Audit Trail Via Fieldbus –

Pharma 4.0 All the Way Down to the Field Level

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October 2026



THE ART
OF MEASURING

Audit Trail via Fieldbus –
Pharma 4.0 All the Way Down to the Field Level

Audit trails have long been established in pharmaceutical manufacturing. Control systems, databases, and manufacturing execution systems routinely document operator actions, parameter changes, and process events to support compliance with FDA 21 CFR Part 11 and EU GMP Annex 11.

However, a significant gap often remains at the field level. Quality-relevant activities such as calibrations, sensor replacements, maintenance interventions, parameter changes, or access events are frequently documented through local device records or manual procedures. While this information is available, it is often not automatically integrated into centralised review, archiving, and data management processes.

Such activities can directly influence measurement quality and process decisions and may therefore be relevant for investigations, deviation management, and batch review. Manual retrieval and transfer of this information increase effort and can affect data availability and traceability.

Pharma 4.0 initiatives aim to improve the integration of operational and quality-related data across manufacturing environments. A fieldbus-based audit trail concept addresses this challenge by making audit-relevant events at the measuring point available directly to higher-level automation systems. The Protos II 4400(X) from Knick demonstrates this approach by providing audit trail records and calibration logs via fieldbus communication.

Why the Audit Trail Must Not End at the Field Level

Quality assurance, validation, automation and production teams understand that relevant interventions on computerised systems must be documented in a traceable manner.

In practice, the vulnerability often lies elsewhere these days. Many audit-relevant events do not occur in the control or database system, but directly at the measuring point:

- A pH sensor is being calibrated
- A threshold value is adjusted
- An operator logs in locally
- A diagnostic message appears
- A sensor is being replaced or changed
- A parameter is being changed

Such events may be relevant to process operation, investigations and subsequent batch review. Nevertheless, in many facilities, they are not automatically available where QA, production, maintenance and validation need them.

This point is particularly crucial in process analytics. Measuring points for pH, ORP, conductivity or dissolved oxygen are often



critical to quality in biopharmaceutical processes. They not only provide measured values but also generate a history of device and operating data that can be important for deviation analysis, batch evaluation, maintenance planning and audit preparation.

What Implementations Have Been Common So Far and What Are Their Weaknesses

1. Local Device Log in the Transmitter

Many transmitters store events locally. These may include calibrations, malfunctions, parameter changes, diagnostics or user actions.

The key limitation is availability. As long as audit trail data remains stored only in the transmitter, it is not automatically included in centralised review and archiving processes. While manageable for a small number of measuring points, this approach can become increasingly resource-intensive in larger facilities. In some cases, specialised manufacturer-specific software must be used to read out the data via a PC connected to the field device. This has further drawbacks and is not future-proof.

2. Storage on a Card or Local Storage Medium



Protos 3400 transmitter with a data card for audit trail recording

Another approach is to store data on a card, as was previously done in Knick transmitters, or on another local storage medium. In this process, audit trail data is collected in the device and read out manually at a later time.

Retrieving audit trail data from removable storage typically involves multiple manual steps, including access to the transmitter, data extraction, transfer to another system and subsequent reintegration of the storage medium. While each step is straightforward, the overall process is time-consuming and introduces several opportunities for handling errors.

These manual transfer steps represent the primary vulnerability of the approach. Risks include loss or damage of the storage medium, incorrect file assignment and delayed availability of audit trail information. In addition, data remains outside centralised review processes until the transfer has been completed.

From a data integrity perspective, this is particularly important because an audit trail should not only be in place but must also be incorporated into the regulated data flow in a timely, complete and controlled manner. A memory card can be a practical storage medium, but it is not a comprehensive integration mechanism.

In addition, audit trail records stored on removable media or exported as files may be more susceptible to alteration, creating additional data integrity risks.

3. Exporting Files to a PC or Server

Another common approach is to export local device data to a PC, a network drive or a document management system. This reduces paper-based processes but does not necessarily eliminate media breaks.

The challenges shift from data collection to data governance: is the exported file complete, correctly assigned and adequately protected against unauthorised modification? Furthermore, audit trail information should remain readily accessible and traceable throughout its lifecycle.

