facilitate both the preparation process and the audit itself. Locating records and verifying that the system works is effortless when compared to traditional calibration record keeping. Regulatory organizations and standards such as FDA and EPA place demanding requirements on the recording of calibration data. Calibration software has many functions that help in meeting these requirements, such as change management, audit trail, and electronic signature functions.

> Based on the results, **analysis** should be performed to determine if any **corrective action** needs to be taken."

Based on the results, analysis should be performed to determine if any corrective action needs to be taken. The effectiveness of calibration needs to be reviewed and calibration intervals checked. These intervals may need to be adjusted based on archived calibration history. If, for example, a sensor drifts out of its specification range, the consequences could be disastrous for the plant, resulting in problems such as costly production downtime, safety issues, or batches of inferior quality goods being produced which may then have to be scrapped.

Just as advancements in tools and the proliferation of the written word has helped shape the evolution of humans, advancements in calibration documentation shape the efficiency and productivity of plants using these technologies. By replacing manual procedures with automated, validated processes, efficiencies should improve. Reducing laborintensive calibration activities will lessen costly production downtime, while the ability to analyze calibration results will optimize calibration intervals, saving time and increasing productivity.

Every type of process plant, regardless of industry sector, can benefit from using calibration management software. Compared to traditional, paper-based systems, in-house legacy calibration systems, or calibration modules of maintenance management systems, using dedicated calibration management software results in **improved quality and increased productivity**, and reduces the cost of the entire calibration process.

Calibration software also gives users **access to data and historical trends,** and these insights help plant personnel to make better decisions. For example, when a piece of equipment needs to be upgraded it can be difficult to get approval based on speculation. Being able to show data of the inconsistencies and malfunctions makes the approval process much easier. In addition, as the volume of work for calibration technicians increases, having insights into the process can facilitate a more streamlined and efficient work schedule. This will in turn improve reliability, make it easier for technicians to manage their workflow, and contribute to a safer and more well-organized process.

As we become a more advanced society our need to share information progresses, as do our methods of collecting, manipulating, storing, retrieving, communicating, and disseminating information. While simply writing calibration data down with a pen and paper is still an effective way of collecting information, it lacks efficiency and hinders the ability of people further down the line to retrieve and process the information.

While databases and maintenance management software are certainly steps in the right direction, they still miss the mark when it comes to disseminating data in a useful and streamlined way. **Implementing calibration software makes it easier to collect, store, analyze, retrieve, and share information.** Until the next technological leap forward, calibration software remains the most advanced solution available to support and guide calibration management activities.

Evolution of Beamex calibration software in brief

Here's a brief list of Beamex's main software products:

> **The very first** calibration software Beamex released was the **PDOC software** back in 1985."

Beamex PDOC (1985)

The very first calibration software Beamex released was the PDOC software back in 1985. The PCAL software automated the documentation of pressure calibration by communicating with a bench-mounted pressure calibrator. It printed a calibration certificate on a narrow paper with the thermal printer integrated in the Epson computer. That was a software that was stored on a small cassette and was used with a kind of a portable Epson computer.

Later, a corresponding **TDOC** program was release for documenting temperature calibrations.

CALDB1 / CALDB3 (Late 80's)

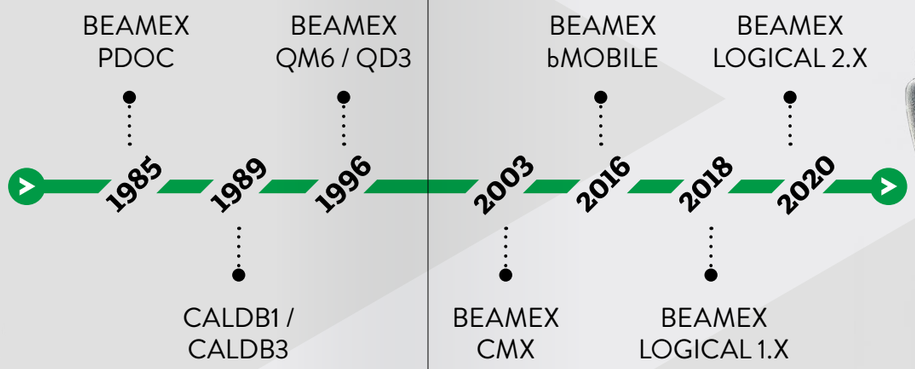
CALDB – Calibration Database – was a DOS-based calibration database software. Our first one for personal computers.

Later, an adder **HISDB** was introduced for reviewing the history of calibration results.

Beamex QM6 Quality Manager – Calibration Management Software (1996)

The Beamex QM6 was our first calibration management software that run in Windows operating system. It had a database for instruments, references and calibration results. It had communication with documenting calibrators, so you could send calibration procedure (work

EVOLUTION OF **BEAMEX** CALIBRATION SOFTWARE **IN BRIEF**



order) to documenting calibrator and receive the results back to QM6 after the calibration was completed.

Beamex QD3 Quality Documenter (1996)

QD3 was software for documenting calibration results. It did not have the same functionality as the QM6 but was a simpler version. It could anyhow communicate with documenting calibrators.

> During the years, the **CMX technology** and functionality have been **developed continuously.**"

Beamex CMX Calibration Management Software (2003)

The very first version of the Beamex CMX calibration management software was launched already in 2003 and it was our first Windows software. The first versions were pretty limited in functionality compared to what CMX is today.

During the years, the CMX technology and functionality have been developed continuously and CMX is still very much under active development. Today, the CMX includes a huge amount of functionality, including seamlessly integrating with many maintenance management systems, and suits smaller customers as well as large enterprise installations.

A lot of functionality has been developed together with leading pharmaceutical customers related to the functionality required in the regulated pharmaceutical industry.

Beamex bMobilde Calibration Application (2016)

Beamex bMobile is a calibration application that can be installed on Android or Windows mobile devices. The bMobile can be used to document calibration results with a mobile device.

The bMobile communicates with Beamex CMX and Logical calibration software, so calibration work can be sent to bMobile and results received back to software.

Beamex LOGiCAL 1.x (2018)

The first version of the Logical cloud-based calibration software was a simple documenting software that could read calibration results from a documenting calibrator and convert the results into a pdf calibration certificate.

The Logical 1.x has been replaced with Logical 2.x.

Beamex LOGiCAL 2.x (2020)

The current Logical 2.x is a subscription-based and cloudbased calibration software as a service. It has a database to store instruments, references and calibration results. It can synchronize procedures to Beamex documenting calibrators and Beamex bMobile, and also synchronize calibration results back to Logical from mobile devices.

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Ready to get your calibration process out of the stone ages? Contact Beamex today.

Contact us

LOGiCAL

MAKES EVERYTHING EASIER

Beamex LOGiCAL Calibration Management Software, launched in mid-2020, is a modern subscription-based (SaaS) calibration software solution that helps companies streamline and digitalize their calibration processes. The software synchronizes with Beamex documenting calibrators and supports the Beamex bMobile Calibration Application. LOGiCAL is the culmination of Beamex's 40 years of experience in developing calibration software.

Since the launch, LOGiCAL has already achieved tremendous success, with hundreds of users from companies of all sizes completing thousands of calibrations with the help of the software.

As evidence of Beamex's commitment to continuously developing LOGiCAL is the introduction of regular releases and improvements, many of which requested by users. Some examples of these releases include improvements to calibration certificate layout and IDs, upgrades to work management and instrument data management, subscription enhancements, and enhancements to mobile device synchronization.

"The cost for LOGiCAL scales based on how much you calibrate, which makes it easy to understand and budget for. The price consists of a base subscription fee plus a fixed cost for each calibration result that is uploaded. We have also integrated the option to buy online, which means that you can adjust your plan whenever you wish. Since Beamex is hosting the service, you will not need to invest in comprehensive IT infrastructure. Basically, you just sign up and start using it, which has been made even easier with a free trial," highlights **Jonas Heinola,** *Commercial Manager for LOGiCAL.*

LOGiCAL communicates with Beamex documenting process calibrators and mobile phones/tablets with the Beamex bMobile Calibration Application, allowing seamless movement between on-line and off-line environments and enabling a digital calibration process even when there is no access to the internet. The software uses web service technologies that enable calibrations to be configured and performed using any device with a web browser connected to the internet. LOGiCAL is compatible with most browsers. "We are excited to bring truly revolutionary technology to the market that delivers a very high value to customers that are currently using a pen and paper or manual processes for calibration," says **Jan-Henrik Svensson,** *CEO of Beamex Group.*

MORE INFORMATION:
www.beamex.com/logical

LOGiCAL VIDEO:
What, when and how to calibrate with Beamex LOGiCAL software

NO MORE DATA ENTRY ERRORS

Many businesses still use a lot of **manual entry** in their industrial **processes**

BEAMEX WHITE PAPER

This is despite the fact that it is commonly known and accepted that it is a slow and labour-intensive process and there are always human errors related to manual data entry.

