A PLATFORM FOR GMP DEVIATION MANAGEMENT

DeviTrack

GMP deviation management, RCA, CAPA and effectiveness verification, with **ALCOA+ compliance from the first record**, no Excel, no paper, no cloud.

100% on-prem · no cloud | **EU GMP** Annex 11 | **21 CFR** Part 11 | **ALCOA+** | **Multi-plant** | **AI** integrated | **ES · DE · EN · DA**

WHY IT MATTERS

A solid-dosage contract manufacturer lives on customer trust and on AEMPS / EMA / FDA inspections. Every poorly documented deviation, every CAPA without effectiveness verification, and every audit trail with gaps puts certificates, contracts and batches at risk. **DeviTrack turns that into a minutes-long routine, not a weeks-long one.**

WHAT THIS DOSSIER SHOWS YOU

A 14-page overview: full deviation flow, multi-plant model, a KPI dashboard with **AI-generated insights**, electronic signature, hash-chained audit trail, DOCX inspector export, and the CSV validation package ready to ship.

1 What a CMO looks like today without DeviTrack

You will recognise at least four of these.

WITHOUT DEVITRACK, THE DAILY REALITY

- Deviations live in Excel, Word and email. Multiple versions, nobody knows which one is official.
- RCA → CAPA → VoE chain broken: effectiveness is not verified, or signed-off afterwards.
- AEMPS / customer audits: QA spends days reconstructing the timeline and traceability.
- 21 CFR Part 11 + ALCOA+: **impossible** to demonstrate on paper.
- Multi-plant = silos. Each site reinvents its numbers, KPIs do not consolidate.
- Batch and supplier data in cloud tools, a contractual risk.

WITH DEVITRACK, FROM DAY 1

- One deviation, one workflow, one responsible person visible at every step.
- RCA (5-Why / Ishikawa) + CAPA + VoE in connected tabs, never sealed until verified.
- Audit trail with a **hash chain** and e-signature. One click and the DOCX dossier is ready for the inspector.
- ALCOA+ by construction: append-only, timestamps, authorship, nothing is deleted.
- Tenant + plants: one group, several subsidiaries, isolated data. KPIs cross over or stay separate, by permission.
- 100% on your server, no cloud, no OpenAI, no Microsoft. Batch data never leaves the building.

2 The five-second argument

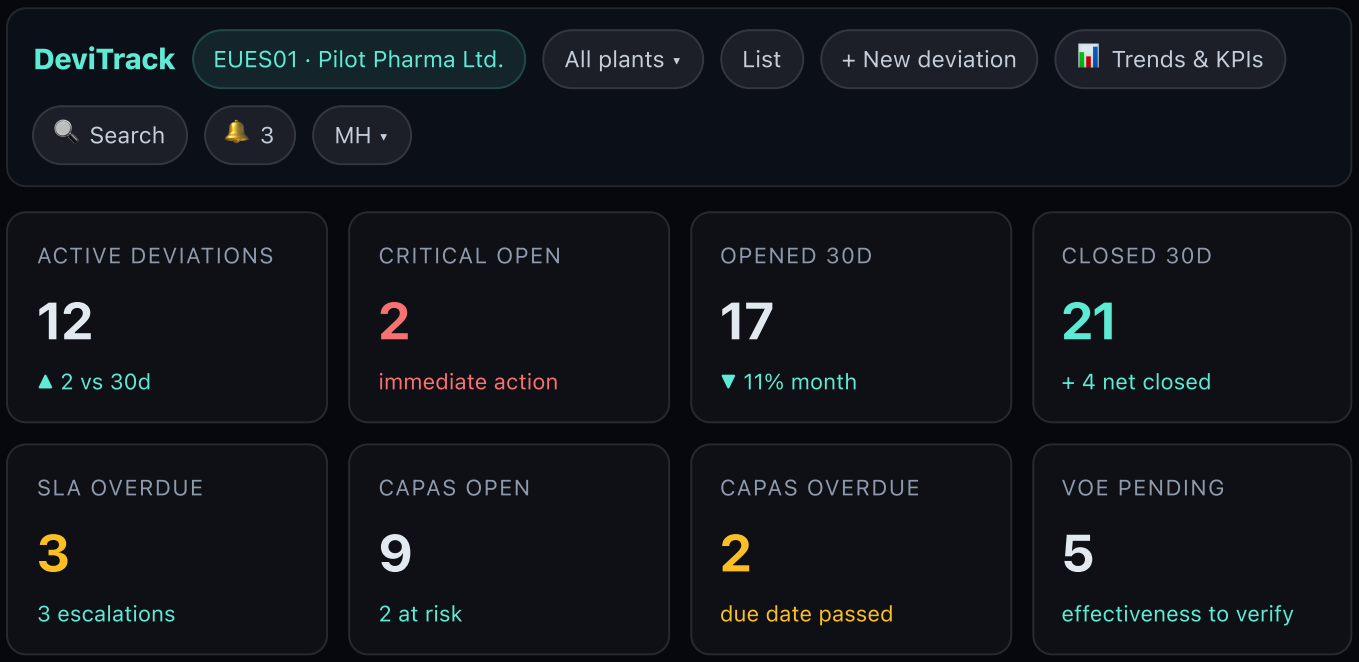
< 5 min Average time to log a deviation with AI classification, assign the matching GMP workflow by severity, and notify the right QA pool. Before: half an afternoon of copy-paste.