File storage can be part of a controlled process. However, it remains heavily dependent on naming conventions, filing discipline, manual attention to details and regular reviews. This often makes it better than paper-based documentation alone, but it is not yet true centralised audit trail integration.

4. Manual Records and Paper Forms

In some facilities, events at measuring points are also documented manually or as an alternative: calibration forms, maintenance records, shift notes, logbooks or nonconformance reports. Paper-based documentation can be managed in compliance with regulations, but it comes with typical drawbacks. For some users, these manual records are also carried out by two people in order to implement a dual-control system.

Typical challenges include legibility, completeness, timely documentation and the effort required to reconcile paper records with electronic process data. As the number of measuring points increases, the associated review and archiving effort can become significant.

The distinction between the reality of the process and the reality of the documentation is particularly critical. The event takes place at the field station. The process is running in the control system. The note is written on paper. The review will come later. The more these levels diverge, the more difficult it becomes to maintain a consistent event history.

Why These Methods Reach Their Limits in Pharma 4.0 Environments

Pharma 4.0 concepts focus on interconnected data, transparency, standardised information flows and improved analysis of process events. If quality-related data from the shop floor still has to be collected manually, a significant portion of the production reality remains outside this digital architecture.

This creates several practical challenges:

- Audit trail information is often not available for centralised review in a timely manner.
- Manual transfer steps introduce risks to data availability, traceability and integrity.
- Review activities become increasingly resource-intensive as the number of quality-critical measuring points grows

Fieldbus Integration as a Technological Step Forward

The transmitter generates audit trail records and makes them available directly to the PLC, control system, or database for automated retrieval and archiving. Only in the event of a communication interruption are the records temporarily stored in an internal buffer until fieldbus communication is restored and automatic transfer resumes. This makes the event at the measuring point part of an automated data flow.

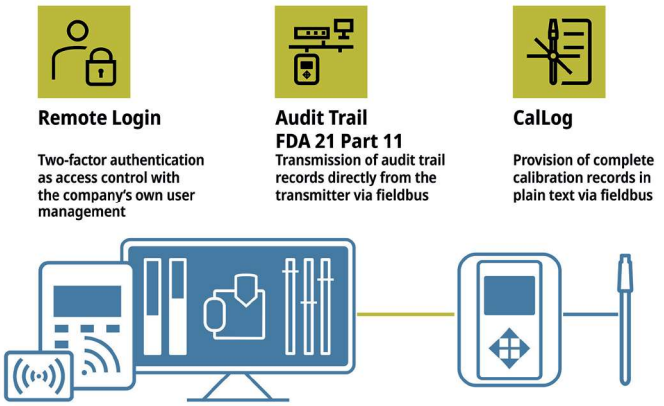
The difference from traditional transmitter communication is significant. Until now, the focus has often been on the transmission of measured values, status signals and diagnostic data. With an extended audit trail integration, event information relevant to documentation is included.

These include, for example:

- Sequential record IDs enable completeness verification and gap detection
- Time stamp, synchronised with the process control system
- Log in and log out
- Parameter changes
- Calibrations
- Adjustments
- Sensor replacement
- Maintenance events
- Diagnostic messages
- Communication events
- Changes to user or access settings
- Reasons for access, must be entered by the operator

What matters is not just the event itself, but its context. These include time stamps, measurement point identifiers, user or role references, event types, sequence information, comments, reasons for access and, if applicable, additional details regarding the parameter in question.

Fieldbus transmission transforms a local event into centrally accessible information that can be incorporated into review, archiving and data analysis processes. This enables a more



Protos II 4400 as an Example of an Audit Trail via Fieldbus

integrated view of process, equipment and audit trail data. This goes a long way towards ensuring a comprehensive, complete and digital batch record, which is stored in the control system and is independent of the manufacturer of the measuring equipment.

Thus, fieldbus integration does not eliminate all regulatory tasks. However, it changes the starting point; instead of having to manage manual media breaks, the operator can specify, test and validate a digital data stream.

