

QUALITY MANAGEMENT FOR REGULATED MANUFACTURERS

The QMS that knows what a failed calibration means for your products.

When an instrument fails its calibration, CycleQA identifies every product it qualified, every open non-conformance on those products, and every customer field report that may be related. In seconds, not half a day.

“A calibration certificate tells you an instrument was in tolerance on a given date. It tells you nothing about which products were qualified using it, or what happens to your quality chain if it later drifted.”

Records that don't talk

Instrument status and product quality live in separate systems that were never designed to connect. That is an architecture problem, not a process problem.

Traceability in one head

The field engineer who saw the anomaly, the test engineer who knows which instrument was used. Knowledge that exists but can't find its destination.

Too small for enterprise, too serious for Excel

Enterprise suites assume a quality department. Spreadsheets assume nobody asks a hard question. Regulated SMEs sit in between.

ONE TRACEABILITY CHAIN



The instrument speaks directly to the record.

△ IMPACT ANALYSIS · MRS-DMM-001 Suspect period: 17 days		
3	5	2
Products	Open NCRs	Field reports
INSTRUMENT	Keysight 34465A DMM · out of tolerance	
LAST GOOD CAL	Calibration record with as-found / as-left	
AFFECTED	Every product it qualified in the suspect period	

½ day

Typical manual effort: certificates, spreadsheets, phone calls.

30 sec

The same answer from CycleQA's calibration consequence chain.

Figures from CycleQA demo scenarios, not customer measurements.

Built for regulated manufacturers with 50–500 people

Medical devices, precision manufacturing, maritime electronics and industrial systems across DACH and Scandinavia. Today managing quality in spreadsheets, or in a system never designed for their industry.

Designed around

ISO 9001	ISO 13485	IEC 62304	IEC 60945
IEC 61340	DNV type approval		

PRODUCTS

One chain. Three ways in.

Every tier runs on the same traceability chain, from the product down to the non-conformance, with calibrated instruments as first-class records. The tiers differ in how much of your testing CycleQA takes off your plate.

CQA-CORE

Full traceability

The complete QMS. Products, requirements, calibration records and non-conformances linked end to end.

- Calibration with the consequence chain
- NCRs with 8D methodology
- Products, specifications, requirements, test definitions
- Standards, risks and mitigation actions
- Suppliers, parts, incoming inspection
- Field reports that work offline

Sounds like you if...

you are a precision-parts subcontractor running NCRs and calibration in Excel and on paper, and proving traceability fast is the hardest part of every audit.

CQA-AUTO

+ automated testing

Everything in CORE, plus scheduled automated tests on standard bench instruments. Configured, not coded.

- **Everything in CQA-CORE**
- Built-in support for multimeters, power supplies, oscilloscopes
- Scheduled test runs, results written into the test record
- Out-of-limit results raise an NCR automatically
- Each test node authenticates on its own, encrypted transport

Sounds like you if...

you are a test house or contract manufacturer running routine bench validation by hand, and want it automated and logged without a software project.

CQA-ENTERPRISE

+ your own instruments

Everything in AUTO, integrated with your own instruments, sensors and systems, with consulting and dedicated partners.

- **Everything in CQA-AUTO**
- Your own instrument and sensor combinations
- Edge nodes that process locally and report structured evidence
- Consulting and partners from CycleQA's network
- Scoped to your standards and approval path

Sounds like you if...

you run distributed sensor systems (edge devices, sensor fusion, field-deployed nodes) and your test setup is one of a kind.

Grow into it, not out of it.

The same data model runs through all three tiers. No migration, no second vendor.

No price list, on purpose.

Instruments, users, standards and integration effort differ too much between manufacturers. We scope it together, starting with one conversation.

Traceability by design

The calibration-to-product chain lives in the data model, not retrofitted onto forms.

A modern stack

Built for what a QMS needs today. New modules arrive without breaking the chain.

Full parity in the field

The same features on a phone on the shop floor as at a desk. Works offline.

Security as a habit

EU servers, encrypted backups and a built-in audit trail, described on the next page.

From the founder

My grandfather spent forty years at Carl Zeiss keeping his gauge blocks true. Precision was always worth preserving; what has changed is how hard it has become to hold onto as a company grows. CycleQA is my answer: a QMS where the workflow carries the standard, so compliance becomes a byproduct of good work instead of a parallel job.

