

GMP SUPPLIER QUALIFICATION PLATFORM

VendorCore

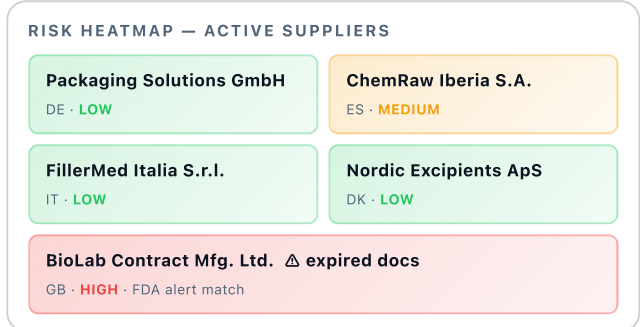
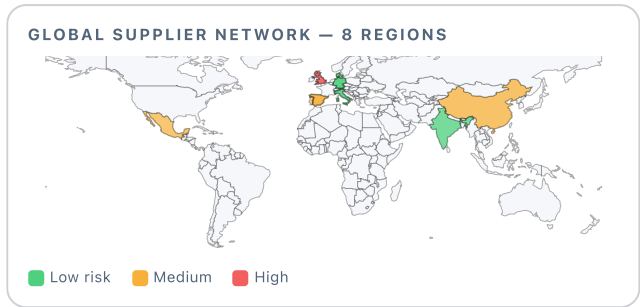
Centralised supplier qualification for pharma, biotech and medical device manufacturers. AI classifies documents, detects compliance gaps and scores supplier risk — **on your own server, with zero cloud dependency.**

- 100% on-prem
- EU GMP Annex 11
- 21 CFR Part 11
- ALCOA+
- Multi-tenant
- AI local
- ERP sync
- ES · DE · EN · DA

- < 2 min**
Upload to AI risk score
- 9 types**
Doc categories auto-classified
- 12 clauses**
QA gap analysis per supplier
- 0 €**
External AI licence cost

WHAT THIS DOSSIER SHOWS YOU

12 pages: supplier registry · AI document classification · QA/SMF gap analysis · questionnaire workflows · ERP connector · FDA/EudraGMDP alerts · inspector dossier ZIP · hash-chained audit trail (21 CFR Part 11, EU GMP Annex 11).



AUDIT TRAIL — SHA-256 CHAIN ALCOA+

#	EVENT	ACTOR	HASH
47	document_approved · GMP cert · Packaging Solutions	j.mueller	a3f8c1d2...
48	compliance_check · QA gap found · ChemRaw Iberia	system	b72e04a1...
49	alert_attached · FDA Warning Letter · BioLab	system	9dc5f3b8...
50	dossier_exported · ZIP · EUES01 inspector audit	m.honda	e1a2d74c...

✓ Hash chain intact · 50 entries · append-only · 21 CFR Part 11 / EU GMP Annex 11

WHY IT MATTERS

Every expired certificate and every gap in a Quality Agreement puts product release and regulatory status at risk. **VendorCore turns months of spreadsheet maintenance into minutes of traceable workflow.**

1 What supplier qualification looks like without VendorCore

Recognise four of these and you have a compliance gap waiting to be found at the next audit.

WITHOUT VENDORCORE, THE DAILY REALITY

- Supplier files live in shared folders: one Excel per supplier, dozens of versions, no clear owner.
- Certificate expiry is tracked in a calendar reminder someone set up two years ago - or not at all.
- Gap analysis of Quality Agreements is done manually, by a QA specialist reading PDFs and highlighting. Takes a day per supplier.
- Inspector arrives: QA spends a week assembling dossiers from email threads, shared drives and handwritten notes.
- FDA Warning Letters and EudraGMDP non-compliance statements are not systematically monitored against your roster.
- Supplier master data in your ERP and the quality file are perpetually out of sync.
- 21 CFR Part 11 / ALCOA+: impossible to demonstrate for documents stored in Windows file shares.