A concrete example of this concept is the Protos II 4400(X) from Knick. To the author's knowledge, the Protos II 4400(X) is currently the only industrial transmitter that provides audit trail records and calibration logs directly via fieldbus to higher-level automation systems.

The information is provided in plain text and can be retrieved by higher-level systems and transferred directly into the automation data flow. The measuring point is thus no longer merely an isolated storage location but becomes a data node within the regulated system architecture.

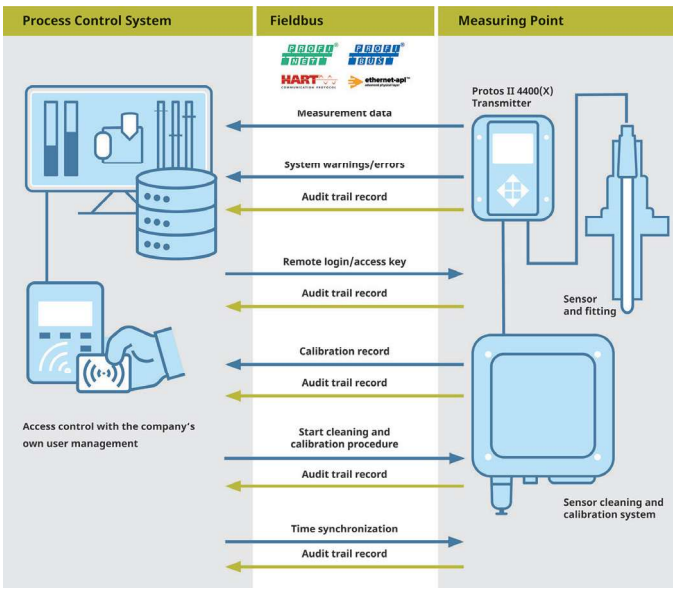
Even if fieldbus communication is disrupted, audit trail data remains buffered in the transmitter until communication is restored and the records can be transferred automatically. In contrast, local storage solutions depend on timely manual retrieval and available storage capacity; if these limits are reached, data availability may be compromised.

The difference is also evident in access control, which in older local systems is often handled directly at the measuring point based on the user, role and passcode. Changes must then be updated at each measuring point. Modern access control via fieldbus with two-factor authentication can be directly integrated with central user management systems and remote login mechanisms. If, in addition, a reason for access is recorded during login and can be associated with the audit trail record, this provides better context for later reviews.

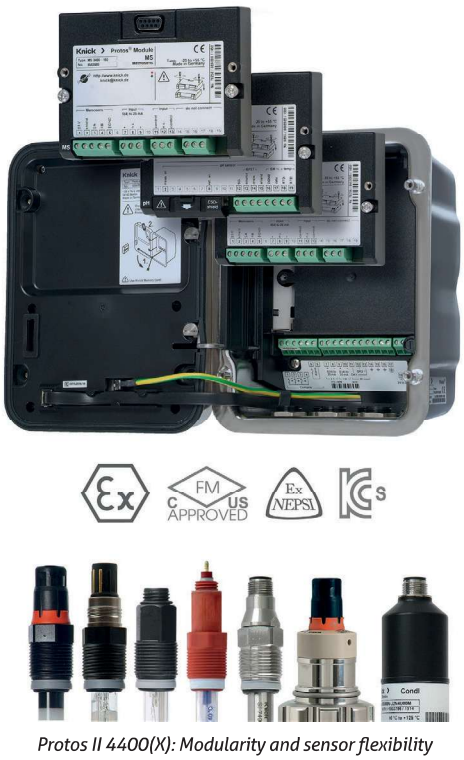
Central availability of audit trail records can also facilitate periodic review activities as part of data integrity governance and lifecycle management processes.

While calibration records are distinct from audit trail records, they document quality-critical activities at analytical measuring points and are therefore highly relevant for review, investigation and lifecycle management processes. Manual creation, transfer or storage of calibration data can introduce risks related to transcription errors, incomplete records or incorrect assignments. Direct transmission from the transmitter to the control system via fieldbus helps to reduce these risks and makes calibration data available centrally in a timely and traceable manner.