It is commonly accepted that the typical error rate in manual data entry is about 1%.

What does this 1% mean in practice in calibration processes, and how can you make it smaller, or even get rid of it?

This article mainly focuses on industrial calibration processes and manual data entry related to these processes.

Common manual data entry steps in calibration processes

To start with, let's take a look at the common ways in which data is handled in industrial calibration processes:

1. PEN & PAPER

It is still very common for calibration data to be captured in the field by writing it on a paper form during the calibration process. Later on, back in the workshop, the calibration data from the paper is manually typed into a computerized system, in some cases by another person.

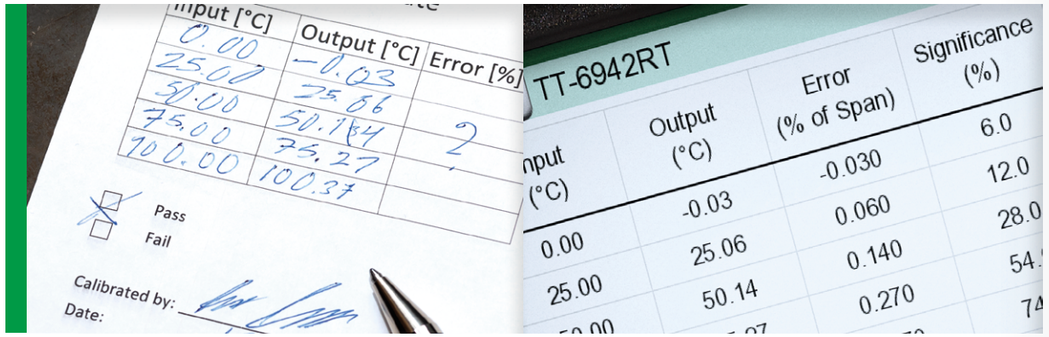
So, with this very common process the calibration data is manually entered twice: first with a pen and paper and later when it is typed into the system.

2. MANUAL ENTRY INTO A CALIBRATION SYSTEM

Another common way is to document the calibration data by typing it into a computer system, using spreadsheet software like Microsoft Excel or dedicated calibration software. If you want to type straight into a software program you need to carry a laptop in the field and you need to be connected to a network, which is not always possible in industrial environments.

If it is not possible to enter the data straight into the calibration application using a computer, in some cases it may be entered on a mobile

Table of contents



device with a relevant application and then later electronically transferred into the calibration software. In this process the data is still entered manually, although only once, not twice like in the previous process.

3. ELECTRONIC STORING OF DATA

The most modern way is to use calibration equipment that can store the calibration data in its memory fully electronically. The calibration data can then be transferred from the calibrator's memory to the calibration software, again fully electronically.

This kind of process does not include any manual data entry steps. This eliminates all human error and is also faster as it does not consume the engineer's time.

> With instruments that need to be **read visually,** some form of **manual data** entry is needed."

This process works only for calibrations where the calibration equipment can measure (or generate/simulate) instrument input and output. If there are any gauges, indicators, displays, or similar that need to be read visually, some form of manual data entry is needed.

But even if some of the calibration data is manually entered into the calibrator, the calibrator may have a feature to check that the data is within accepted values and may also have an informative graphical indication of the data quality for easy verification.

The calibration data is then sent electronically from the calibrator to the calibration system.

In the above picture, the left side shows an example where the calibration data has been entered manually on a paper form. Possibly some numbers have been entered incorrectly, it is difficult to read some of them, and manual error calculation is difficult. Is it a pass or a fail? Who signed that? And so on.

On the right side you can see data from the same calibration performed with a Beamex MC6 Advanced Field Calibrator and Communicator.

All calibration data is stored automatically and electronically in the calibrator's memory, errors are calculated automatically, the pass/fail decision is performed automatically, and the results are sent electronically to the calibration software for storing and certificate printing.

What about the 1% typical error rate?

It is obvious that there are errors in manual data entry. It seems to be a commonly accepted rule that in manual data entry human errors will cause a 1% average error rate.

> It seems to be a **commonly accepted** rule that in manual data entry, human errors will cause a **1% average error rate.**"

This error rate is based on research published in several articles, but I must admit that I don't know the scientific background for it. While we can argue about what the real error rate is, we can all agree that there are always errors in manual data entry.

After reading about this 1% error rate in a few places, it got me thinking about what this means for calibration processes. So, let's stick with that 1% average error rate in the following considerations.

The error rate can grow quickly if the data to be entered is complicated, if the user is tired or in a hurry, and for many other reasons. For example, some people (like me) may have handwriting that is difficult for others to read.

To reduce errors, companies can train employees, highlight accuracy over speed, double-check the work, ensure optimal working conditions, and naturally try to automate their processes and get rid of manual data entry.

Calibration processes

Calibration data includes a lot of numbers, often with many decimals. The numbers also typically fluctuate up and down with the decimals changing all the time. Very rarely is calibration data an easy-to-enter "even" number (20 mA is more likely to be 20.012 mA). This makes it challenging to manually enter data correctly.

When calibrating a process instrument, for example a transmitter, the input and output data should be captured at the same time, which is difficult. If the values are drifting, additional error will be introduced if the numbers are not recorded at the same time.

In a process instrument calibration both input and output need be recorded, typically at five calibration points (0%, 25%, 50%, 75%, and 100%). This already makes 10 calibration data points. Other data

> With a **1% error rate**, this means that **every fifth** calibration will include **faulty data.**"

also needs to be entered during the calibration, such as the reference standards used, environmental data, date, time, signature, etc.

On average we can say that 20 data points need to be entered during the calibration process. With a 1% error rate, this means that every fifth calibration will include faulty data.

Every fifth calibration? Why is that? Because if one calibration includes 20 data points then five calibrations include 100 data points. A 1% error rate means that data is entered incorrectly once in every 100 data points entered. So, every fifth calibration will include a faulty data entry. Every fifth calibration means that 20% of the calibrations performed will be faulty, each including one faulty data point on average.

The above is true if the data is entered manually only once. But as discussed earlier, often the data is entered manually twice, first on paper in the field and then when it is transferred from the paper to the system in the workshop. This means that there are double the number of data entry points, with one calibration event having 40 data points to be entered instead of 20. This means that statistically, 40% of the calibrations made will include a faulty data entry!

Wow, so the modest-sounding 1% error rate in manual data entry means that often 40% of calibrations will include faulty data in practice.

To repeat: The 1% error rate just turned into 40%!

So, this means almost half of these calibrations will include faulty data.

If you do manual calibration data entry using the two-phase system, about 40% of your calibration records will most likely have errors. Let that sink in for a while.

In a typical process site that performs 10,000 calibrations annually, all manually entered using the two-phase data entry process, statistically there will be 4,000 calibrations with faulty data!

Wow, that escalated quickly!

Naturally, the calibration process may be way more complicated and may contain many more data points.

If an instrument's calibration process includes 100 data points and the results are manually recorded, a 1% error rate means that statistically every calibration includes one faulty data entry! So statistically, 100% of the calibrations include a faulty data point!

Significant or insignificant error?

The significance of error varies according to the situation.

If the manually entered calibration data is wildly inaccurate it is likely

going to be noticed at some point. For example, if the nominal 4 mA zero point of a transmitter is entered as 40.02 mA (wrong decimal point) that will most likely be noticed at some point, at the latest when the data is entered into the calibration system, assuming the system gives a warning when the error is too big.

But what to do then? Do you consider that it is ok to move the decimal and assume it is then correct, or does the calibration need to be repeated – which means going back to the field and doing the calibration again?

If the error is small enough, it may not be noticed anywhere in the process. Using the previous example, if the transmitter's zero point is erroneously recorded as 4.02 mA when it is actually 4.20 mA, that error may not be noticed at all. Even if the transmitter's current of 4.20 mA is out of tolerance, which should be noticed and corrective actions taken, it will not be noticed because the erroneously entered 4.02 mA is a good enough reading and the calibration will pass without any further action. This leaves the transmitter in the process continuously measuring with a too-large error.

So, in the worst-case scenario, human error in manual data entry will lead to a situation where a faulty calibration is considered as passed!

Unintentional or intentional error?

Most human errors in manual data entry are naturally unintentional.

It is however not totally impossible that calibration data could sometimes be intentionally entered incorrectly. Manual data entry gives the opportunity to falsify results, and it is almost impossible to stop that.