WITH VENDORCORE, FROM DAY 1

- One structured supplier record, one version, one owner visible at every step.
- AI reads every uploaded document, classifies it (GMP cert, ISO cert, QA, SMF ...) and extracts expiry dates. **Alerts sent automatically 60 days before expiry.**
- Gap analysis runs in seconds: AI checks the QA or SMF against 12 mandatory clauses and flags each one present / partial / missing with a page reference.
- Inspector calls: one click generates a ZIP dossier with a PDF report, all documents, findings, KPIs and the full audit trail.
- Regulatory news feed checks FDA and EudraGMDP every 12 h and flags any match against your supplier roster.
- ERP connector (SQL or Excel) keeps supplier master data in sync without manual copy-paste.
- Hash-chained, append-only audit log. Every action: actor, timestamp, IP, chained hash. **Zero silent edits.**

2 The numbers

< 2 min

Time for VendorCore to classify a newly uploaded document, extract issuer, certificate number and expiry date, and score the supplier's risk profile. Before: hours of manual data entry into the qualification spreadsheet.

100%

Audit trail coverage. Every upload, classification, finding, approval and dossier export is logged with actor, timestamp, IP and a SHA-256 hash chained to the previous entry. **No silent edits, ever.**

0 €

Cost of external AI licences. Document classification, gap analysis, risk scoring and trend detection **run on your own server** (Ollama / LM Studio). Your supplier data never leaves the building.

3 One-minute dashboard

VendorCore supplier list, demo data (pharmaceutical CMO with 31 active suppliers).

VendorCore
 EUES01 · Pharma Group S.L.
 All sites v
 Suppliers
 + New supplier

Documents
 Trends
 Search
 4
 QA v

TOTAL SUPPLIERS 31 + 3 this quarter	ACTIVE 27 87% of roster	EXPIRING < 60D 4 certs due for renewal	HIGH / CRITICAL RISK 2 immediate review
OPEN FINDINGS 11 3 critical	QA GAPS (MUST) 6 across 3 suppliers	QUESTIONNAIRES SENT 8 5 responses received	DOSSIERS EXPORTED 19 last 90 days

Supplier list - risk · status · next cert expiry

SUPPLIER	COUNTRY	STATUS	RISK	OPEN FINDINGS	NEXT EXPIRY
Packaging Solutions GmbH	DE	Active	Low	1	2026-09-14
ChemRaw Iberia S.A.	ES	Active	Medium	3	2025-07-01
Nordic Excipients ApS	DK	Active	Low	0	2027-02-28
BioLab Contract Mfg. Ltd.	GB	Suspended	Critical	5	2025-05-30 ⚠
FillerMed Italia S.r.l.	IT	Active	Medium	2	2025-06-15

AI insights - anomaly detection, last 180 days

Critical supplier suspended BioLab Contract Mfg. suspended since 2025-05-02. 5 open findings, GMP cert expired. Dossier review pending.	Certificate wave due Q3 4 suppliers have certs expiring before 2025-07-31. Renewal requests not yet sent for 2 of them.
Data integrity clause gap 3 of 8 Quality Agreements are missing the ALCOA+ / data integrity clause. Must-have under EU GMP Annex 11.	No FDA / EudraGMP alerts All active suppliers checked against latest FDA Warning Letter RSS and EudraGMP feed. No matches found.

4 Document management and AI classification

Every supplier document runs through a four-step pipeline. No manual labelling required.






Document types recognised by AI

ISO	ISO certificate 9001 / 13485 / 15378 + scope	GMP	GMP certificate EU / FDA / WHO GMP + site
AUD	Audit report Customer / third-party audit	SMF	Site Master File ICH Q7 / EU GMP Annex 15
QA	Quality Agreement Customer / supplier QA + clauses	CoA	Certificate of Analysis Batch / material CoA
LIC	Business license Trading / manufacturing licence	OTH	Other Free classification + notes

Expiry alert system

Every document with a **valid_until** date is watched. A background loop runs every 6 hours and sends a digest email per tenant when any certificate enters the alert window.

	60 days before expiry First email digest to QA manager
	30 days before expiry Escalation digest, supplier flagged high-risk
	Expired Supplier status auto-flagged, finding raised

Alert window and recipients are configurable per tenant. Emails are sent from the shared kAlra SMTP relay - no external service required.

5 AI gap analysis - Quality Agreement and Site Master File

VendorCore checks every uploaded QA or SMF against a catalogue of mandatory clauses and reports present / partial / missing with a page reference.

QUALITY AGREEMENT · 12 MANDATORY CLAUSES

MUST	Scope of supply and product list	Present
MUST	Responsibilities (RACI matrix)	Present
MUST	Change control + notification timeline	Partial
MUST	Deviation and OOS handling	Present
MUST	Audit rights for the customer	Missing
MUST	Sub-contracting and approval flow	Present
MUST	Product recall procedure	Present
MUST	Customer complaint handling SOP	Partial
MUST	Data integrity (ALCOA+) commitment	Missing
OPT	Storage and transport conditions	Present
OPT	Term and termination clauses	Present
OPT	Confidentiality and IP	Partial

Each gap is automatically raised as a **finding** linked to the supplier record, included in the risk score and traceable in the inspector dossier.