100% Audit trail coverage. Every action: capture, transition, RCA, CAPA, VoE, signature, export. Each one signed with actor, timestamp, IP and chained hash. **Zero silent edits.**

0 € Cost of external AI licences. Classification, RCA suggestion, inspector summaries and trend insights all **run on your own server** (Ollama / LM Studio).

3 One-minute dashboard

DeviTrack module screenshot, demo data (solid-dosage CMO).



Automatic insights - anomaly detection over 6 months

Critical backlog
3 critical open deviations. Click for the filtered list.

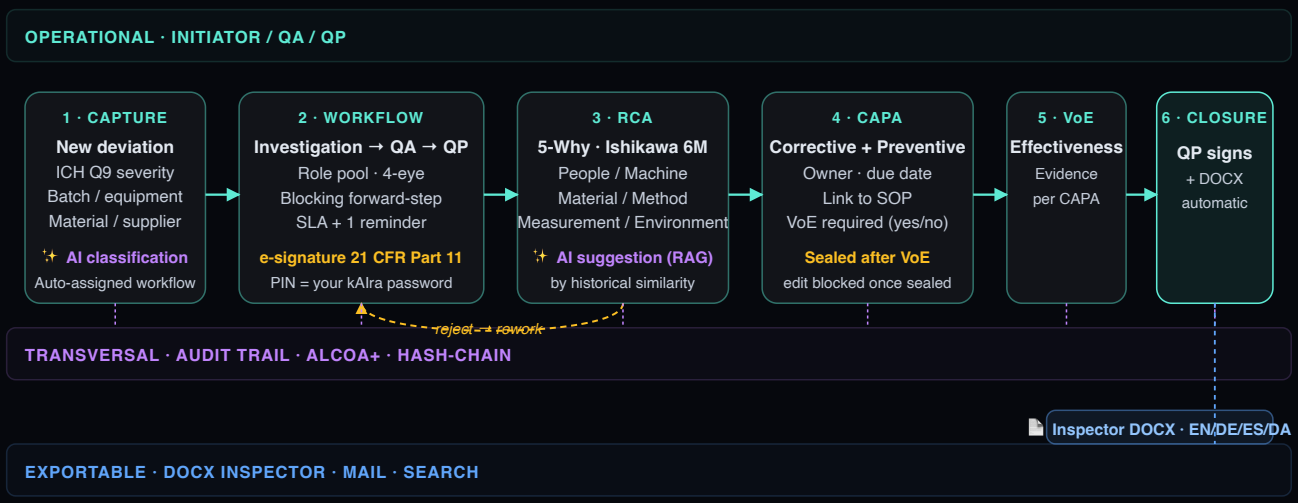
Spike on "Tablet line 2"
30 days: 6 cases vs 6-month baseline (1.4 / 30d). Possible press or granulation issue.

Cycle-time creep
Last 4 weeks: 1.7× the previous quarter. Review QP workload.

CAPAs overdue
2 CAPAs past their due date. Direct link to filtered list.

4 Full lifecycle of a deviation

From capture to closure, with 21 CFR Part 11 e-signature on every critical transition.