If the results are on the limits of being a pass or fail, it is possible that in some cases the data is entered so that it is a pass. Maybe a fail result would cause a lot of extra work, and maybe it is already late in the afternoon and time to go home.

> If the results are **on the limits** of being a pass or fail, it is possible that in some cases the data is entered so that **it is a pass.**"

For example, if you see a pressure transmitter calibration certificate with a pressure reading of 10.000 psi (or bar) and a current reading of 20.000 mA, it is probably too good to be true.

I apologize for bringing up this kind of possibility, but this kind of information may be found in some publicly available audit reports. This is also something the US Food and Drug Administration (FDA) pays attention to when auditing the pharmaceutical industry.

But let's assume that the errors are unintentional human errors. Manual data entry is still being used in surprisingly many

calibration processes, even in highly regulated industries such as the pharmaceutical and food and beverage industries, nuclear power, and many others.

When entering data manually on a paper form, the paper form will not automatically alert the user if the entered data is outside of accepted tolerances. It is up to the user to notice it. The calibration system often has an alarm if the entered data is outside of accepted tolerances. At that point the calibration is already done, and it needs to be redone.

Would this error rate be accepted in other situations?

If we use manual data entry in our calibration processes and accept the risk of error that comes with it, would we accept the same error rate in other applications?

Would we accept that our salaries don't always come on time or are wrong? Or that our credit card repayments have a big error rate?

Obviously, these applications rely on electronic not manual data entry.

In most applications we would simply not accept the kind of error rate that comes with manual data entry. But like I said, many people still accept it in their calibration data entry process.

This article has about 15,000 characters, so with manual writing there would be about 150 errors (with a 1% error rate). Well, frankly with me writing, there would be a lot more!

Luckily I can use a computer with spellchecking and the text is also proofread by colleagues, but I am sure there are still some errors. In this text the errors don't have serious consequences, which they do with calibration data.

> "Would we accept that **our salaries** don't always come on time or are wrong? Or that our credit card repayments have **a big error rate?**"

At the same time, industry is moving fast towards the world of digitalization, where data is more important than ever and decisions are based on data. We should also take a good look at the quality and integrity of the data we gather!

There has to be a better way!

What if you could avoid all human errors related to manual calibration data entry?

What if you could even avoid the intentional errors? What if you could also save time by making the data entry process much faster?

What, you may ask, would be the cost for such a system? Can you afford it?

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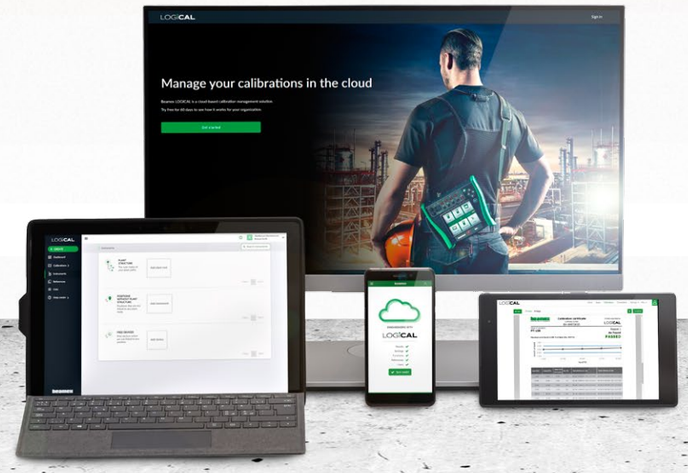

WEBINAR:
Easy and cost-efficient way to digitalize your calibration process

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Jonas Heinola,
Commercial Manager for LOGiCAL

"**Beamex LOGiCAL** makes it easy and inexpensive for everyone to take their first steps towards a streamlined and digitalized calibration process".

Jan-Henrik Svensson,
CEO of Beamex Group

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beamex

In return I would ask what are the costs of all the errors in your calibration data? What would be the value of such a system to you? Can you afford to be without it?

There has to be a better way.

> The **Beamex system** comprises calibration software, documenting calibrators and mobile data-entry devices **communicating seamlessly.**"

There is a better way – the Beamex way!

So, what about the Beamex way? What is it?

With the Beamex integrated calibration solution, you can replace manual calibration data entry with the most highly automated calibration data collection system on the market.

In a nutshell, the Beamex system comprises calibration software, documenting calibrators, and mobile data-entry devices, all of which communicate seamlessly. Also, the calibration software can be integrated with your maintenance management system (CMMS) to enable a paperless automated flow of calibration work orders from the CMMS to the calibration software and acknowledgement of the work done from the calibration software to the CMMS.

It all starts from you planning the work in the CMMS or the calibration software. When it is time to perform the calibration, the work orders are synchronized to documenting calibrators or to mobile devices (phones or tablets).

In the field, when you perform a calibration the calibration data is stored automatically in the documenting calibrator or manually entered on a mobile device.

If you work in a highly regulated environment, mobile devices can be provided with additional data security functions to ensure the integrity of the data. The Beamex calibration solution fulfills the requirements of 21 CFR Part 11 and other relevant regulations for electronic records, electronic signatures, and data integrity. This lowers the risk of ALCOA (data integrity) violations by identifying those using offline mobile devices by their electronic signature and by protecting the offline data against tampering – eliminating the possibility to falsify calibration records.

From the mobile devices, the calibration data can be synchronized back to the calibration software for storage, analysis, and certificate generation.

The calibration software can also send an automatic notification to the CMMS when the work is done.

WRITTEN BY
HEIKKI LAURILA

Heikki Laurila is Product Marketing Manager at Beamex Oy Ab. He started working for Beamex in 1988 and has, during his years at Beamex, worked in production, the service department, the calibration laboratory, as quality manager, as product manager and as product marketing manager.

BEAMEX WHITE PAPER

DATA INTEGRITY
IN CALIBRATION PROCESSES

What is **Data Integrity?**
Why is it important and acute?
What could a breach cause?
What is **ALCOA Plus?**

As a concept, data integrity is by no means a new one; it has been around for several decades. Anyhow, in this article, we look at data integrity more from the calibration process point of view, and focus mainly on the pharmaceutical industry. First we take a look at data integrity generally: what it is, why it is important, and what a breach could cause. The ALCOA plus concept is also briefly discussed. Data integrity was already on the agenda back in the early 90s when we had pharmaceutical customers auditing us prior to a calibration software purchase.

It's all about trust

Often, when we buy an everyday product, we can quickly see if the product is operating properly or if it is faulty. For example, if you buy a new TV and turn it on, you can quickly see if it is working or not. But with other products it is not so easy. This is especially the case with medicines. When you pick up a medicine, how do know that it is working properly according to design specifications? In most cases you can't tell that, so it is all about trust – you must be able to trust that the medicine you take is genuine.

What is data integrity?

Data integrity is fundamental in a pharmaceutical quality system ensuring that products are of the required quality. In every process, there is a lot

of data produced. Data integrity is the maintenance and assurance of the accuracy and consistency of the data over its entire life cycle. It is a critical aspect of the design, implementation, and usage of any system which stores, processes, or retrieves data. The term is old and was initially used in computing; today it is widely used and has different meanings in different contexts. The integrity of the data collected and recorded by pharmaceutical manufacturers is critical to ensuring that safe, high-quality products are produced. To ensure the integrity of data, it should be protected from accidental or intentional modifications, falsification, and deletion.

> With **many processes** in the process industry, you cannot just simply test the final product to see if it is a **proper one.**"

With many processes in the process industry, you cannot just simply test the final product to verify that it meets the design specifications. Instead you must assure that the conditions during the process are correct. These critical conditions must naturally be recorded and maintained. This is certainly the case in many processes in a pharmaceutical plant.

Why is Data Integrity important at the moment?

Data integrity has recently become an even more important topic than before.

Data integrity related violations have led to several regulatory actions such as warning letters and import alerts. Actually, a large number of the warning letters issued by the US Food and Drug Administration (FDA) are somehow related to data integrity.

As international regulatory agencies have more focus on data integrity, auditors from the FDA, WHOA, and the UK's Medicines & Healthcare products Regulatory Agency (MHRA) have been trained to better recognize data integrity issues.

In March 2015 the MHRA released a new guide, "GMP Data Integrity Definitions and Guidance for Industry". Companies were required to comply with the guidelines by the end of 2017. In 2016 the FDA released "Data Integrity and Compliance With CGMP – Guidance for Industry". Both of these naturally had an impact on the pharmaceutical industry. Prior to this there had been guidance for good manufacturing practice (CGMP), such as 21 CFR parts 210, 211, and 212, discussing data integrity related issues, the aforementioned updates increased the focus on data integrity.