SITE MASTER FILE · 9 MANDATORY CHAPTERS

MUST	General site info and ownership	Present
MUST	Quality Management System overview	Present
MUST	Personnel and organisation chart	Partial
MUST	Premises and equipment list	Present
MUST	Documentation system	Present
MUST	Production processes	Missing
MUST	Quality control and laboratory	Present
MUST	Distribution, complaints and recalls	Present
MUST	Self-inspection programme	Missing

RISK SCORE - CHEMRAW IBERIA S.A.

Score: 58 / 100

Medium

2 missing must-clauses in QA

1 missing chapter in SMF

3 open findings (1 critical)

0 · High risk

100 · Approved

AI compliance check - RAG-grounded findings with page references (FA-01)

Beyond clause detection, VendorCore can run a deeper compliance check grounded in the regulatory corpus (GMP guidelines, ICH Q7, EU GMP Annex 11). Each finding includes the paragraph from the document and the relevant regulatory citation.

[FINDING] `change_control` • ChemRaw QA v2.3, p. 8 – "Changes to the process will be communicated" lacks a defined notification timeline. EU GMP Annex 15 §7.3 requires 30-day prior notice for major changes.

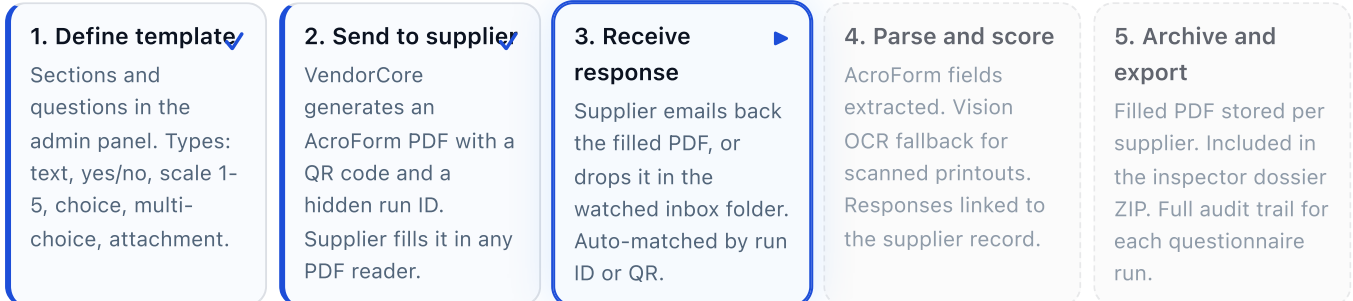
[FINDING] `data_integrity` • ChemRaw QA v2.3 – No ALCOA+ commitment found. ICH Q9 and EU GMP Annex 11 §4.1 require documented data integrity obligations from the supplier.

[OK] `recall` • ChemRaw QA v2.3, p. 14 – Recall procedure clause present and complete. 24-hour notification timeline confirmed.

6 Structured supplier questionnaires

Send, track and archive qualification questionnaires without a single email attachment.

Questionnaire workflow



Sample questionnaire

INITIAL QUALIFICATION QUESTIONNAIRE
Packaging Solutions GmbH
 Run ID: VC-2026-0447 · EUES01 · Due 2026-06-30



SECTION 1 — COMPANY & QMS

1. Company registration number

2. ISO 9001 certificate currently valid?
 Yes No

3. Quality system maturity (1-5)
 1 2 3 4 5

4. Attach current GMP certificate

Scan QR code to answer on any device · 12 questions · 3 sections 1 / 3

Built-in templates

VendorCore ships with two standard templates that cover the most common initial qualification scenarios. Both can be extended or replaced in the admin panel.

Initial Qualification Questionnaire

General company info, QMS overview, key personnel, manufacturing capabilities, GMP / ISO certification status, regulatory history, subcontracting policy, references.

Annual Self-Assessment

Year-on-year update: changes to processes, equipment or key personnel since last qualification, regulatory inspections received, complaints and recalls, CAPA status.

Custom templates are defined in the admin panel as JSON sections and questions. No coding required. QR code and run ID are generated automatically per send.