Two ways to start a deviation

1 · FROM INSIDE THE TOOL

- Operator / QA with normal login clicks **+ New deviation**.
- Optional AI classification from the free-text description.
- GMP workflow is auto-assigned by severity.

2 · VIA TOKEN LINK

- QA mints tokens **per department** (Production, Warehouse, Suppliers) or **per person**.
- The operator opens the link (poster, QR code, email) **without logging in** and describes what happened.
- QA receives it in the triage queue and decides whether to promote it to an official deviation.
- Tokens individually revocable, with anti-spam rate-limit.

Local AI

Classifies, suggests RCAs by similarity, and writes inspector summaries, all on your server.

e-Signature

21 CFR Part 11. PIN + hash + actor + timestamp into the audit trail. No critical step without a signature.

Inspector DOCX

One click → cover page, RCA, CAPA, audit trail, signatures, attachments with SHA-256, ready for any inspector.

5 GMP Workflow — templates & rules

Four built-in templates, all customisable. Role pools. Optional 4-eye.

GMP Critical Strict (6 steps · QP · signature)
GMP Major Standard (5 steps · default)
GMP Minor Lite (4 steps · 240 h SLA)
GMP Critical Dual-Control (4 eyes)

Workflow detail view (case: "GMP Critical Strict")

Capture ✓	Investigation ✓	RCA + CAPA ✓	QA approval ▶	Effectiveness verification	QP closure
Diego, 04/05 09:12	Sara QA, 04/05 14:01	Marina QA, 06/05	QA pool · 2/3 · 4-eye ★ Action required	VoE per CAPA	✦ electronic signature

Role pool

A deviation is assigned to a role (qa/qp), not to a name. The first available person claims it. The rest stay notified.

SLA & reminders

One reminder 6 h before due, one escalation to the parent role if missed. No spam.

Forward-step

"Maintenance must confirm before closure." Blocks the parent step until the recipient approves or rejects.

Integrity rules

Reject = rework

Each retry is a sub-step with a badge **#N**. No overwriting, everything stays in the trace.

Real 4-eye

Con `min_approvals: 2`, the same user can fill only one slot. The second signature requires another member of the role.

Sealed after effectiveness

A CAPA becomes immutable once effectiveness verification (VoE) is confirmed. The system blocks any further edit and the ALCOA+ trace stays intact.

Append-only comments

Threaded discussion per deviation, never editable. To correct a comment you write another one — ALCOA+ "Original".

CUSTOMISE WITHOUT A DEVELOPER

6 Custom templates — AI generates the flow for you

The 4 built-in templates cover typical GMP cases. For your own flows — HPLC OOT, dual-control for high-potency, supplier qualification — add unlimited custom templates. **No extra licence, no code.**

From free-text prompt to template, in 10 seconds

QA

PROMPT — NATURAL LANGUAGE

> *"I need a flow for potency failures in finished product: QA investigation, dual-control CAPA by two QPs, e-signature on approval and closure, 72 h SLA per step. On reject, back to investigation."*

↓ ✨ ↓

✨ GENERATED TEMPLATE, EDITABLE

1 · Investigation ✓	2 · RCA + CAPA ✓	3 · QP-A approves ✓	4 · QP-B approves ✓	5 · Closure ✓
QA · 72 h	QA · 72 h reject → 1	QP · 72 h · ✦ e-sign	QP · min_approvals: 2 · ✦ e-sign	QP · e-signature

→ edit name · adjust SLA · add escalation · save as a new template "Potency-Dual-OOT"

✓ **21 CFR Part 11 e-signature included** on every step where the prompt asks for a signature or QP approval. The AI sets `requires_signature: true` just like the built-in templates. No custom workflow is "less compliant" because the AI wrote it.

What's inside a custom template

✨ AI suggestion from prompt

Describe in plain English. The AI generates name, steps, roles, SLAs and signatures. You edit what does not fit and save.

📝 Configurable step schema

Each step: role · SLA · e-signature · number of approvals · destination on reject · automatic escalations.

🔄 Mid-flight template swap

As long as no step has been decided, a deviation's template can be swapped. The swap is recorded in the audit trail.