In short, the concept is designed for automated retrieval for central processing, not for manual collection of events. In this approach, audit trail functionality is integrated into the digital automation architecture rather than remaining confined to the field device, extending fieldbus-based traceability down to the process analytical measuring point.



Communication between the process control system and the measuring point (Illustration showing the optional sensor maintenance system)



Protos II 4400(X): Modularity and sensor flexibility

Protos II 4400(X) – A Modular Transmitter for Pharmaceutical Process Analytics

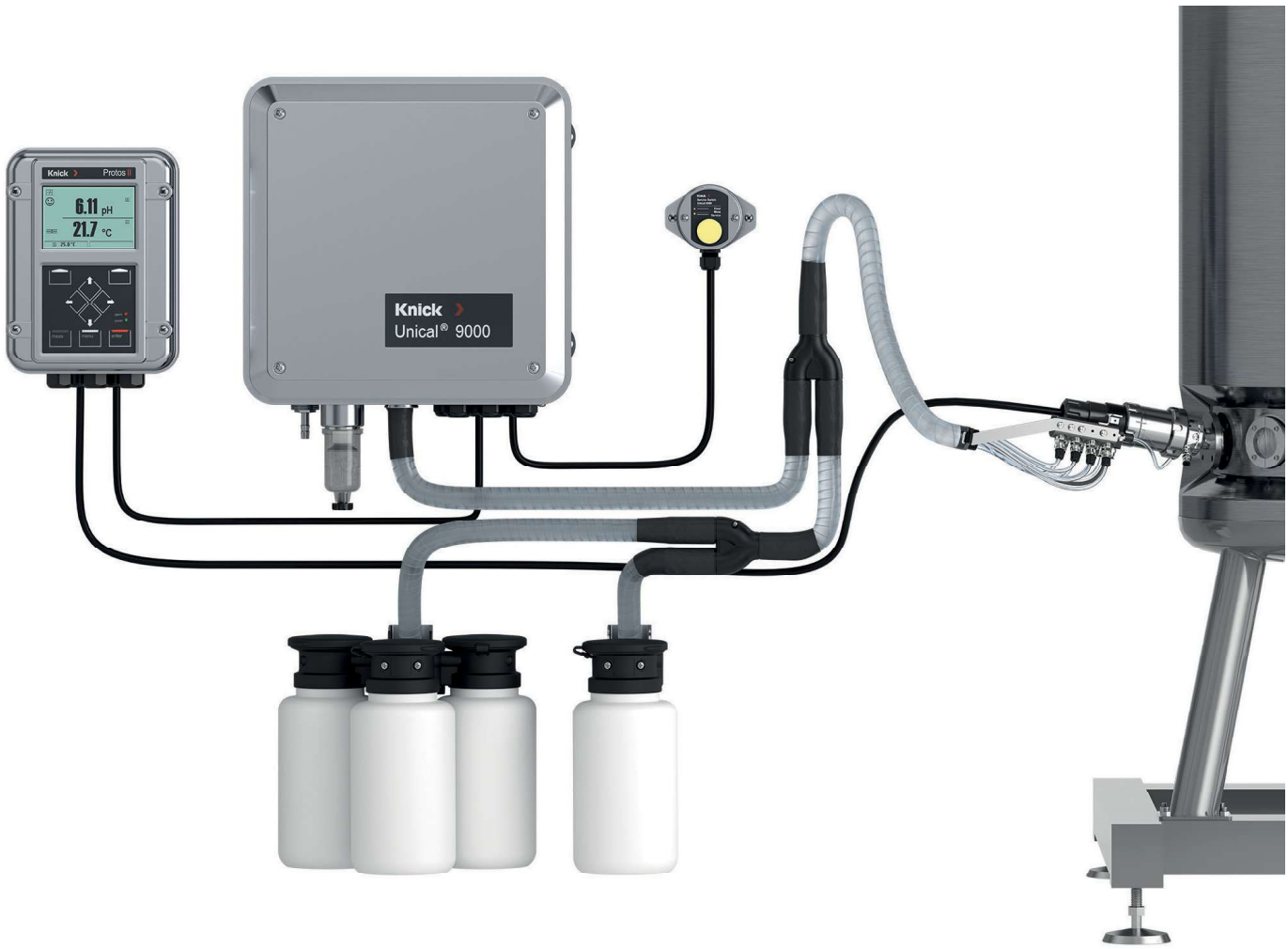
The Protos II 4400(X) is designed to address the diverse requirements of pharmaceutical process analytics. Its modular architecture, hygienic stainless steel housing and certification for use in hazardous areas enable deployment across a wide range of applications, from fermentation and cell culture processes to CIP/SIP systems and utilities.

