Apps for Specialized Industries | Best Rovo Agent | Best MCP Server | Teamwork Graph

TrialGuard GxP

Tamper-evident **FDA 21 CFR Part 11** electronic-signature audit chains, **ICH Q9** FMEA risk scoring, and **Rovo + MCP** inspection readiness built natively on Atlassian Forge.

SHA-256	**0 LLM $**	**4 + 4**	**25 / 25**
PART 11 SIGNOFF CHAIN	DETERMINISTIC MATH CORE	ROVO ACTIONS & MCP TOOLS	VITEST ASSERTIONS PASS

Why Clinical & Biotech Teams Struggle in Jira & Confluence

The Regulatory Gap

- **Mutable Ticket History:** Standard Jira issue transitions and comments lack cryptographic tamper-evidence required by **FDA 21 CFR Part 11 §11.10(e) & §11.50**.
- **Subjective Deviation Triage:** Without deterministic **ICH Q9 FMEA** math (`RPN = S × O × D`), Major/Critical cold-chain or sterile-fill deviations risk missed containment SLAs.
- **SOP Drift & Training Exposure:** Controlled SOPs in Confluence expire silently while linked Jira CAPAs stay open.
- **LLM Hallucination Risk:** Sending GxP risk math to paid external LLMs introduces non-determinism and data-residency liability.

The TrialGuard GxP Solution

- **Cryptographic Signoff Ledger:** Chained SHA-256 digests bind `Author → Clinical_Lead_Approval → QA_Review` with instant tamper detection.
- **Deterministic FMEA Engine:** Pure TypeScript rules classify Minor (72h), Major (24h), and Critical (4h) SLAs with automatic patient-safety / batch-quarantine overrides.
- **Teamwork Graph Lineage:** Traverses `Protocol → SOP → Deviation → Signoff` to flag orphan SOPs and unsigned CAPAs.
- **Zero Paid External LLM Cost:** Rovo Agent + MCP Server invoke deterministic Forge resolvers directly inside Atlassian Cloud.

Forge + Rovo + MCP + Teamwork Graph Architecture

1. Custom UI Surfaces

Jira Issue Panel & **Confluence Byline** (`static/panel/`, Vite + TS, relative `./` assets) with interactive FMEA sliders, tamper toggle, and dossier export.

→

2. Forge Resolvers

`nodejs24.x` runtime (`src/resolvers/`) routing UI invocations, Rovo actions, and MCP tool calls to a single deterministic core.

→

3. Deterministic Core

`hashChain.ts` (SHA-256), `capaEngine.ts` (ICH Q9 FMEA + SOP drift), and `regulatoryGraph.ts` (Teamwork Graph lineage).

Rovo QA Officer (`rovo:agent`)

4 native actions: `classifyDeviationSeverity`, `verifyAuditHashChain`, `auditSopExpirationRisk`, and `generate21CFRPart11Report` (dual Markdown + Atlassian Document Format JSON).

Atlassian MCP Server (`rovo:mcp`)

4 schema-validated tools: `evaluate_fmea_risk`, `verify_part11_chain`, `scan_sop_compliance`, and `export_inspection_dossier`, paired with `skill.md` for external AI clients.

Tamper-Evident SHA-256 Electronic-Signature Chain

Canonical Digest Binding

Each signoff step hashes `sequence`, `recordId`, `signerAccountId`, `meaning` (`Author` / `Clinical_Lead_Approval` / `QA_Review`), `timestampUtc`, `payloadDigest`, and `previousHash` (genesis `0000...`).

Live "Simulate Tamper" Proof

Modifying a single character in an upstream signoff payload immediately breaks the downstream `previousHash` invariant, surfacing the exact broken sequence index in both the Custom UI and Rovo verification output.

```
// src/compliance/hashChain.ts
1. [Seq #1] Author — Dr. Elena Vance
   prev: 0000000000000000...
   hash: 8f3a91c4e2b0... (VALID)
      |
      ▼
2. [Seq #2] Clinical_Lead_Approval — Dr. Marcus Chen
   prev: 8f3a91c4e2b0...
   hash: 4c7d19a8f012... (VALID)
      |
      ▼
3. [Seq #3] QA_Review — Priya Nair, RAC
   prev: 4c7d19a8f012...
   hash: e19b04d3c77a... (VALID)

// Tamper Simulation: mutate Seq #1 payloadDigest
// ✗ Result: valid = false, brokenAtSequence = 1
```