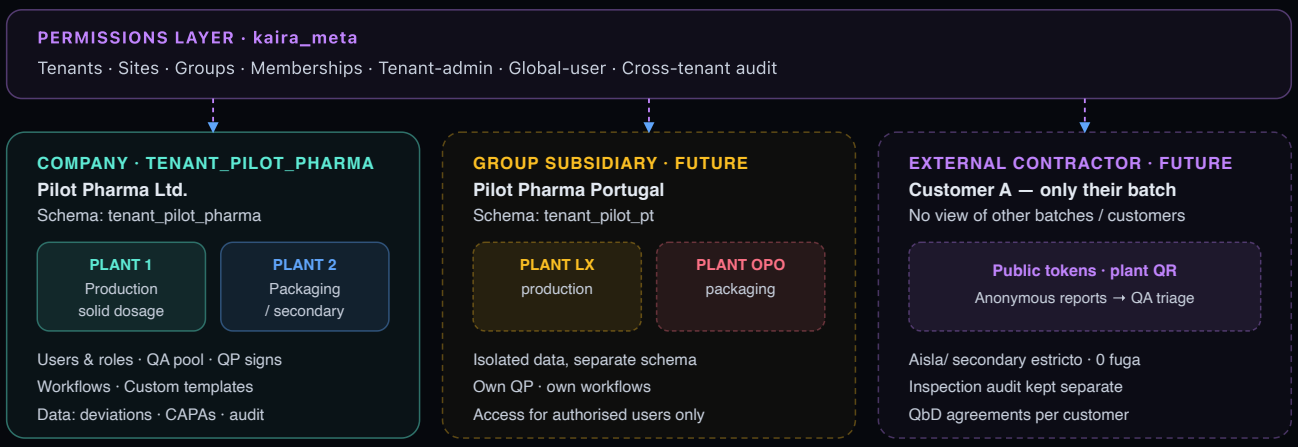
📦 Archive without losing history

Obsolete templates can be archived. Built-ins are immutable. Existing deviations keep their original template — the audit trail does not move.

DESIGNED FOR PHARMA GROUPS

7 Multi-tenant + multi-plant — one system, many subsidiaries

Today: one company, several plants. Tomorrow: the whole group, isolated data, consolidatable KPIs.



Active tenant (customer) · Future tenant in the group · Permissions layer (kaira_meta) · Site / Plant

What this means, concretely

Aisla/ secondary por schema

Each company lives in its own `tenant_*` PostgreSQL schema. No possible leak between subsidiaries.

Site = permission boundary

A user linked to "Plant 1" cannot see "Plant 2" data. Lists, KPIs, AI — everything respects the boundary (HTTP 403 on cross).

New tenant in 30 s

Create tenant → automatic bootstrap: schema, tables, audit trigger, 4 workflow templates, full-text indexes. No DBA needed.

Group-global view

Users with the **global** permission see aggregates across every subsidiary, for corporate reporting, without breaking each tenant's isolation.

8 Compliance by construction

ALCOA+ is how the system works, not a label added on top.

EU GMP
Annex 11
Validated computerised systems. Full CSV package (URS · FS · DS · FMEA · IQ · OQ · PQ) delivered on day 1.

FDA
21 CFR Part 11
Electronic signature with PIN, hash + actor + timestamp. Distinct from a wet-ink signature, on screen and in DOCX.

PIC/S
PI 041 — Data Integrity
Append-only audit trail, no DELETE, no silent UPDATE. The hash chain catches any tampering.

EMA · ICH
ICH Q9 — Risk
ICH Q9 severity (critical / major / minor) at capture. The matching GMP template is auto-assigned.

EU AI ACT
Article 50 — Explainable AI
Every AI output is disclosed. The decision is human — the AI **proposes**, never decides.

RGPD / LOPDGDD
Data on your server
Personal and batch data never leave the building. No international transfers. The data processor is you.

ALCOA+ in practice

A Attributable
Every action → username + IP + display name + session-token actor. Never "user1".

C Contemporaneous
Server timestamp (UTC + Europe/Madrid in exports). No "signed afterwards".

O Original
Append-only via a PostgreSQL trigger. UPDATE/DELETE rejected at the engine level.

+ Complete · Consistent · Enduring · Available
Retention ≥10 years. Bind-mount backups. Restore tested in OQ.