7 ERP connector and regulatory alert monitoring

Keep supplier master data in sync with your ERP and catch regulatory alerts before your inspector does.

ERP connector (CM-01)

Pull supplier master data and performance KPIs from any tenant-configured source and upsert into VendorCore by [external_ref](#). No manual copy-paste.

SQL connector

Direct read-only SELECT against your ERP database:

- MS SQL Server (ODBC Driver 18)
- PostgreSQL (psycopg3)
- MySQL (PyMySQL)

DSN stored Fernet-encrypted. Statements validated against INSERT / UPDATE / DELETE / DDL. Row cap: 50,000 per sync run.

Excel import

One .xlsx workbook (header row + one supplier per row). Columns: [external_ref](#), name, country, status, notes. Upload once, or replace and re-sync on demand. Rows matched by [external_ref](#) for insert-or-update.

Sync runs on demand or on a configurable schedule. Last sync timestamp and row count visible in the admin panel. Errors shown in [last_error](#), loop stays healthy even when ERP is down.

Regulatory news feed (CM-03)

A background loop checks public regulatory feeds every 12 hours and matches entries against your supplier roster by name and country. Matches appear in the supplier record and trigger a webhook.

FDA

Warning Letter — Apex Ingredients Ltd.

Inadequate investigation of OOS results, 21 CFR 211.192. Match: name_exact

EUDRAGMDP

Non-compliance — NorPharm S.A., Poland

GMP certificate suspended following unannounced inspection. Match: name_fuzzy

CLEAR

ChemRaw Iberia S.A.

No matches found in latest FDA or EudraGMDP feed check.

Match logic: exact name match → fuzzy token overlap (≥50%) → country filter. Each alert stored with source, date, severity and match basis. Webhook fires on first match so you can route it to Slack, email or your internal ticketing system.









Sources: FDA Warning Letters RSS feed. EudraGMDP non-compliance statements via configurable adapter - operators can wire in a paid feed or their own scraper without changing any other code.

8 Inspector dossier and hash-chained audit log

One click. A complete, tamper-evident package ready for the inspector.

Dossier ZIP contents (UI-02)

Generated on demand per supplier. Suitable for AEMPS, EMA, FDA and customer auditor reviews.

	inspector_report.pdf	AI narrative summary + tables
	master.json	Supplier profile + risk score
	documents/	All original PDFs + index.json
	findings.json	Open + resolved findings, page refs
	kpis.json	Last 12 quarterly KPI rows
	questionnaires/	Filled response PDFs + index.json
	audit.jsonl	Full audit log for this supplier
	README.txt	Provenance + hash-chain hint

The inspector PDF is generated by the kAlra AI and includes an AI-written narrative summary for the inspector, pulled from findings, KPIs and documents. Languages: EN / DE / ES / DA.

Hash-chained audit log

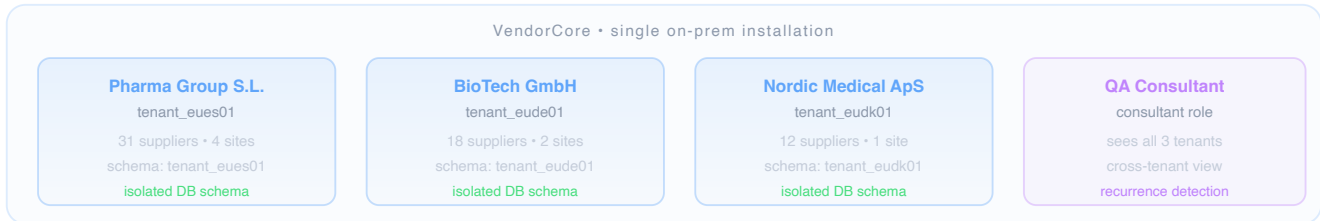
Every mutation in VendorCore creates an immutable audit_log row. Each row carries a SHA-256 hash of its own content chained to the previous row's hash - enforced at the database level by a PL/pgSQL trigger that also blocks UPDATE and DELETE.

```
2025-05-12 09:14:02Z qa.user document.upload
ChemRaw_QA_v2.3.pdf • sha:a3f1c...
2025-05-12 09:14:44Z ai.worker document.classify
quality_agreement • sha:7bc4d...
2025-05-12 09:14:51Z ai.worker gap_analysis.run 2
missing, 2 partial • sha:f9e2a...
2025-05-12 09:15:03Z ai.worker finding.create
data_integrity • severity:must • sha:12c7b...
2025-05-12 09:15:04Z ai.worker finding.create
audit_right • severity:must • sha:88d3e...
2025-05-12 10:02:18Z qa.manager finding.assign
data_integrity → qa.user • sha:d4f1a...
2025-05-12 14:37:09Z qa.user risk_score.update
medium (58/100) • sha:3c9b2...
2025-05-12 15:01:42Z qa.manager dossier.export 8
files, 4.2 MB • sha:a1e7f...
```

Hash-chain verification: `verify_chain(tenant_slug)` recomputes the entire chain and flags any gap or tampered row. Chain integrity is shown in the admin dashboard and exported in every dossier ZIP.

