

Beamex

Calibration White Paper

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Improve safety and ensure compliance in the fine chemicals industry through automated calibration

beamex

Smart, safe, compliant – the benefits of automated calibration

1. SUMMARY

In the fine chemicals industry, it's essential to maintain the highest possible safety standards while ensuring compliance with all applicable regulations. At the same time, optimizing efficiency, improving sustainability, and minimizing waste are key. Automated calibration can help with all these challenges. An automated calibration solution supports compliance with strict industry regulations and helps with adherence to all documentation requirements while maintaining the highest level of safety.

2. MARKET TRENDS

Fine chemicals are complex, pure chemical substances, such as active pharmaceutical ingredients (APIs), the part of a drug that produces the desired effects. The volume of fine chemicals is often relatively small but the value of the end products is usually high.

Fine chemicals are produced in batches and typically require a large number of inputs for a small amount of product. Because of this, the production of fine chemicals tends to lead to a lot of waste. The high ratio of waste to active product makes waste management and efficiency improvements key. Getting things right the first time saves time and resources – and since chemicals production is highly energy intensive, it also improves energy efficiency.

If an instrument is found to be out of tolerance, at minimum it requires that the produced product is quarantined and a risk analysis and investigation held. In the worst case, the entire batch will have to be discarded, increasing waste and potentially leading to large financial losses. Digitalization, where manual processes are automated using data in a machine-readable format, can help to ensure better efficiency and less waste. This is transforming the industry and making digitalization an essential tool for manufacturers. Resource efficiency is critical as well. Automation enables producers to do more with less, which is important in order to stay competitive.

The pressure to digitalize also has to do with improved compliance. For example, production processes for APIs need to follow the Food and Drug Administrations (FDA) Good Manufacturing Practice (GMP) and 21 CFR part 11. Audit trails also become easier to follow when data is in a digital format.

3. THE CHALLENGES SURROUNDING CALIBRATION IN THE FINE CHEMICALS INDUSTRY

Fine chemicals are batch driven, with complicated, multistage processes that need to be set up correctly. All inputs and processes must be correct and all measurement instruments need to be calibrated to the required tolerances. Because each measurement has to be calibrated to the specifics of the chemical

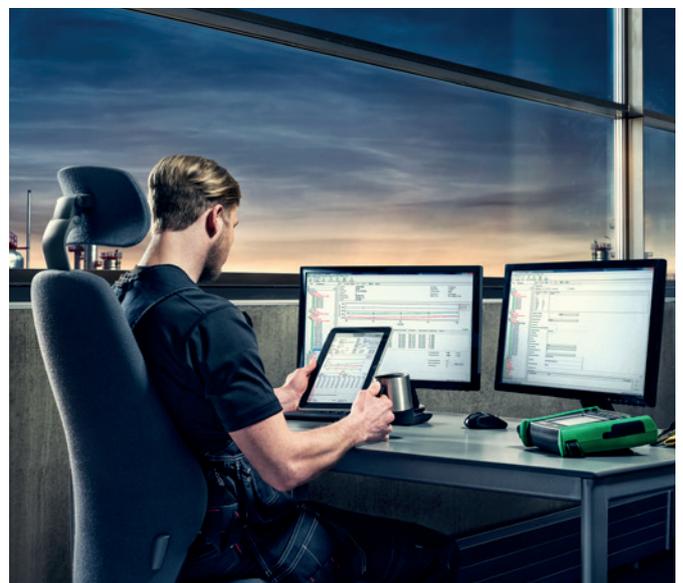
being produced in a given batch, this increases complexity. For example, if a specific batch requires a fermentation process, ensuring the right temperature tolerances is going to be absolutely critical. The right temperature tolerance also helps with producing the desired form, analyzing the rheology/viscosity, and improving flowability.

Calibration has traditionally been a multistep and manual process. Such a process might begin by using the maintenance management system to print a document with a calibration order. The technician takes the order and looks up the correct instrument in the database and goes to the plant to calibrate the transmitter. The results are documented in paper format. After the technician returns from the plant, the results are manually entered into the system. With a manual process like this, there is an increased risk of human error – and an increased risk of a mistake being made that can lead to a rejected batch.

One important thing to note is that if human error is often seen as an issue, this may also indicate there is an underlying problem with the process itself. If the process has not been properly designed and validated, this can lead to sub-optimal results no matter how well people perform the associated tasks.

4. HOW AUTOMATED CALIBRATION SOLUTIONS WORK AND THE BENEFITS OF USING THEM

Automated calibration solutions combine software, hardware, and calibration expertise to deliver an automated, paperless flow of calibration data to improve operational efficiency. Any solution should be based on a thorough understanding of a specific customer's needs to ensure the process is well designed and error-free.



