lenkwerk.

IN DEVELOPMENT · LOOKING FOR PILOT CUSTOMERS

Lenkwerk

Controlled documents. Provable approvals.

WHAT IT IS

Your entire management system in one application

Lenkwerk runs your entire management system on a standard-neutral core. Profiles decide which standards apply: ISO 13485 with IVDR or MDR and ISO 9001 to start with, plus ISO 27001 and the FDA additional profile, built and in testing, then more. Your existing QMS is migrated, every approval is electronically signed and provable, and every version comes with a validation package. On your own servers.

ISO 27001 runs as an additional profile to any standard profile and as a standalone base profile; the FDA profile is an addition to ISO 13485. Lenkwerk prepares and checks, but submits nothing to the FDA and does not replace regulatory advice.

EN ISO 13485	IVDR · MDR	ISO 9001	ISO 9001 + 13485 combined	FDA add-on (built, in testing)
ISO 27001 (built, in testing)	ISO 14001 · 50001 · 45001 (planned)	ISO 15189 · 17025 (planned)	IEC 62304 (planned)	Open source · self-hosted

FEATURES

Everything auditors want to see, in one place.

Control, signature, evidence

Document control

Exactly one valid version per document. Review and approval with a status model, changes visible line by line, PDF/A only on approval.

Electronic signature

Every signature requires a passkey or password and second factor and is bound to the content. If the text changes, the signature becomes invalid.

Audit trail

Every action is logged: who, what, when, old and new value. Append-only, with a hash chain against tampering.

Processes

Complaints, vigilance with reporting deadlines, CAPA, change control, audits, suppliers and training, all linked together.

Document assistant

New SOPs and forms through guided input, with a template, suggested roles and linked related documents. Optionally with an AI draft.

Integrated management system

A standard-neutral core following the harmonized structure, with a profile for each standard. ISO 13485 with IVDR or MDR and ISO 9001, with separate certificates. ISO 27001 and the FDA additional profile are built and in testing.

Audit, training, risk, operation

Audit preparation

The notified body's requirements become items with evidence and owners. Readiness check, audit binder and read-only access for the auditor.

Training and learning

Competence profiles, training matrix, learning modules with knowledge checks and effectiveness review. Only trained people can sign.

Risk and design

Risk management file per ISO 14971 with a configurable matrix, a register of risks and opportunities, design projects with a design history file. Can be switched off.

Self-hosted, well protected

Runs on your hardware. Encrypted, immutable backup at a second site, rehearsed recovery, emergency manual.

Computer system validation

A validation package for every Lenkwerk version. Planned: a module with software inventory and templates to validate other software too.

For software manufacturers

Planned: a profile for IEC 62304 and IEC 82304-1 with safety classes, SOUP list, problem reports and traceability.

Fitting your operation

Modules to choose

The core of document control, signatures, audits, CAPA and training is always included. Standard profiles and modules as you need them; German and English to start.

Sign-in through your company

Sign in through your user directory (e.g. Microsoft Entra ID, Keycloak, Active Directory), locked as soon as someone leaves. Signing remains a separate confirmation.

Easy migration

Your existing QMS is taken over: Word documents, signed scans with text recognition and your lists. Lenkwerk matches them, you confirm.

HOW AN APPROVAL WORKS

Only those allowed can sign, and only what they have seen.

STEP 1

Draft

The text is written in Markdown, from a template or as a new revision. Every version is stored in full.

STEP 2

Review

The content is locked. Reviewers see the changes against the valid version and sign “reviewed”.

STEP 3

Approval

Fresh confirmation with a passkey or password and second factor. The system checks role, four-eyes principle and that nothing has changed.

STEP 4

Valid

The signed PDF is created, the old version is superseded, read confirmations and training are triggered.

VALIDATION

Built for validation from day one.

Under ISO 13485 clause 4.1.6, software used in the QMS must be validated. Lenkwerk is planned so that the evidence comes out of development, not after the fact.

Numbered requirements

Every test refers to a requirement; traceability is generated automatically.

Risk-based

Test depth by risk, following ISO/TR 80002-2, GAMP 5 and the FDA guidance on Computer Software Assurance.

Negative tests for what is critical

Signing without second factor, editing in a locked state, tampering with the audit trail: all of it must provably fail.

Open components, locked versions

Python, PostgreSQL and a bill of materials for every component. Updates go through change control.

ROADMAP

Stage by stage to version 1.0.

K · DONE
Concept
Requirements, data model, validation plan, alignment with the auditor

0.1 · BUILT
Approval core
Accounts with passkey or 2FA, documents, signature, audit trail, PDF

0.2 · BUILT
Control
Document assistant, references, permissions, languages, company sign-in, document migration

0.3 · BUILT
Processes I
Complaints and vigilance, CAPA, changes

0.4 · BUILT
Processes II
Suppliers, learning, audits, risk, design, ISO 9001 + 13485 combined

0.5 · 0.6 → 1.0 · NOW
Validation and pilot
Built: backup, emergency access, validation package; 0.6 in part. Pilot ahead.

1.1 · IN TESTING
ISO 27001 and FDA
Built ahead, in testing: ISO 27001 (additional and base profile) and FDA additional profile (package A).

FROM 1.2
Then
Computer system validation, GMP, software manufacturers, environment, energy, safety, laboratories. No dates.

IN DETAIL: 1.2 COMPUTER SYSTEM VALIDATION · 1.3 GMP · 1.4 SOFTWARE MANUFACTURERS · 510(K) PREPARATION (ONLY ON DEMAND) · 1.5 ISO 14001 · 1.6 ISO 50001 · 1.7 ISO 45001 · LABORATORIES (ISO 15189, ISO 17025)

PILOT CUSTOMERS

Help shape Lenkwerk.

We are looking for small and medium-sized manufacturers of medical devices and in-vitro diagnostics, and organisations with ISO 9001 or another ISO management system, that want to run their management system digitally and self-hosted.

What you get

- Early access to every stage
- Influence on requirements and priorities
- Migration of your existing QMS
- Support with roll-out and validation
- Your data stays on your servers

Software from Heidelberg.

Lenkwerk is by Lutz Rothe. It grows out of working with management systems under ISO 9001, ISO 13485 and ISO 27001 and out of experience with how tedious controlled documents on paper and in folder structures are.

Lenkwerk is built entirely on open-source components, runs on your own hardware and needs no licence fees for those components.



CONTACT

Become a pilot customer: lutz@rothe.it

LENKWERK · LUTZ ROTHE · KRANICHWEG 74 · 69123 HEIDELBERG