9 Multi-tenant architecture and consultant mode

One VendorCore installation, multiple fully isolated customer tenants - with cross-tenant intelligence for consultants.



Schema-per-tenant isolation

Each tenant runs in a dedicated PostgreSQL schema. The database layer pins `search_path` on every connection, so a query on tenant A physically cannot touch tenant B data, even in the case of an application bug. A static lint check (`lint_vendorcore_isolation.py`) enforces that no VendorCore module imports kAlra auth internals directly.

PER-TENANT SCHEMA

- suppliers, sites
- documents, findings
- risk_scores, approvals
- performance_kpis
- erp_sources, audit_log

PUBLIC SCHEMA

- rule_corpora (shared)
- schema-migration ledger
- cross-tenant metadata

Consultant mode - cross-tenant recurrence

A consultant who qualifies the same supplier for several customers can enable cross-tenant view. VendorCore matches suppliers across tenants by `external_ref`, exact name or fuzzy token overlap ($\geq 50\%$). Side-by-side findings and risk trajectories surface recurring issues that individual customers would miss.

RECURRENCE EXAMPLE

ChemRaw Iberia S.A. appears in tenant_eues01 (medium risk, 3 findings) and tenant_eude01 (low risk, 1 finding). Cross-tenant view surfaces the total picture: 4 findings across both, including a shared data integrity gap in both Quality Agreements.

Access control: cross-tenant data is only visible to users who are members of ≥ 2 tenants. Single-tenant users see an empty list. No cross-contamination of data.

10 Regulatory and compliance coverage

VendorCore is built for regulated industries. The compliance requirements are baked in, not bolted on.

<p>EU GMP ANNEX 11</p> <p>Computerised Systems</p> <p>Validation approach (GAMP 5 Cat. 4), access controls, audit trail (ALCOA+), backup procedures, incident management, periodic review.</p>	<p>21 CFR PART 11</p> <p>Electronic Records & Signatures</p> <p>Hash-chained audit log, e-signature on critical transitions, unique user IDs, session management, tamper-evident storage.</p>	<p>EU GMP CHAPTER 7</p> <p>Outsourced Activities</p> <p>Supplier qualification workflow, Quality Agreement management, gap analysis, risk scoring and periodic re-qualification.</p>
<p>ICH Q10</p> <p>Pharmaceutical Quality System</p> <p>Supplier management as part of PQS: qualification, monitoring, performance KPIs, trend detection and escalation workflow.</p>	<p>ISO 13485:2016</p> <p>Medical Devices QMS</p> <p>Section 7.4 supplier evaluation and re-evaluation: structured qualification, documented criteria, records of evaluation outcomes.</p>	<p>GAMP 5</p> <p>Software Validation</p> <p>Category 4 (configured product). Includes URS, FS, FMEA and validation protocol templates. CSV package generated per tenant.</p>

Evidence-grade audit trail - what the inspector actually sees

<p>ALCOA+</p> <p>ATTRIBUTABLE · LEGIBLE · CONTEMPORANEOUS · ORIGINAL · ACCURATE + COMPLETE · CONSISTENT · ENDURING · AVAILABLE</p>	<p>Append-only</p> <p>UPDATE AND DELETE BLOCKED BY DB TRIGGER</p>	<p>SHA-256</p> <p>HASH CHAIN PER TENANT, VERIFIED ON EXPORT</p>	<p>E-sig</p> <p>USER + TIMESTAMP + IP ON EVERY CRITICAL ACTION</p>
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Feature-to-regulation mapping