A key advantage is its configuration flexibility. The transmitter supports Memosens sensors as well as a broad range of digital and analogue sensors for pH, ORP, conductivity and dissolved oxygen measurements. This allows operators to continue using established and validated sensor technologies while standardising on a single transmitter architecture.

The modular concept also extends to measurement parameters and communication interfaces. Depending on the application, users can configure the system for different analytical tasks and integrate it into automation environments using technologies such as PROFINET, PROFIBUS, Ethernet-APL or HART. In addition to measured values, the transmitter can provide extended diagnostic information, including NAMUR Open Architecture (NOA) data for predictive maintenance strategies.

An additional differentiator is that audit trail functionality is implemented as a software feature within the transmitter firmware. This simplifies upgrades in validated installations because existing hardware configurations can remain unchanged; the functionality can be enabled through licensing and integrated into the existing system architecture. Audit trail entries, calibration records, user actions, maintenance events and access-related activities can therefore be transmitted directly via fieldbus and incorporated into centralised review and archiving processes.

The transmitter is also integrated into the cCare system for automated sensor cleaning and calibration. By standardising maintenance procedures and reducing operator-dependent variability, cCare supports reproducible calibration workflows for pH measuring points. Cleaning and calibration sequences can be initiated, monitored and documented directly from the control system via fieldbus communication. As a result, maintenance activities and the associated audit-relevant events become part of the centralised data flow.



cCare pHarma: Automated, standardised cleaning and calibration of pH sensors for reliable measurements at all times. Audit trail transmission via fieldbus is available independently of cCare. When cCare is used, additional maintenance and calibration activities can be incorporated into the same digital information flow.



Source: SANOFI

Regulatory Context
Data integrity is a core principle of regulated manufacturing. Relevant data should be complete, traceable, legible, recorded in a timely manner, correctly categorised and have permanent availability. The well-known ALCOA and ALCOA+ principles summarise this expectation. 21 CFR Part 11 and EU GMP Annex 11 also address electronic records, access controls, audit trails and the traceability of relevant changes.

A transmitter, a fieldbus function, or a single software option does not automatically make a system FDA- or GMP-compliant. Compliance results from the interplay of appropriate technology, validated implementation, documented processes, access policies, SOPs, training and technical review. However, technology can significantly support these requirements by reducing manual vulnerabilities and transferring audit-relevant information in a structured manner into central data flows.

Conclusion: Progress Lies in Automatic Availability
The value of an audit trail lies not only in recording events, but also in making relevant information available for review in a timely and controlled manner. Extending audit trail functionality to the field level supports the integration of process analytical data into centralised review and archiving workflows while reducing manual handling steps. The Protos II 4400(X) illustrates this concept by enabling the transmission of audit trail records directly via fieldbus, thereby closing a long-standing gap between field devices and higher-level automation systems. As pharmaceutical manufacturing moves toward increasingly connected and data-driven operations, such capabilities can play an important role in supporting data integrity and Pharma 4.0 initiatives.



Dr. Knut Georgy

Dr. Knut Georgy has a PhD in Food Chemistry from the University of Münster, with a focus on the analysis and characterisation of polysaccharides and food technology. His career began in the sales of industrial gases for food, beverage and pharmaceutical applications. He later worked at Hamilton Bonaduz AG in the process analytics division as a market segment manager and product manager before moving to Knick Elektronische Messgeräte GmbH. Here, he brings his wide-ranging experience to his role as Global Market Manager.

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- With its **modular design**, adaptable to all installation situations and process connections.
- **Cleanability and sterilizability** have been documented in a test by a laboratory specializing in medical products.
- Can be used in **upstream processes**.

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