Audit trail — real example

```
2026-05-08 14:02:11 · deviation.create · DEMO_OP · DEMO-202605-0017 · severity=critical · hash=a8f2…3c91
2026-05-08 14:18:44 · workflow.step_assigned · system · step=Investigation · pool=qa(3) · prev=a8f2…3c91
2026-05-08 16:31:09 · workflow.claimed · DEMO_QA1 · step=Investigation
2026-05-08 17:22:55 · rca.save · DEMO_QA1 · 5why="press…" · embedding=re-computed
2026-05-09 09:14:02 · capa.create · DEMO_QA1 · type=corrective · owner=DEMO_QA2 · due=2026-05-22
2026-05-09 11:48:31 · workflow.step_approved · DEMO_QP · step=Closure · e-sign=hash=7c4d…e21f
2026-05-09 11:48:33 · inspector.export · system · format=docx · lang=es · sha256=f02a…b517
```

9 AI integrated, 100% on your server

Open-weight models on your own server. Zero data to OpenAI, Google or AWS.

✨ UC-1 · Automatic classification

Reads the free-text description and proposes severity, area, equipment and batch. **Editable. Never decides alone.**

🔍 UC-2 · RAG-based RCA suggestion

Embedding + search of similar past deviations (pgvector, cosine ≥ 0.78). Proposes historical "whys". QA confirms or rewrites.

UC-4 · Inspector narrative

Executive summary in the exported DOCX, in the selected language (EN/DE/ES/DA). The inspector reads it as if the QP wrote it.

UC-5 · Trend Insights Report

Window 1–36 months. Five dimensions (area, equipment, material, supplier, time). 2–5 findings per dimension + executive summary.

Trend Insights — AI report view

AI report — last 6 months

Generated 2026-05-09 · 23 deviations analysed · local model llama3.1:8b

FINDING · HIGH · EQUIPMENT

Concentrated on Tablet line 2 — 6 deviations (of 23) in 30 days, vs 1.4/month baseline. Pattern suggests press condition.

Cases: DEMO-202605-0017, …0014, …0011 (clickable)

FINDING · MEDIUM · SUPPLIER

Lactose monohydrate 200, 3 batches with friability OOS in 90 days. Recommend: extra check on receipt.

Executive summary: the dominant risk of the last 6 months is concentrated on Tablet line 2 and on lactose from a single supplier. Acting on those two vectors covers > 60 % of the observed variance.

Full-text cross-resource search

One search box covers, only inside your tenant:

- deviations · id · title · description · area · equipment · batch
- CAPAs · description · VoE evidence
- comments
- public reports

Trigram-based (PostgreSQL `pg_trgm`) · GIN-indexed per tenant · results with type + direct link.

10 Permissions, roles and audit trail — all in one language

Five roles, one plant boundary, two levels of admin, one unified audit.

Module roles

ROL	CREATE DEV.	EDIT RCA/CAPA	APPROVE QA	APPROVE QP / CLOSE	TENANT ADMIN
initiator	✓	✓	-	-	-
qa	✓	✓	✓	-	-
qp	✓	✓	✓	✓ e-sign	-
admin	✓	✓	✓	✓	✓ full tenant

Site boundary (security boundary, v1.1)

📍 **User with assigned plant**

Sees and edits only "their" plant data. Lists, detail, KPI, export, search — everything is filtered automatically.

👁️ **Tenant-admin sees everything**

Within their company, the tenant-admin crosses plants. The group-global user sees every tenant, without breaking isolation.

What you cannot do (and that is the point)

- Delete a closed deviation — the system blocks it.
- Edit a comment — append-only by ALCOA+ design.
- Tamper with the audit trail — DELETE/UPDATE rejected at the PostgreSQL trigger level.

MAIL + BELL, WITHOUT SPAM

Notifications for every workflow step, by group or by person

Every step opening, SLA reminder, escalation, forward and rejection fires an in-app notification and, if an email is configured, an email too. Anti-spam: at most 2 emails per step per recipient.

By group (pool) or by person

When a step goes to a role (qa, qp, initiator), every member of the pool gets notified. Forward or reassignment goes to a specific person.

In-app + email, always paired

Bell in the toolbar for everyone. Email if an address is configured. The 📧 icon in the list shows what was sent by mail and what was in-app only.

Anti-fatigue reminders

One when the step opens, one 6 h before SLA. After that: silence. No "still pending, still pending".

DND opt-out per user

Any user can disable email in their profile. The in-app bell keeps working as usual.