One additional reason why more focus has been put on data integrity is the increase in the use of mobile devices in calibration processes. This includes applications used on tablets and mobile phones. It also includes

the increase in the use of documenting calibrators, which automatically store the calibration results in their memory during a calibration and transfer this data to calibration software. Since the use of automated documenting calibrators improves the business case for a calibration system, they are being more widely used.

To learn more about what a documenting calibrator is and how it benefits the calibration process, please check this blog post: What is a documenting calibrator and how do you benefit from using one?

Impacts of breach of data integrity

A data integrity breach will impact both patients and the pharmaceutical company.

For patients the impact can be that the medicine does not have the required effect, patient safety can be compromised, and in the worst-case scenario it can even cause loss of life.

For the pharmaceutical company a breach can result in a warning letter from the relevant regulatory authority, removal of their license to produce, reputational damage, loss of customer confidence, reduction of market share, and reduction of share price.

> Often there are **computerized systems** involved to handle the data and the users may not be **aware of any issues** in such systems."

Accidental vs. intentional. breaches

A breach of data integrity may be accidental or intentional. Often there are computerized systems involved in handling the data and the users may not be aware of any issues in such systems. Certainly the majority of data integrity issues are accidental and non-intentional. Anyhow, in looking at some of the FDA warning letters, it indicates that in the very worst cases there has even been intentional falsifying of records.

Main steps towards better data integrity

Many pharmaceutical companies seems to agree that the main steps towards better data integrity are:

- Better education and communication
- Detection and mitigation of risks
- Focus on technology and IT systems
- Governance of data integrity

Validation is also something that is a must for any computerized system in the pharmaceutical industry. And it is good to remember that The American National Standards Institute (ANSI) defines systems as follows: "people, machines and the methods organized to perform specific functions". So it is not only the computer system that needs to be validated.

ALCOA and ALCOA plus

ALCOA has been around since the 1990s. It is used by regulated industries as a framework for ensuring data integrity, and is key to good documentation practice (GDP). ALCOA relates to data, whether paper or electronic, and is defined by FDA guidance as:

- Attributable
- Legible
- Contemporaneous
- Original
- Accurate

ALCOA plus adds a few more attributes to the list:

- Complete
- Consistent
- Enduring
- Available

A brief description of these attributes are included in the following table:

ALCOA	Attribute	Description of attribute
A	Attributable	Who performed an action and when? If a record is changed, who did it and why? Link to the source data.
L	Legible	Data must be recorded permanently in a durable medium and be readable.
C	Contemporaneous	All data should be recorded at the time the work is performed. All date and time stamps should be in order (based upon date and time).
O	Original	Is the document the original (raw) data? This should be the first time the information is recorded. In some cases, the original may not be available, but a "certified true copy" is available, e.g., a copy may be from a thermal printer and photocopied to preserve the printing. It should be signed, dated, and include the wording that "this is a certified copy".
A	Accurate	This refers to the data being entered without errors or editing. If editing occurred, it must be properly documented, e.g., audit trail, traceable to original data.

ALCOA	Attribute	Description of attribute
+	Complete	All of the data generated is included in the analysis. This includes all runs, whether good or bad. In some cases data may not be used in an analysis, but it is addressed in a deviation or investigation and shown to be invalid.
+	Consistent	This refers to the consistent use of date and time stamps and that the data is collected/ reported in the proper sequence (as expected).
+	Enduring	The original data is recorded in controlled records, e.g., controlled (numbered) worksheets, laboratory notebooks (bound) or electronic media.
+	Available	One can access the data throughout the lifetime of the record (and the associated retention period required).

What could cause data integrity issues?

Some practical and general things that could cause data integrity issues in any systems are, for example: lack of training, user privileges, weak or shared passwords, control of a computerized system, incomplete data entry, and lack of audit data records for changes and modifications.

The first trap to avoid for consumers – counterfeit drugs

Although not really a data integrity issue for the industry, this is an important point for consumers. People are nowadays able to buy medicines online, but unfortunately you don't always get what you

> **Counterfeit drugs** present a huge risk to patient safety and may even **be lethal.**"

WRITTEN BY
HEIKKI LAURILA
Product Marketing Manager at Beamex.

order. A huge amount of the medicines bought online are counterfeit. Sometimes it is obvious from the packaging that the medicine is counterfeit. But, unfortunately that is not always the case and people do, at times, consume counterfeit medicine. Beyond not having the desired effect, counterfeit drugs present a huge risk to patient safety and may even be lethal.

New regulation for product packaging to prevent counterfeiting

In 2011 the European Medicines Agency (EMA) published a Directive that required all prescription drug makers in all but three EU countries to incorporate new safety features into their product packaging by February 2019. The Directive, which is part of a broader effort to combat falsified medicines in the EU, requires drug manufacturers to add a unique identifier and an anti-tampering device to the packaging of most centrally authorized products. This naturally added another burden and cost for manufacturers, to build the systems to support this, but has proven beneficial for consumers. Although this specific regulation applies within the EU, it has had a global impact.

CONCLUSION & REFERENCES

SUMMARY

Although concept of data integrity has existed for a long time, it has recently become a hot topic with the increased use of mobile devices and in the light of new regulatory frameworks.

Although in the end, data integrity is common sense – to assure the integrity of data throughout its life cycle – in practice with various systems and tools being used, it gets more complicated. Since the impacts of the breach of data integrity can be enormous, it is something that needs to be a high priority.

USEFUL LINKS

- 21 CFR Part 11, Electronic Records; Electronic Signatures
- MHRA GMP Data Integrity Definitions and Guidance for Industry, March 2015
- Data Integrity and Compliance with CGMP Guidance for Industry DRAFT GUIDANCE, April 2016
- FDA warning letters are public and can be found here
- European Medicines Agency (EMA), recent regulation for product packaging

CMX
CALIBRATION SOFTWARE NOW AVAILABLE IN THE CLOUD

Did you know that **Beamex CMX** Calibration Management Software can also be used in the cloud?

Our all-in-one solution for planning, managing, analyzing, and documenting calibration work and assets can be used in cloud services provided by **Microsoft** (Azure), **Amazon** (Amazon Web Services), or **Alibaba** (Alibaba Cloud).

Using CMX in the cloud enables efficient scaling when you add new sites and means you can access the software from anywhere in the world.

"**Beamex CMX calibration software** ensures we comply with all relevant GxP regulations and removes the risk of manual error, while working in the cloud with Azure gives us access to new technologies and enhanced performance that further improve the user experience."

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GSK, Ireland

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CONNECTED SYSTEMS

CONNECTED CALIBRATION

MAINTENANCE MANAGEMENT SYSTEMS

The **benefits of uniting** calibration & maintenance management systems

For process manufacturers, having reliable and integrated IT systems across a single plant or multiple sites is critical to business efficiency, profitability and growth. Although many manufacturing companies understand that maintenance management deserves enterprise-wide attention, it is still often viewed as nothing more than a necessary cost of doing business. However, integrating maintenance management systems more closely with plant processes – for example, by connecting them with a calibration management system – can improve operational efficiency while saving costs.

The rise of maintenance management systems

Maintaining plant assets such as production-line equipment, boilers, furnaces, conveyor systems or hydraulic pumps is critical in process industries. This is particularly true if the company is part of an asset-intensive industry where equipment and plant infrastructure is large, complex and expensive.

Production outages caused by breakdowns are costly, so implementing a modern digitalised calibration and maintenance management (CMM) system can save time and money. Organisations may also have their own in-house software systems for maintenance management.

The importance of calibration management

In process industries, a small but critical part of a company's asset management strategy should be the calibration of process instrumentation. Manufacturing plants need to be sure that their instrumentation devices – temperature sensors, pressure transducers, flow meters and the like – are functioning correctly and measuring to specified tolerances. If sensors drift out of their specification range, the

BEAMEX CALIBRATION ARTICLE

> **Calibration management** software helps companies document, schedule, plan, analyse and **optimise their calibration** work."

consequences can be disastrous, perhaps resulting in costly production downtime, safety issues or batches of inferior quality goods that then have to be scrapped.

Calibration management software helps companies document, schedule, plan, analyse and optimise their calibration work. Communication between the software and smart calibrators means that companies can automate predefined calibration procedures. As well as retrieving and storing calibration data, the software can also download detailed instructions for operation before and after calibrating.

The limitations of standalone systems

There are some limitations to using a standalone maintenance management system. Although plant hierarchy and work orders can be stored in the CMM system, calibration cannot be automated because the system cannot communicate with smart calibrators. This leads to duplicated effort and re-keying the same data into multiple databases, reducing efficiency and increasing the risk of human error in the process.

Because the CMM system is also likely to have been implemented before the calibration management software, it will normally be the first port of call for maintenance staff and for generating work orders.

