Collo Quality, Validation and Compliance

in Process Intelligence Platform

ColloidTek Oy
Visiokatu 1, 33720 Tampere
Finland

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1. Introduction

Food quality and safety are central concerns in modern production. Manufacturers are under continuous pressure to ensure that processes remain stable, contamination risks are managed, and compliance with regulations is maintained. Inline monitoring has become an essential tool to achieve these goals. Unlike laboratory testing, which can cause delays and provides results only afterwards, inline analyzers deliver continuous, real-time information directly from the process. This allows producers to react faster, reduce risks, and operate more efficiently.

The Collo Analyzer has been developed as a Process Intelligence Platform to respond to these industry needs. Its design is based on robust engineering, structured validation, and strict compliance measures. The outcome is a system that delivers reliable performance in demanding food production environments and provides customers with confidence, efficiency gains, and strong audit support.

2. Quality and Validation

Collo describes its quality process through three principles: validation, verification and monitoring.
Validation asks ‘does it work in your process?’ and is confirmed with field trials in real food production.
Verification answers the question "does it work as expected today?’ and is confirmed through factory acceptance tests and calibration.
Monitoring considers ‘will it keep working tomorrow?’ and is supported by built-in diagnostics and traceable calibration records.

2.1 Hardware Release Protocol and Product Acceptance

Quality at Collo is built on three complementary principles: validation, verification, and monitoring. Validation ensures that the analyzer is suitable for its intended use. This is confirmed through structured field trials where the analyzer is tested in real food production environments under actual operating conditions. Verification demonstrates that the analyzer works as expected at the point of delivery. This includes factory acceptance testing (FAT), calibration checks, and inspection before shipment. Monitoring safeguard’s long-term reliability by ensuring that the analyzer continues to perform over time. Built-in diagnostics and traceable calibration records provide assurance that the system remains stable throughout its lifecycle.