AN AUTOMATED CALIBRATION SOLUTION CAN BE DEFINED AS A SERIES OF SIMPLE STEPS. WHILE THE NUMBER OF STEPS CAN VARY, IN GENERAL THE PROCESS TYPICALLY LOOKS SOMETHING LIKE THIS:

Step 1: The process begins when a work order is created in the maintenance management system and automatically sent to the calibration software to select the appropriate calibration procedures.

Step 2: The device information and calibration procedures are then sent to a documenting calibrator or tablet and the calibration is performed.

Step 3: The device automatically documents the results, storing them in the calibrator. The user signs off on the results electronically.

Step 4: The results are automatically transferred to the calibration software for storage, and the work order is closed in the maintenance management system.

Having a trusted advisor who can help analyze the process and find areas for improvement is key to ensuring all potential benefits are realized. Deep insight into the process on the part of the implementor is needed in order to understand how to best improve existing processes while ensuring compliance with industry-specific requirements.

The process is paperless and minimizes the need for manual data entry. This not only saves time and makes the process far more effective, but it also helps to avoid mistakes typically associated with manual data entry – thus improving the quality and integrity of the calibration data. Furthermore, calibration results are safely stored, tamper proof, and easily accessible in the calibration software for review, for example for audit or analysis purposes.

AN AUTOMATED CALIBRATION PROCESS IN THE FINE CHEMICALS INDUSTRY WILL:

Ensure product safety

When upgrading from a traditional calibration system to an integrated solution, the automation of the calibration process eliminates all manual steps that are prone to human error. Removing human error reduces the chance that a batch will be rejected due to out of tolerance calibrators.

Ensure compliance

Automatic electronic documentation ensures that all data is present and in a format that can't be tampered with to ensure compliance with regulations like GMP and 21 CFR part 11.

A paperless, automated calibration process saves time, increases efficiency, and improves data quality and integrity.

Enable data analysis for more informed decisions

Digitalization enables data analysis and analytics to improve visibility and provide insights. Data from calibrations can be integrated with ERP systems, helping management to understand what's going on and make more informed decisions. Data across factories can be easily compared to spot trends and find areas for improvement.

Increase production

Automated processes save time, meaning an installation is ready for a new batch more quickly, which leads to greater production – which in turn leads to financial benefits.

Make audits easier

When combined with a search function, digital calibration data makes it easy to locate any record that is requested by an auditor.

Save time and optimize your workforce

With automation, the people involved in the calibration process can get more done in a shorter time. Data can also be easily analyzed to determine the most appropriate intervals for conducting important calibrations, saving time and effort.

Improve operational efficiency

Not only do automated solutions reduce the time spent on the calibration process by up to 50%, analyzing trend data is much easier with digital records. Using multifunctional calibrators can also lower equipment lifecycle costs and improve efficiency, as less equipment is needed in the field.

Provide guidance to decrease errors

Digital systems can offer step-by-step guidance for users on the steps involved, reducing the need for training and removing a further potential error source.

Safeguard the integrity of calibration data

A calibration system ensures the integrity of the calibration data with automatic electronic data storage and transfer, and user authorization functionalities.

5. HOW BEAMEX CAN HELP YOUR DIGITALIZATION EFFORTS

Beamex has a long history of working with the chemicals industry to create calibration solutions that are built around the key drivers of safety and compliance. Beamex is a trusted partner and advisor that supports its customers throughout the process of choosing the right calibration solution.

OUR SOLUTIONS COVER THE FOLLOWING AREAS:

Expertise

Calibrations are at the core of process industries but every industry also has their own unique requirements. Beamex has extensive experience in the chemicals industry and our expertise ensures that relevant requirements are taken into account when designing automated calibration processes.

An automated calibration solution

The Beamex Integrated Calibration Solution is a combination of software, hardware, and calibration expertise that delivers an automated and paperless flow of calibration data. Traditional, paper-based calibration processes require seven steps from start to finish, leaving a lot of opportunity for error. The Beamex Integrated Calibration Solution cuts the steps required to perform and document calibrations down to only four, saving time and maximizing efficiency without compromising quality.

Software for gathering and analyzing data

Beamex's calibration software integrates directly into computerized maintenance management systems (CMMS). Detailed calibration data and traceable calibration records are stored in the software, while plant hierarchy and instruments are created and maintained in the CMMS. When calibration work has been performed, work-order acknowledgements can be automatically sent to the CMMS – and since there is no need to manually re-enter the data, input errors are eliminated.