How integration works in practice

An integration project for a CMM and calibration management system will normally involve three parties: the customer; the CMM system software partner; and the calibration management software partner. The calibration management software created by technology and service company Beamex can be integrated with commonly used CMM systems, including Maximo, SAP and Datastream. Beamex offers a standard integration package that can be customised to suit each customer's existing software and maintenance strategy.

To connect CMM systems and calibration software management systems, the integration interface relies on Extensible Markup Language (XML), which enables the sharing of structured data across different information systems. Data fields such as position ID, device ID, location, serial number and work order number can be transferred from the customer's CMM system to the calibration management system. Similarly, data can be transferred the other way, including work order numbers, position ID, maximum error, pass/fail notifications, calibration date and time and the name of the person who carried out the calibration task.

The benefits of integration

Integrating a calibration management system with a CMM system means that the plant hierarchy and all work orders for process instruments can be generated and maintained in the customer's CMM system; calibration work orders can also be easily transferred to the calibration management system. Once a work order has been executed, the software sends an acknowledgement order back to the customer's CMM system. Detailed calibration results are stored and available on the calibration management software database.

The benefits of this kind of integration come from streamlining processes and combining data in one easily accessible location and enabling companies to automate their calibration management process. Managers can make more informed decisions as all necessary data related to compliance reporting and overall calibration is in one place. In addition, the audit process is easier and more stress free as the needed information is readily available.

> CASE STORIES

CASE STORY: Braskem America

THE **LARGEST PETROCHEMICAL** COMPANY IN THE AMERICAS

How Braskem integrated their computerized maintenance management systems and calibration management software.

Braskem, a Beamex customer, uses MC6 calibrators to calibrate field instruments, Beamex CMX software, and the Beamex bMobile solution to perform electronically guided function tests.

In order to improve the automation of their maintenance and calibration work process, they choose to integrate the Beamex calibration software into their plant maintenance management software, SAP and Maximo, using a business bridge.

A business bridge simply allows communication between the maintenance management software (SAP and Maximo, in this case) and the calibration software (Beamex CMX) via an XML (Extensible Markup Language) data file format.

This enables the sharing of structured data, including position ID, location, serial number, and work order numbers, across the different information systems.

With the implementation of this business bridge, Braskem has reduced manual interventions and human error. Additionally, their management team can now see all necessary data related to compliance reporting and overall calibration in one place.

Prior to Beamex, Braskem had a pen and paper calibration process. That process consisted of an Instrumentation and Electrical (I&E) Technician being assigned a work order, writing down the results, turning the results into an I&E Supervisor who would scan it to a pdf document, and then mark the SAP work order as completed. **Patrick Zhao**, *Corporate Instrument & Analyzer SME* for Braskem America, notes that, "A lot of times that calibration data gets lost. That piece of paper gets lost."

After Beamex was implemented, prior to the Maximo bridge integration, a similar process was used. Calibration Tech would be assigned a work order and they would use a Beamex calibrator out in the field to perform the calibration. From here, Beamex CMX could automatically send an email to the Process Maintenance Coordinator (PMC) who would then close the SAP work order. An I&E Approver would have to go back manually into Maximo and scan the Beamex calibration certificate into a pdf and manually attach that pdf to the appropriate work order to close it.

According to Patrick, this could take anywhere from 10–20 minutes per calibration.

With the implementation of the business bridge between Maximo and Beamex, once the calibration is completed, Beamex sends an email to the PMC. The I&E Approver logs into Beamex CMX software and clicks on an approve button, once he enters his username and password, which serves as an electronic signature, the calibration results are automatically sent to Maximo and the appropriate work order is automatically completed.

"We save about 20 minutes per calibration/ work order with this integration." states Patrick.

Read the full case story online

CASE STORY: Salt River Project's

ONE OF **AMERICA'S LARGEST** PUBLIC POWER UTILITIES

How Salt River Project integrated its asset management software with calibration software to reduce risk and increase efficiency.

Jody Damron, a *Business Analyst* at Salt River Project, started to investigate the possibility of linking their calibration software, Beamex CMX, to their asset management software, Maximo. Jody began by researching IT integration projects.

Upon completion of in-depth analysis, Jody and the team determined that the integration could be completed to meet both the business and IT needs.

THE RESULTS

The most significant impact overall is that Salt River Project has been able to save about 30 minutes per calibration using an automated approach. Other major benefits of the automated calibration system include:

- System oversight has been minimized.
- Audits are easy to perform and are less stressful.
- Defined calibration procedures provide a corporate "best practices" approach to calibration.
- Better decision making because of accuratedata.

In the simplest terms, the new Beamex/Maximo calibration system gives back time to the people working in the field. As a result, as Jody explains, "With this software integration project, we were able to realize a significant return on investment during the first unit overhaul. It's unusual, since ROI on software projects is usually nonexistent at first."

THE BASIC RULES OF SRP'S SYSTEM:

1. Beamex CMX is the calibration system of record that stores the detailed calibration information.
2. Maximo tracks all plant assets and is the master of scheduling.
3. As for calibration, the only information Maximo needs is if an instrument passed or failed during the calibration event.
4. In Maximo, there are two types of instrument assets – those that are calibrate-able and those that are never calibrated.
5. For a Maximo asset to be transferred into CMX, the asset has to be defined as a calibrate-able asset.
6. If a Maximo work order is written or automatically generated by the preventive maintenance application for a calibrate-able asset, it automatically flows into CMX.
7. Work orders are generated by a planner. Technicians will paperlessly pick them up and calibrate them. This process allows field personnel to work only within CMX, and they do not deal with work orders in Maximo, saving them time, money and frustration.

Read the full case story online

AUTOMATING

THE CALIBRATION MANAGEMENT ECOSYSTEM

BEAMEX WHITE PAPER

Calibrations are **at the core** of process industries – but every industry also has their own unique requirements

Calibration is a vital component of process industries, and most process plants have some sort of system in place for managing instrument calibration operations and data. However, the systems and processes can be very different even within the same company across different plants. Methods often differ greatly in terms of cost, quality, efficiency, accuracy of data, and level of automation.

In many plants, calibration is still done manually with paper certificates – a time-consuming process that increases the possibility of human error while limiting the ability to perform analysis. Automating the calibration ecosystem to produce traceable calibration data reduces errors and increases efficiency. An automated process also makes it easier to analyze data to implement preventive maintenance, maintain quality, and reduce costs while ensuring compliance.

The calibration ecosystem is about technology, services, and expertise with a focus on traceability of results. This means knowing what device was calibrated, who performed the calibration, what equipment they used, and when they did it. Creating an automated ecosystem requires both hardware and software combined with expertise – both on the part of the solution provider as well as those training the personnel who will use the system. The end result is a range of benefits, from assured compliance and improved quality to better efficiency and cost savings.

Market background

All process plants need to manage the calibration process ecosystem, including storing calibration assets, defining and documenting calibration processes and procedures, carrying out calibration, and storing and analyzing calibration data.

Traditionally, engineers and technicians used pen and paper to record calibration results while out in the field. On returning, notes were tidied up or transferred to another paper document, after which they were archived. This resulted in thousands of pieces of paper stored in binders, which risked being misplaced, lost, or damaged.

Using a manual, paper-based system like this is very laborintensive and means that errors are commonplace. It also means that historical trend analysis is very difficult to carry out as the calibration data is not easily accessible – even drawing trend data for a single calibrator can take a matter of hours or even days.

The real issue is one of ensuring traceability. Traceability means that you can quickly and easily find what device was calibrated and knowing who did the calibration, using what equipment, and when it was done. When everything is recorded on paper in binders in a storage room, traceability suffers and calibrations become merely very accurate measurements – meaning that the potential to use this data for the benefit of the business is lost.

> The trend of **digitalization** is affecting most industries, and **process industries** are no exception."

DIGITALIZING THE PROCESS

The trend of digitalization is affecting most industries, and process industries are no exception. Automating, streamlining, and avoiding errors in the calibration process is key to improving efficiency. To do this, process industry players have attempted to integrate calibration data with maintenance management systems, typically by entering calibration data manually into a spreadsheet or database. The data is stored electronically, but the recording of calibration information is still time-consuming and typing errors are common. Also, the calibration process itself isn't automated. For example, automatic alarms cannot be set up on instruments that are due for calibration.

Some use the calibration module of their maintenance management software for calibration management. In this kind of setup, plant hierarchy and work orders can be stored, but calibration cannot be automated because the system can't communicate with 'smart' calibrators.

To move beyond the limitations of such a system, an automated calibration ecosystem is key. In general, a calibration management system allows calibration certificates to be generated and calibration data to be delivered to external systems.