ICH Q9 FMEA Risk Scoring & SOP Drift Detection

Deterministic Containment Matrix

BAND	RPN / TRIGGER	CONTAINMENT SLA
Minor	RPN < 60 (no safety flag)	72 hours
Major	60 ≤ RPN < 150	24 hours
Critical	RPN ≥ 150 or Safety / Quarantine	4 hours + QA Escalation

Safety-critical or batch-quarantine deviations automatically escalate to **Critical (4h SLA)** regardless of raw RPN.

Confluence SOP Drift & Graph Lineage

- **Expiration Window:** Flags Controlled SOPs expiring within 30 days or already overdue.
- **Training-Gap Exposure:** Surfaces active deviations linked to SOPs with uncertified operators.
- **Teamwork Graph Audit:** Validates `ClinicalProtocol → ControlledSOP → QualityDeviation → CapaApprovalSignoff` edges and catches orphan SOPs or unsigned CAPAs.

Tested by tests/capaAndGraph.test.ts (7/7 PASS)

Atlassian MCP Server & `skill.md` Integration

4 Schema-Validated MCP Tools

TOOL NAME	PURPOSE
`evaluate_fmea_risk`	Compute RPN, band & containment SLA
`verify_part11_chain`	Audit SHA-256 signoff integrity
`scan_sop_compliance`	Detect expiring SOPs & training gaps
`export_inspection_dossier`	Build FDA/EMA Markdown + ADF pack

Portable `skill.md` Contract

Ships a self-contained `skill.md` specification so external AI coding agents, QA copilot workflows, and CI pipelines can invoke TrialGuard MCP tools with exact parameter schemas and deterministic expectations.

```
manifest.yml → rovo:mcp ("TrialGuard GxP MCP Server")
  ├── Strict JSON input schemas (zero free-form drift)
  ├── Deterministic TypeScript execution in Forge
  └── Dual Markdown + Atlassian Document Format (ADF)
```


Tested by tests/rovoAndMcp.test.ts (8/8 PASS)

End-to-End Verification & Zero-Cost Runtime Metrics

25 / 25
VITEST SUITE PASS

0
CONSOLE / PAGE ERRORS

0
FAILED NETWORK REQUESTS

$0.00
PAID FORGE LLM COST

4 Automated Test Suites

- `tests/hashChain.test.ts` (5 tests): genesis chain, tamper detection, sequence gaps, meaning validation.
- `tests/capaAndGraph.test.ts` (7 tests): FMEA RPN bands, safety overrides, SOP drift, graph orphan/unsigned detection.
- `tests/rovoAndMcp.test.ts` (8 tests): all 4 Rovo actions, ADF structure, all 4 MCP tool schemas.
- `tests/manifest.test.ts` (5 tests): valid `nodejs24.x` Forge manifest, modules, and permissions.

Headless Browser & Security QA

- Headless Chrome verified live rendering, inline SVG favicon (0 404s), **Simulate Tamper** chain-break toggle, FMEA sliders, and all 4 Rovo simulator actions.
- Zero secrets confirmed via `gitleaks`; clean MIT-licensed TypeScript codebase.

Codegeist 2026 Category & Bonus Track Fit

Primary Category: Apps for Specialized Industries

Purpose-built for **Biotech, Clinical Trials, and Medical Device** teams who already manage protocols in Confluence and deviations in Jira, but need audit-grade **21 CFR Part 11**, **ISO 13485**, and **ICH Q9** guardrails.

- Standalone interactive preview works immediately without an Atlassian tenant.
- 3-minute Forge CLI deployment via `DEPLOY_CHECKLIST.md`.

3 Bonus Track Alignments

- **Best Rovo Agent:** *TrialGuard Regulatory QA Officer* with 4 structured actions + dual Markdown/ADF inspection dossier generation.
- **Best MCP Server:** *TrialGuard GxP MCP Server* exposing 4 typed compliance tools + `skill.md`.
- **Teamwork Graph:** Explicit `Protocol → SOP → Deviation → Signoff` lineage graph surfacing compliance blind spots.

MIT License · github.com/alphonshhhomenicmtu/trialguard-gxp-codegeist