VENDORCORE FEATURE	EU GMP ANNEX 11	21 CFR PART 11	ICH Q10	ISO 13485
Hash-chained audit log	✓ §9	✓ 11.10(e)	-	-
Append-only, no silent edits	✓ §10	✓ 11.10(k)	-	-
AI gap analysis - QA & SMF	-	-	✓ 6.5	✓ 7.4.1
Certificate expiry alerts	-	-	✓ 6.5	✓ 7.4.3
Inspector dossier export	✓ §17	✓ 11.10(b)	✓ 6.5	✓ 4.2.5
Risk scoring (low/med/high)	-	-	✓ 6.5	✓ 7.4.1
ERP sync by external_ref	-	-	✓ 6.5	✓ 7.4.2

11 Feature roadmap - v1 and v2

VendorCore is built in two tiers. v1 delivers the full qualification workflow on SQLite. v2 adds enterprise integrations on MS SQL / PostgreSQL.

v1 — Available now

- Supplier registry with status, sites, external_ref
- Document upload, AI classification (DM-03)
- Metadata extraction (DM-04): issuer, cert no., dates
- Certificate expiry alerts (60 d / 30 d email digest)
- Gap analysis - QA and SMF (FA-02)
- Compliance check with page references (FA-01)
- AI risk scoring (FA-05): low / medium / high
- Questionnaires: AcroForm PDF + QR + watch-folder
- ERP connector: SQL (MSSQL/PG/MySQL) + Excel import
- Regulatory news feed: FDA WL + EudraGMDP stub (CM-03)
- Cross-tenant recurrence detection (consultant mode)
- Inspector dossier ZIP with audit.jsonl (UI-02)
- Hash-chained audit log (PL/pgSQL trigger)
- Multi-tenant isolation (schema-per-tenant)
- Performance KPIs tracking (quarterly)
- Webhooks: new finding, cert expiry, alert match
- i18n: DE / EN / ES / DA
- Admin panel: tenant + user management

Ongoing updates

- MS SQL adapter for enterprise RDBMS environments
- Advanced regulatory news: EudraGMDP live API connector
- Autopilot inbox: watch-folder runs without manual trigger
- Vision OCR fallback for handwritten questionnaire responses
- Supplier portal: self-service document upload (read-only link)
- Trend clustering across all tenants for group KPI view
- DS / IQ / OQ validation protocol export per GAMP 5
- LDAP / SSO integration (SAML 2.0)
- CM-03 paid feed adapter (Sesami, Compliance AI)
- Per-tool permission matrix (view / edit / approve / export)

Standalone vs. kAlra-integrated

STANDALONE

- VendorCore Python package
- Own FastAPI shell
- No kAlra dependency
- Bring your own auth
- Docker or bare-metal

KAIRA-INTEGRATED

- Router module in kAlra
- Shared auth + sessions
- Shared LLM pool
- Shared nginx + HTTPS
- One Docker compose stack

12 Get started with VendorCore

A pilot installation is running in two weeks. No cloud setup, no subscription required to evaluate.



Pilot in two weeks

A VendorCore instance installed on your server with demo data from a solid-dosage CMO scenario. Your QA team evaluates the full workflow end to end before any commitment.



100% on your infrastructure

VendorCore runs on any Linux server or Mac. Supplier certificates, audit logs and ERP data never leave your building. No cloud account, no OpenAI key, no Microsoft licence required.



AI runs on your own models

Document classification, gap analysis, risk scoring and trend detection use your local Ollama or LM Studio models. Model choice is configurable per tool. Zero per-query AI cost.



CSV validation package included

GAMP 5 Category 4 validation package delivered with the installation: URS, FS, FMEA, IQ / OQ / PQ templates and traceability matrix. Ready for your QA sign-off.



Consultant licencing available

Use VendorCore across multiple customer tenants from a single installation. Cross-tenant recurrence detection and side-by-side risk comparison out of the box.



Modular - buy what you need

VendorCore is a standalone module. You do not need to deploy the full kAlra platform. Add LeanPulse (OEE / huddles) or DeviTrack (GMP deviation management) later if relevant.

Request a pilot or a live demo

We install VendorCore on your test server, load a representative demo dataset and walk through the full workflow with your QA and IT teams.

✉ info@freshlab.es 🌐 freshlab.es

ALSO FROM FRESHLAB

DeviTrack

GMP deviation management, RCA, CAPA and effectiveness verification. Companion module to VendorCore.

ALSO FROM FRESHLAB

LeanPulse

OEE monitoring, VSM, daily huddles and wallboard. Shop-floor operations intelligence for manufacturing.

PLATFORM

kAlra

The full AI platform: chat, RAG, document tools, translation, voice, compliance and more. On-prem, one server.