Key elements in the automated calibration ecosystem

The calibration ecosystem is made up of everything that's connected to the calibration process, including the actual calibration data from field calibration, calibration management software, compliance, services to ensure everything works smoothly, and the expertise of the people involved in the process.

> The calibration **ecosystem** is made up of everything that's connected to the **calibration process.**"

EXPERTISE

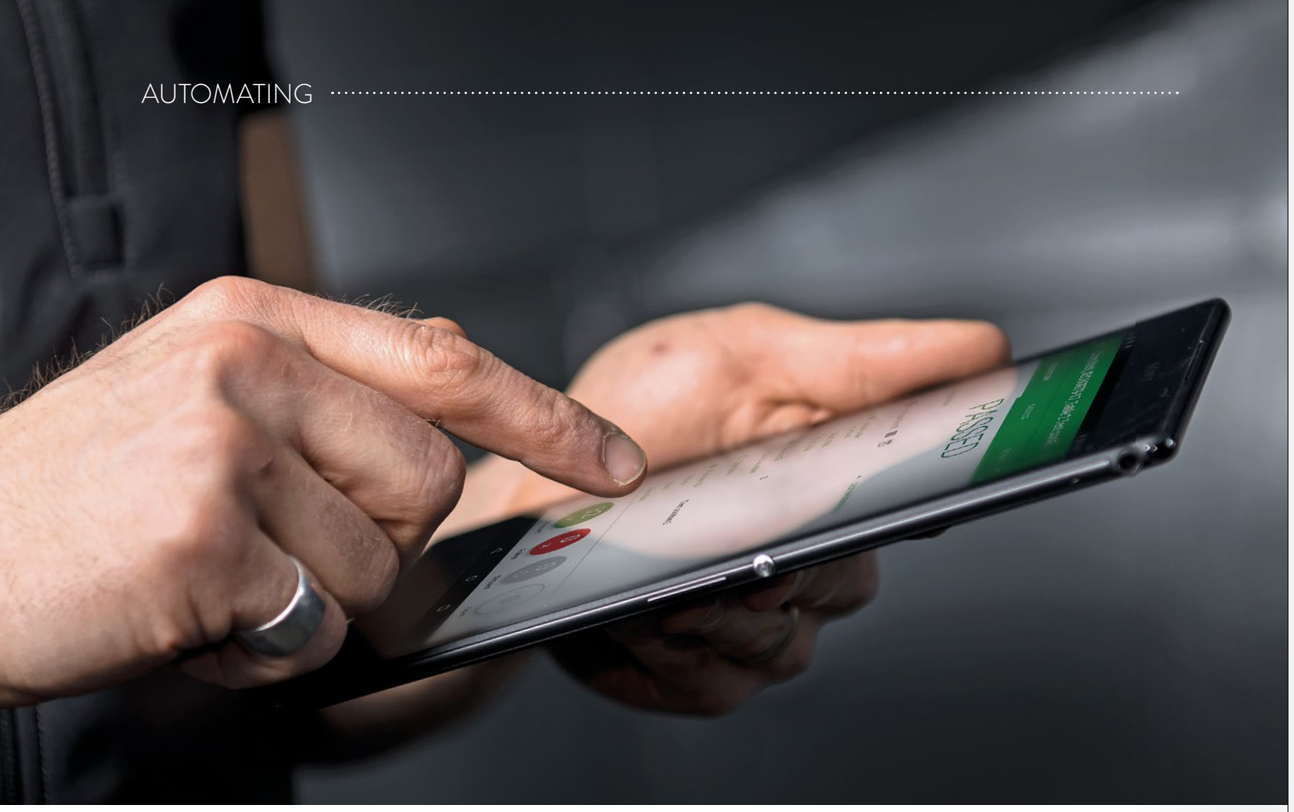
Calibrations are at the core of process industries – but every industry also has its own unique requirements. Expertise on the part of the calibration provider is necessary to ensure that all requirements are met. To take just one example, in the pharmaceuticals industry compliance with the Food and Drug Administration's Good Manufacturing Practice (GMP) requirements is critical. The GMP requirement 21 CFR Part 11, which regulates how the calibration certificate is documented and signed electronically, must be adhered to in order to create a compliant process. Obviously, such requirements need to be taken into account by the vendors designing automated calibration processes.

Expertise also allows a calibration provider to be a trusted advisor. It's important to ask the right questions and ensure that the system being delivered meets the unique process needs of a given company. Understanding change management and having a set process is also essential to ensuring a smooth roll out of new processes and technology.

In addition to expertise on the part of the solution provider, personnel using the calibration ecosystem need to be trained to use it. One benefit of modern digital systems is that such training can be built in as on-system guidance for users, allowing them to use the system to full effect. Calibration instructions are created using the software to guide engineers through the calibration process. These instructions can also be downloaded to a technician's handheld documenting calibrator while they are in the field.

HARDWARE

Unsurprisingly, calibrators are at the heart of the calibration ecosystem. A modern documenting multifunction calibrator can act as an all-in-



one solution for basic needs, especially when using instrument-based calibration management. The calibrator provides a traceable calibration reference.

> **Calibration software** provides users with an **easy-to-use** interface."

SOFTWARE

Calibration software provides users with an easy-to-use interface. The software manages and stores all instrument and calibration data and processes. This includes:

- planning and scheduling of calibration work
- analysis and optimization of calibration frequency
- production of reports, certificates, and labels
- communication with smart calibrators
- easy integration with maintenance management systems such as SAP and Maximo

Software as a service (SaaS) is increasingly being offered with cloud-based solutions, meaning companies need to invest less in backend

systems to keep everything running and instead subscribe and scale up services as needed.

RECALIBRATION AND SERVICE

Even the best device will occasionally drift and need to be recalibrated. Regular inspection – or even better, using data and analysis to determine if a device is starting to drift so targeted maintenance can be performed – is key.

Benefits of automated calibration infrastructure

BETTER PLANNING AND DECISION-MAKING

With software-based calibration management, planning and decision-making improve. Procedures and calibration strategies can be planned and all calibration assets managed by the software. Instrument and calibrator databases are maintained, while automatic alerts for scheduled calibrations can be set up.

ENSURE COMPLIANCE

Regulatory organizations and standards such as FDA and EPA place demanding requirements on the recording of calibration data. Easily traceable calibration data is important for audits and for ensuring calibrators are in tolerance. For regulated industries, managing user permissions and the integrity of calibration data is highly important, which is enabled by a calibration management system.

> Regulatory organizations and **standards** such as FDA and EPA place demanding requirements on the recording of **calibration data.**"

INCREASED EFFICIENCY THAT LEADS TO TIME SAVINGS

With an automated system, calibration is more efficient and errors are eliminated. Smart devices guide technicians through the calibration so they know exactly what needs to be done. This increases trust in the results of the calibration as what needs to be done and what has already been done is transparent and clear to all technicians and managers in the ecosystem. Using software-based calibration management systems in conjunction with documenting calibrators means that calibration results can be stored in the calibrator's memory, then automatically uploaded into the calibration software. There is no re-keying of calibration results from a notebook to a database or spreadsheet. Human error is minimized and the whole process takes less time, meaning technicians are freed up to perform more strategic analyses or other important activities.

> With traceable **calibration data**, analysis becomes easier."

AUTOMATED CALIBRATION AND DOCUMENTATION

The system generates reports automatically and all calibration data is stored in one database rather than multiple disparate systems. Calibration certificates, reports, and labels can all be sent in electronic format. Everything is documented and saved, which is important for compliance and audit purposes.

ANALYSIS CAPABILITIES OF CALIBRATION DATA

With traceable calibration data, analysis becomes easier. Engineers can optimize calibration intervals using the software's trending function. In addition, when a plant is being audited, calibration software can facilitate both the preparation and the audit itself. Locating records and verifying that the system works is effortless when compared to traditional calibration record keeping. Business benefits arise from being able to analyze data and compare the performance of different shifts or production facilities.

CONDITION-BASED MAINTENANCE

Rather than rely on the manufacturer's recommendation for calibration intervals, plants may be able to adjust these intervals by looking closely at historical trends provided by calibration management software. Instrument drift can be monitored closely over a period of time and then decisions made with respect to amending the calibration interval.

QUALITY ASSURANCE

With all calibrators in tolerance, easy traceability, and the ability to fix calibrators before they drift out of tolerance, the quality of a given process can be assured.

COST REDUCTION

Implementing software-based calibration management means overall plant costs will be reduced. These savings come from fully digitalized calibration procedures that are paperless with no need for manual documentation.

Implementing an automated calibration ecosystem step by step

Implementing an automated calibration ecosystem includes several steps, from planning to execution.