Markus Hein · Founder, CycleQA AS

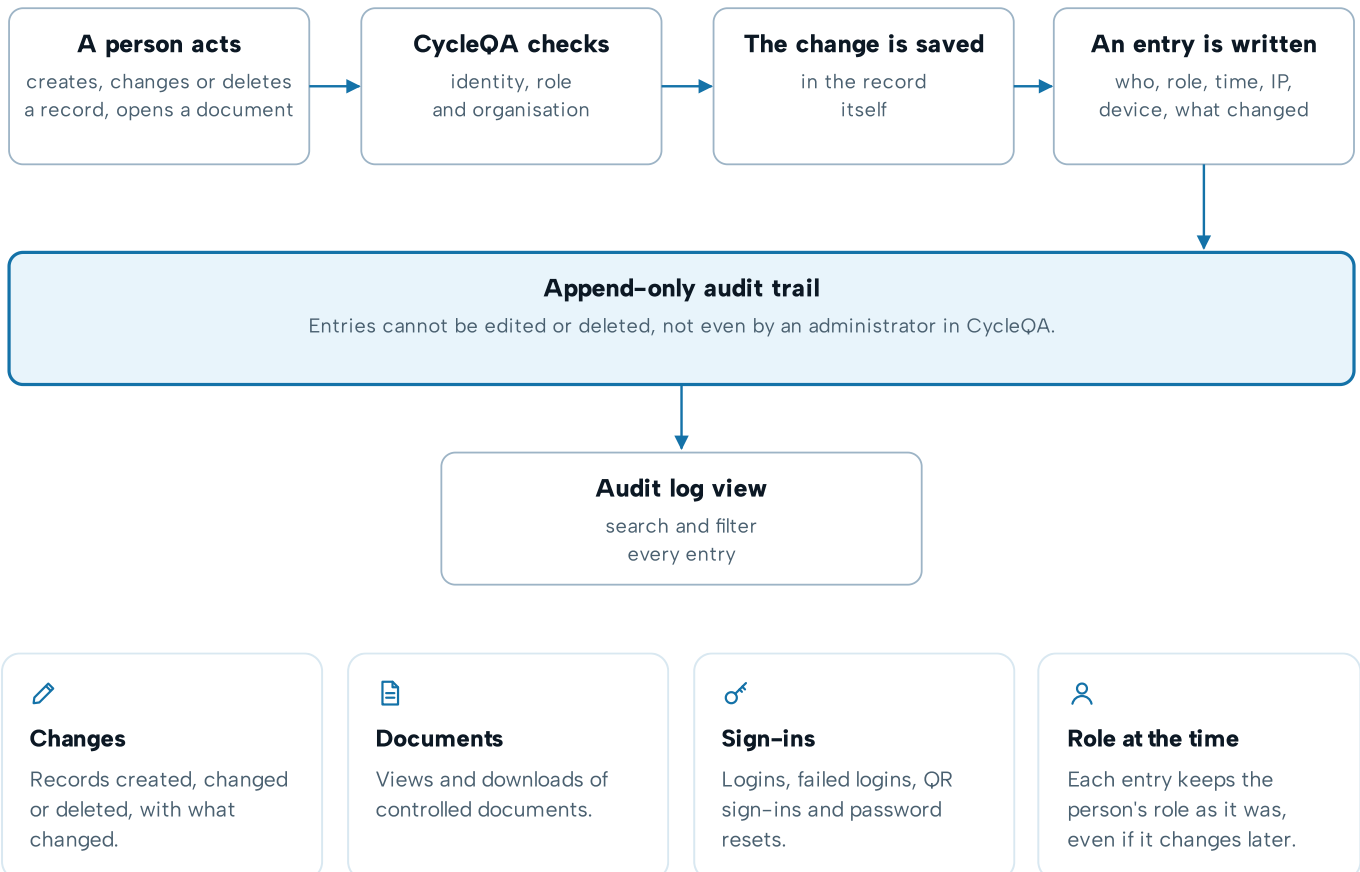
How we start

- 1 **A conversation.** Your products, instruments, standards, and the audit question that worries you most.
- 2 **A tier recommendation and a scoped proposal.** Built for your setup, not taken from a price list.
- 3 **Founder-led onboarding.** Your equipment list, your roles, your real data.

BUILT INTO EVERY CQA-CORE

Who did what, when, in which role, and from where.

CycleQA writes an audit entry as part of the work itself. Nobody has to remember to document it, and nothing has to be configured: the audit trail is there from the first day, for every organisation.



EXAMPLE ENTRY

WHEN	2026-10-02 14:31:07
WHO	Anna Sørensen
ROLE	QA manager
ACTION	Updated test definition
CHANGE	max limit ~~0.05~~ → 0.04 D
FROM	203.0.113.24 · Firefox

For your auditor

Record control is a core requirement of ISO 9001 (7.5.3) and ISO 13485 (4.2.5). The audit trail shows that records are controlled, not just stored.

For you

When something goes wrong, you see what happened, in which order and who was involved, without asking around.



Append-only by design. The database itself refuses to edit or delete audit entries, so the history you show an auditor is the history that happened.