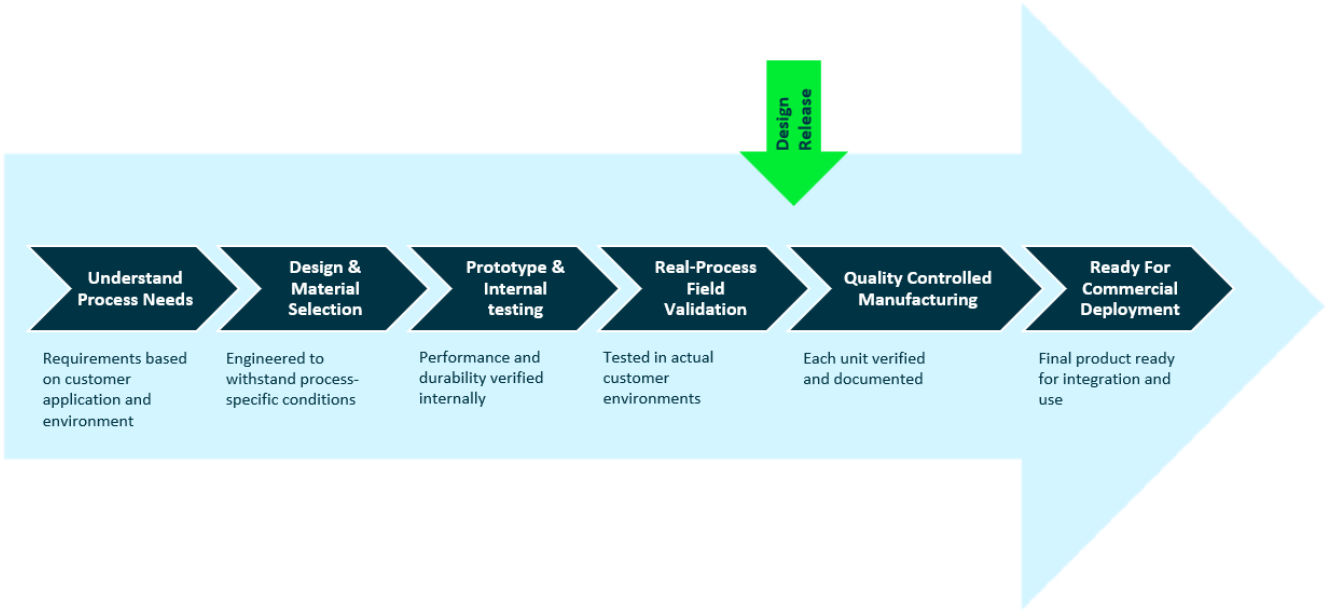

Figure 1 Hardware Development and Release Process

2.1.1 Research and Development Phase

Collo analyzers are developed through a structured, multi-stage R&D process designed to ensure mechanical integrity, long-term measurement stability, and suitability for demanding industrial environments. This process ensures that the hardware performs reliably under defined process conditions and complies with applicable quality and safety expectations.

Development begins with a thorough understanding of the intended application environment. Key design inputs include chemical exposure, temperature and pressure variations, hygienic requirements, and physical integration constraints. Based on this input, suitable materials are selected and verified using supplier documentation, compatibility assessments, and historical data. The mechanical design is then optimized to support installation, robustness, and safety.

Design reviews and risk assessments (e.g. FMEA) are performed to evaluate functional and structural performance. Once the design is approved internally, prototype units are built and subjected to structured verification activities. These include mechanical, thermal, chemical, and signal-related evaluations that are aligned with general industrial testing principles and applicable international standards (e.g. IEC 60068-series for environmental testing, where applicable).

After internal verification, analyzers are deployed in controlled field-testing environments in collaboration with industrial partners. The purpose of these field tests is to validate actual operational performance, mechanical durability, and measurement stability in real-world use. The results are used to finalize both hardware and configuration parameters before release to manufacturing.

2.1.2 Production Quality Control and Factory Acceptance

Once the design is finalized and validated, each manufactured analyzer is subject to defined quality control and factory acceptance process. The purpose is to ensure that every unit meets the validated design specification and is fully functional prior to shipment.

The acceptance process includes dimensional inspection, mechanical assembly verification, and functional checks of critical features. Product performance is confirmed through standardized acceptance procedures designed to evaluate signal stability, system responsiveness, and interface behavior under expected operating conditions. Pressure integrity and temperature resistance are assessed in accordance with applicable regulatory and mechanical design requirements.

Each analyzer undergoes a factory acceptance process, where results are documented, reviewed, and signed by qualified personnel. This includes visual review, calibration traceability confirmation, and verification of measurement consistency. All quality documentation, including FAT records and calibration certificates, is archived per unit and linked to its serial number for full lifecycle traceability.

This structured protocol ensures consistent product quality and readiness for deployment in demanding industrial environments.

2.2 Compliance & Traceability

Before delivery, each Collo analyzer must pass final product approval to confirm that it meets all defined operational, mechanical, and measurement performance requirements. This includes compliance with applicable safety, quality, and food-contact standards.

Collo analyzers are approved in accordance with relevant regulatory and customer-specific requirements. These include CE-marking for European safety, health, and environmental protection, as well as compliance with EC No 1935/2004 and U.S. FDA guidelines regarding materials intended for contact with food.

As part of the final approval process, each device is issued a Certificate of Conformance (CoC). This certificate confirms that the unit has passed final inspection and that supporting documentation is complete and traceable.

The following table summarizes the main validation areas included in the Certificate of Conformance

Table 1. Certificate of Conformance - Validation areas.

Validation	Details
Declaration of Compliance	Confirms the unit meets required quality and performance criteria with necessary certifications.
Traceable Documentation	Includes operating manuals, calibration certificates, and version-controlled design records (if requested).
Technical Approval	Verifies design compliance, performance stability, and validated calibration prior to release.
Certifications & Compliance	CE-marked for safety and environmental protection; compliant with EC No 1935/2004

3. Conclusion

Collo analyzers are developed and released under a controlled process that combines engineering validation, production quality control, and regulatory compliance. This ensures reliable performance even in demanding food industry environments and provides customers with solid evidence for audits and certifications. The analyzers are not only technically robust but also fully documented and traceable, giving quality managers confidence and peace of mind. For customers, this structured approach means faster audits, fewer process deviations, and clear, well-documented evidence of compliance. This translates into lower operational costs and a stronger competitive advantage for food manufacturers.