CMX
ANALYTICS DASHBOARD
www.beamex.com/software

DATA IS TODAY'S GOLD. By analyzing your calibration data you will get a quick overview of all your calibrations. Do you know how well utilized your reference standards and modules are? Are the calibration intervals really optimized and how easily available are your calibration data for audits?

Beamex software data can be transferred into the Power BI analytics tool in order to make all your calibrations visible. The reports can be easily accessed, filtered, and adapted according to your specific needs. Harnessing the full potential of the calibration data will make your decision making easy.

WHY USE CALIBRATION DASHBOARDS?

- Gain quick access to your needed data and KPIs
- Filter data according to your needs
- Gain insights easily
- View all crucial calibration data in one place
- Detect potential risks/problems
- Access calibration history and predict trends
- Optimize your calibration interval
- Predict how an instrument will drift
- Easy overview of your scheduled calibrations

VIDEO: CMX Analytics Dashboard Introduction
WEBINAR: Your window into calibration data

beamex

PLANNING AND DECISION-MAKING

There are two main ways to manage calibrations:

- Process-based calibration management is mainly concerned with where a measurement task must be performed. Users want to ensure the accuracy of the measurement tasks performed **in a given location.**
- Instrument-based calibration management is mainly concerned with the physical devices that are used to perform measurement tasks. Users wants to ensure the accuracy of the measurement tasks performed **with a given device.**

Whichever method is chosen, all plant instruments and measurement devices need to be listed and classified into critical and non-critical devices. Once these have been set up, the calibration ranges and required tolerances are identified. Decisions then need to be made regarding the calibration interval for each instrument.

The creation and approval of standard operating procedures (SOPs) for each device should be defined, followed by the selection of suitable calibration methods and tools to execute these methods. Finally, the current calibration status of every instrument across the plant needs be identified.

Having a trusted advisor at this step is critical as they can ask the right questions and identify potential areas for improvement and where key decisions need to be made. While final decisions are made by the customer, an advisor can help ensure that all relevant information is taken into account.

> **Without training,** there is a risk that new assets will not be fully utilized, meaning the full benefits of the investment **won't be realized.**"

ORGANIZATION-RELATED NEEDS

The next stage involves training calibration staff – typically maintenance technicians, service engineers, process and quality engineers, and managers – in using the chosen tools and how to follow the approved procedures. Without training, there is a risk that new assets will not be fully utilized, meaning the full benefits of the investment won't be realized. Resources also need to be made available to carry out the scheduled calibration tasks.

EXECUTION AND ANALYSIS

When executing the automated calibration ecosystem, the assigned calibration tasks must be supervised. Staff carrying out these activities

must follow the appropriate instructions before calibrating the device, including any associated safety procedures. The calibration is then carried out according to the plan, although further instructions may need to be followed after calibration.

The documentation and storage of calibration results typically involves electronically signing or approving all calibration records generated. Based on the results, analysis should be performed to determine if any corrective action needs to be taken.

Beamex can support you in creating an automated calibration ecosystem

THE BEAMEX INTEGRATED CALIBRATION SOLUTION (ICS)

The Beamex ICS is a combination of software, hardware, and calibration expertise that delivers an automated and paperless flow of calibration data.

When upgrading from a traditional calibration system to an integrated one, the calibration process is automated and all error-prone manual steps are eliminated. Upgrading typically decreases how long the entire calibration process takes while improving the quality of calibration records and ensuring quick and easy retrieval for audits.

Creating an automated calibration ecosystem is not just about buying another piece of software or more hardware. Beamex uses its expertise to

> **The Beamex solution** is a combination of software, hardware, and calibration expertise that delivers an **automated and paperless** flow of calibration data."

support successful change management, helping customers to evaluate their current calibration processes and find areas for improvement using a set process. We can then help to ensure a smooth and efficient transition to a new and optimized calibration process.

BEAMEX CMX CALIBRATION MANAGEMENT SOFTWARE

Beamex CMX is calibration software located on the customer's premises. When combined with a documenting calibrator, it means users can entirely remove paper from their calibration process. All records are safely stored in a database resulting in new possibilities for analyzing calibration data and improving processes.

> Creating an **automated calibration** ecosystem requires a combination of software, hardware, services, and **expertise.**"

BEAMEX LOGiCAL CALIBRATION MANAGEMENT SOFTWARE

Beamex LOGiCAL is a subscription-based calibration software using cloud technology. It is easy to start using LOGiCAL and the costs are scalable based on usage. Users can start with a low-cost monthly fee and still benefit from a digitalized paperless calibration environment. Because LOGiCAL is cloud based, users can access it anywhere there is an internet connection, meaning no expensive IT infrastructure is needed and updates are automatic.

BEAMEX bMobile CALIBRATION APPLICATION

Beamex bMobile is an application for mobile devices that allows paperless calibration, documentation, and inspection activities in the field. Beamex bMobile works offline and in conjunction with the online Beamex CMX calibration management software to support users who don't always have a reliable network connection when working.

HARNESSING NEW TECHNOLOGIES

Beamex is continuing to develop our calibration management ecosystem to take advantage of emerging technologies that further automate the process and increase data quality. These include artificial intelligence, machine vision, and augmented reality, among others. The goal is to harness these technologies in a way that delivers concrete benefits – ensuring that the right person uses the right tools to calibrate the right equipment in the most efficient way possible.

CONCLUSION

Creating an **automated calibration ecosystem** requires a combination of software, hardware, services, and expertise. When such a system is in place, traceable calibration data is automatically created when a calibration is performed and digitally stored, reducing the need for error-prone manual steps. Data can also be easily found for audit purposes or analyzed to discover trends, to perform targeted maintenance when needed, or used to find areas for improvement – ultimately increasing efficiency and reducing costs.

Learn more about Beamex products and services:
www.beamex.com

Beamex Worldwide Contacts:
www.beamex.com/beamex-worldwide/

DO MORE WITH LESS

AND GENERATE ROI WITH AN INTEGRATED CALIBRATION SOLUTION

BEAMEX WHITE PAPER

Process instrument **calibration** is just one of the many **maintenance related** activities in a process plant

The last thing you want to do is to have your limited resources wasting time performing unnecessary calibrations or using time-consuming, ineffective calibration procedures.

Yet, you need to make sure that all critical calibrations are completed, ensuring the site stays running efficiently with minimal downtime, product quality is maintained, and the plant remains safe, compliant with regulations, and audit ready.

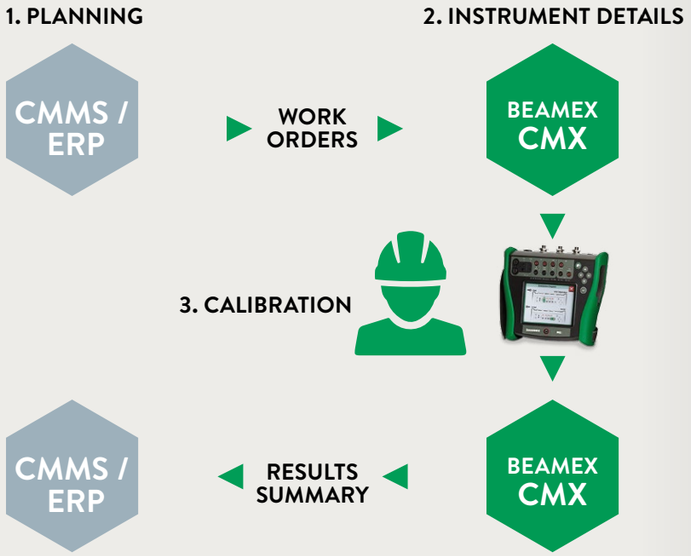
Typically you can't just go and hire an army of external calibration specialists, so you need to get more done with your existing resources.

In this article, let's examine at what an integrated calibration solution is and how it can help you make your calibration process more effective, save time and money, and improve the quality and integrity of the calibration results. We will also discuss how it can quickly generate a great return your investment.

Improve the whole calibration process with an integrated calibration solution

It is not enough to just buy some new calibration equipment or calibration software – that will not make your calibration process leaner and more

INTEGRATED CALIBRATION SOLUTION
CALIBRATION PROCESS



▶ You should analyze all the steps of your calibration process, and with the help of a suitable solution and expertise, find ways to improve the whole calibration process.

“With an **integrated solution,** these work orders move **automatically.**”

effective. Instead, you should analyze all the steps of your calibration process, and with the help of a suitable solution and expertise, find ways to improve the whole process.

Let’s quickly look at a typical calibration process from the beginning to the end and explore how an integrated system could help.

Typically, work is planned and work orders are created in the maintenance management system. With an integrated solution, these work orders move automatically and digitally from the maintenance management system to the calibration software. There is no need to print work orders and distribute them manually.