12 CSV package — ready to deliver on day 1

Full computerised-system validation, aligned with EU GMP Annex 11 and GAMP 5. Bilingual DE / EN.

11 validation documents, from Validation Plan to Periodic Review Template, delivered with the rollout. No last-minute drafting before an inspection.

00	Validation Plan	01	User Requirements Specification (URS)
02	Functional Specification (FS)	03	Design Specification (DS)
04	Risk Assessment / FMEA	05	IQ Protocol, Installation Qualification
06	OQ Protocol, Operational Qualification	07	PQ Protocol, Performance Qualification
08	Validation Summary Report	09	Change Control Template
10	Periodic Review Template	DOC	AI-Compliance Dossier (EU AI Act)

URS — blocks covered

A · Capture & lifecycle
B · Workflow & e-Signatures
C · RCA + CAPA + VoE
D · Audit Trail (ALCOA+)
E · Inspector Export
F · Multi-Tenant + Permissions
G · Notifications & Mail
H · AI Use-Cases
I · Trend & KPIs
J · Backup & Recovery
K · Performance
L · Public Reports
M · Cross-resource Search
N · Demo Data & Seed

FMEA — areas assessed

⚙ Workflow + e-sign

Pool, 4-eye, reject, SLA, escalation, reassignment, 21 CFR Part 11 e-signature.

📚 Audit trail ALCOA+

Append-only trigger, hash chain, tamper integrity, tested restore.

✨ AI use-cases

Five use-cases with assessed risk. Disclosure, human override, fallback without AI.

All validation documents are delivered in editable form (Markdown + DOCX). Your QA can adapt them to internal nomenclature and sign them with your system.

THE ARGUMENT THAT CLOSES THE DEAL

13 100% on your server, no cloud, no compromises

Your QP signs with their PIN, on your server, with your model. The OEM customer sees that in any audit.

On-premise by design

Mac Studio, Linux server, Windows with WSL — one Docker Compose and one hour. **No OpenAI, Microsoft, Google.**

No telemetry

No background pings. No "help us improve the product". Your data is yours, no asterisks.

Simple backups

PostgreSQL bind-mount + JSON config. Restore: copy + restart. Tested in OQ.

Historical-data migration

If today you have Excel, another QMS or a deviation module in your MES, we assess the migration of your historical data. The data is normalised to the DeviTrack structure and feeds the AI-RAG so it can suggest RCAs based on your own experience.

Multilingual

UI and inspector export in **EN · DE · ES · DA**. Translated workflow templates.

Rollout roadmap (4 weeks)

WK.	MILESTONE	DELIVERABLE
1	Installation + tenant for Pilot Pharma + plants + users	DeviTrack live, demo data loaded, 4 active users
2	Validation: URS / FS review · IQ executed · OQ on site	IQ + OQ signed off by customer QA
3	PQ — pilot run with 5 real deviations · workflow templates fine-tuned	PQ signed · custom templates aligned with SOPs
4	Go-live · Validation Summary Report · operator + QA + QP training	System in production · 11 signed CSV documents · active support

14 Management summary

< 4 weeks	11 docs	100%	∞
IMPLEMENTATION	CSV PACKAGE	ON-PREM · NO CLOUD	SUBSIDIARIES AT NO EXTRA COST

What you receive

Full software
DeviTrack + the kAIra platform (chat, RAG, translation, templates) on your server.

CSV documentation
11 validation documents · DE+EN user manual · AI-Compliance dossier.

Turnkey implementation
Installation · tenant configuration · custom templates · operator+QA+QP training.

Ongoing support
Agreed SLA · platform updates · audit support.

And tomorrow, as the group grows?

+ tenant

Adding a second subsidiary is **creating a tenant** in the global admin panel. 30 seconds. Separate schema, its own workflows, its own QA and QP. Corporate KPIs keep consolidating. **No extra licences.**

What we would ask of you to start

- A QA point of contact to align workflow templates with your SOPs.
- Access to the server where DeviTrack will run (Mac Studio or a Linux server, 16 GB recommended).
- A list of plants + users + initial roles (operator / QA / QP / admin).
- If you wish, historical-data migration: provide your historical data so we can scope the migration.

Let's talk

We propose a 1-hour on-site demo and, if you wish to proceed, a commercial offer with the 4-week timeline.

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DeviTrack is a module of the **kAIra** platform · v1.1 (2026-05-10)