This standardized but configurable software solution keeps the CMMS informed of work orders that have been completed, while the software provides a database for storing vital instrument information necessary for quality control and audits. The calibration software can be integrated into leading maintenance management systems, such as IBM Maximo, SAP, or Infor EAM. A dashboard for visualizing data makes it easy to create reports and analyze trends.

An automated multifunction calibrator

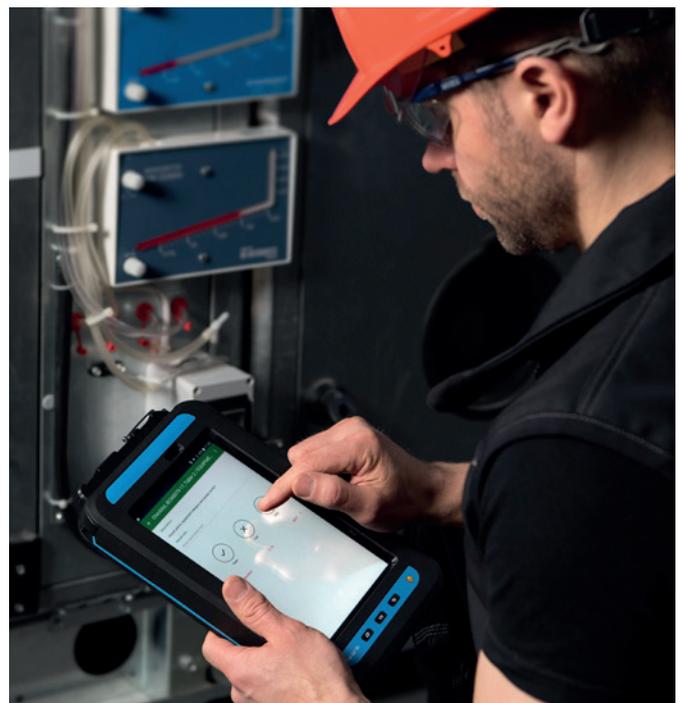
The Beamex multifunction calibrator is an advanced, high-accuracy field calibrator and communicator. It offers calibration capabilities for pressure, temperature, and various electrical signals. It also includes a fieldbus communicator for HART, FOUNDATION Fieldbus, and Profibus PA instruments.

The Beamex multifunction calibrator is also a documenting calibrator. When it is used in conjunction with Beamex calibration software, it creates a fully paperless calibration process where there is no risk of human error and no need to manually enter results into the software.

Traditional manual processes for calculating the measurement error used for pass-fail determination require making a calculation and then comparing the result to the allowable tolerance. The Beamex multifunction calibrator automates this calculation, saving time and eliminating human error.

A mobile application

Beamex's application for mobile devices enables paperless execution and documentation of calibration and inspection activities in the field. It works in conjunction with Beamex calibration management software. The Beamex mobile application works offline, complementing the online Beamex calibration management software. This is because in a process plant, users don't always have access to a reliable network connection.



Services

Beamex offers a range of services to help keep calibrators within the required tolerances, including:

- **Recalibration and repairs:** Keeping a calibrator up to date with regular recalibration is important for maintaining high-quality specifications. Furthermore, a traceable, accredited calibration certificate is needed for plants that operate according to a quality control system.
- **Equipment care plan:** All calibrators need regular maintenance to stay accurate and traceable, and repairing damage can be expensive and time consuming. The Beamex Care Plan is designed to maintain the accuracy and reliability of Beamex measurement equipment throughout its lifetime. The Care Plan includes automated reminders, shipping, priority service, and repair of accidental damage while minimizing the need for procurement resources.
- **Implementation, migration, and support:** Implementing a new calibration system is about more than just buying and installing new software and tools. To ensure a successful rollout, Beamex follows a series of steps including process consulting, software specification and configuration, migration and system integration, validation, and onboarding support.
- **Training:** Beamex offers various training courses to ensure that users and managers are able to learn the necessary skills to operate and manage the calibration system correctly and gain maximum benefit from it.

6. CONCLUSION

An integrated automated calibration process can help to ensure safety and compliance in the fine chemicals industry. Such a solution removes manual and error prone steps from the calibration process, helping to ensure all calibrators are in tolerance. In addition, digitalizing data from the process allows for efficiency improvements and clear audit trails when needed. Beamex offers a complete automated calibration solution that combines expertise, hardware, software, and services.

Learn more about Beamex products and services on our website or contact your local Beamex representative:

Contact us: www.beamex.com