The necessary calibration details are handled by the dedicated calibration software, which sends the work orders to the mobile calibration equipment. Again, this happens digitally.

While the technicians are out in the field performing the calibration activities, the results are automatically stored in the mobile devices, and users signs off the results using an electronic signature. From the mobile device the results are automatically transferred back to the calibration software and saved ready for analysis.

Once the work orders are completed, the calibration software automatically sends an acknowledgement to the maintenance management software and the work orders are closed.

So, the whole process is paperless and there is no need for manual entry of data at any point. This makes the process far more effective and saves time. This also helps minimize mistakes typically caused by manual data entry, so it improves the quality and integrity of the calibration data.

Furthermore, calibration results are safely stored and easily accessible in the calibration software for review, for example in case of audits and for analysis purposes.

As mentioned, improving the calibration process is not just about buying some new equipment or software; the project should also include improvement of the whole calibration process together with the new tools supporting it. Implementing a new process should be a project with a formal implementation plan, ensuring that the new system/ process is adopted by the users.

“The whole **process is paperless** and there is no need for **manual entry** of data at any point.”

The key benefits of an integrated calibration solution

IMPROVE OPERATIONAL EFFICIENCY – DO MORE WITH LESS

Automate calibrations and calibration documentation. Eliminate all manual entry steps in the calibration process. Use multifunctional tools to reduce the amount of equipment you need to carry in the field and lower equipment life-cycle costs.

SAVE TIME AND REDUCE COSTS – GET A GREAT ROI

With automated processes, get more done in less time. Don’t waste time on unnecessary calibrations. Let the data from the system guide you to determine the most important calibrations and the most appropriate intervals to perform them..

IMPROVE QUALITY

With electronic documentation, avoid all errors in manual entry, transcriptions, and pass/fail calculations.

GUIDE INEXPERIENCED USERS

Let the system guide even the most inexperienced users to help them perform like professionals.

AVOID SYSTEM FAILURES AND OUT-OF-TOLERANCE RISKS

Use a calibration system that automatically ensures you meet required tolerance limits, to avoid system downtime and expensive out-of-tolerance situations.

BE COMPLIANT

Use a system that helps you comply with regulations and meet internal standards of excellence.

ENSURE SAFETY

Ensure safety of employees and customers with a calibration system that helps you navigate safety-critical calibrations.

SAFEGUARD THE INTEGRITY OF CALIBRATION DATA

Use a calibration system that ensures the integrity of the calibration data with automatic electronic data storage and transfer and relevant user authorizations.

MAKE AUDITS AND ACCESSING DATA EASY

Use a system that makes it easy to locate any record an auditor asks for.

RELATED ARTICLES

If you like this article, you could also like these articles in Beamex blog:

- Top 5 reasons why companies update their calibration systems
- How to implement calibration software
- The key aspects of building a calibration system business case
- Data Integrity in Calibration Processes
- How a modern calibration process improves power plant performance
- How often should instruments be calibrated?

WHAT DO THE USERS SAY?

Here are just a few testimonials on what the users have said about the Beamex Integrated Calibration Solution:

"With the Beamex solution, we have complete flexibility, so we can perform many calibrations in between other daily tasks. This flexibility is important in a busy workplace where more urgent tasks often arise and need to be prioritized."

E&I TECHNICIAN, DENMARK

"With this software integration project, we were able to realize a significant return on investment during the first unit overhaul. It's unusual, since ROI on software projects is usually nonexistent at first."

BUSINESS ANALYST, SALT RIVER PROJECT, USA

"After implementing the Beamex CMX calibration management system, GSK will be able to eliminate 21,000 sheets of printed paper on a yearly basis, as the entire flow of data occurs electronically, from measurement to signing and archiving."

GLAXOSMITHKLINE LTD, IRELAND

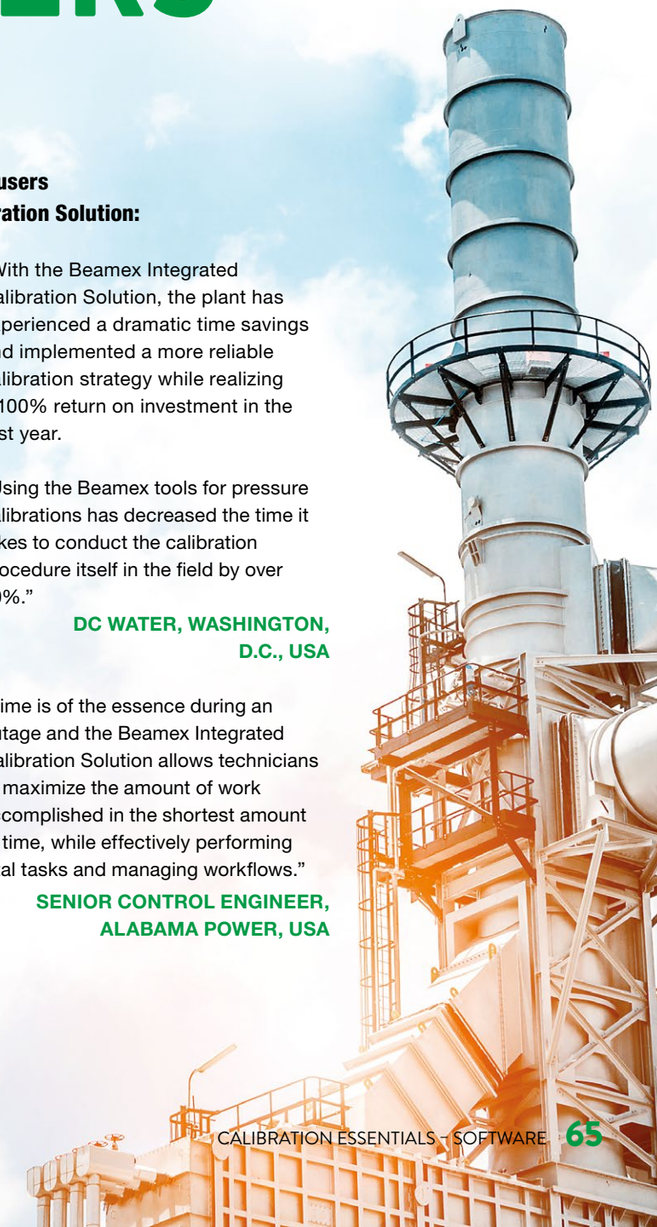
"With the Beamex Integrated Calibration Solution, the plant has experienced a dramatic time savings and implemented a more reliable calibration strategy while realizing a 100% return on investment in the first year.

"Using the Beamex tools for pressure calibrations has decreased the time it takes to conduct the calibration procedure itself in the field by over 80%."

DC WATER, WASHINGTON, D.C., USA

"Time is of the essence during an outage and the Beamex Integrated Calibration Solution allows technicians to maximize the amount of work accomplished in the shortest amount of time, while effectively performing vital tasks and managing workflows."

SENIOR CONTROL ENGINEER, ALABAMA POWER, USA



BEAMEX IN BRIEF

PRODUCTS & SERVICES

BEAMEX is your trusted partner for calibration excellence, providing accurate measurements, reliable data, and traceability for a safer and less uncertain world. Beamex helps improve efficiency, ensure compliance, and increase safety with its comprehensive ecosystem calibration solutions – from field calibration to workshop calibration, calibration management, and services. Through its subsidiaries, branch offices and partner network, Beamex products and services are available in more than 80 countries

Learn more about Beamex calibration solutions
www.beamex.com

Beamex Worldwide Contacts
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beamex

THE BEAMEX INTEGRATED CALIBRATION SOLUTION is a unique combination of software, hardware, and calibration expertise that delivers an automated and paperless flow of calibration data. It is the only solution available that can completely automate your calibration work.

When upgrading from a traditional calibration system to an integrated one, you automate the calibration process and eliminate all error-prone manual steps. Upgrading typically decreases the time spent on the entire calibration process by 50%, while improving the quality of calibration records and ensuring quick and easy retrieval for audits.

FIELD CALIBRATION

Beamex's range of portable calibrators for field calibration is known for its accuracy, versatility and meeting both high and uncompromised quality standards.

CALIBRATION MANAGEMENT

Plan, manage and document all your calibrations efficiently and safely using Beamex's calibration software.

WORKSHOP CALIBRATION

A workstation is ideal when most of the maintenance and calibration tasks are performed in the workshop.

SERVICES

An essential part of a complete calibration solution is professional services – service and calibration, installation and training, software support and validation and integration services.

ACCESSORIES

Beamex's calibration accessories complete your investment in calibration equipment. Order your accessories and spare parts from **shop.beamex.com**

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www.beamex.com