



Transvolve Consultancy Ltd

Phase-1 Engagements

Audit-Ready Engineering Baselines for Regulated Healthcare Systems

Senior-led, time-boxed engagements designed to reduce delivery and regulatory uncertainty before deeper execution begins.

Phase-1 engagements are typically completed over a short, focused time window, agreed during discovery based on scope and organisational readiness.

Why Phase-1?

Regulated product teams often face uncertainty before audits, releases, or scale-up:

- Architecture drift across software, hardware, cloud, and data
- Risk controls that exist but are weakly linked to evidence
- Verification activity that does not support confident release decisions
- DevSecOps pipelines that ship builds but fail regulatory scrutiny

Phase-1 engagements establish clarity, confidence, and a defensible narrative — without committing to large delivery programmes prematurely.

Phase-1 Engagement Options

1. Architecture & Risk Baseline

Purpose

Establish a clear, defensible system architecture and risk posture aligned to regulatory expectations.

Scope

- System boundaries, interfaces, assumptions, and dependencies
- Architecture alignment with IEC 62304 expectations
- Risk posture review aligned to ISO 14971 intent

You leave with

- Executive-readable architecture & risk gap summary
- Prioritised remediation themes linked to regulatory impact
- Audit-ready technical narrative suitable for internal and external review

2. Evidence Chain Recovery

Purpose

Restore coherence between requirements, risk controls, and verification evidence.

Scope

- Review of traceability across requirements ↔ risk ↔ verification
- Identification of evidence gaps and weak controls
- Definition of a defensible release position

You leave with

- Coherent traceability model
- Clear release defensibility position
- Verification roadmap aligned to risk



3. Regulated DevSecOps Foundation

Purpose

Define how CI/CD should generate audit-useful evidence by design.

Scope

- Pipeline intent and evidence generation strategy
- Quality gates and release decision model
- Alignment with QMS and regulatory expectations

You leave with

- DevSecOps reference architecture
- Evidence-ready pipeline blueprint
- Foundation for automation and AI-enabled tooling

Engagement Principles

- Senior-led delivery (no junior substitution)
- Time-boxed and scope-defined
- No over-commitment before clarity
- Designed to scale into delivery only if appropriate

All engagements are scoped following a short discovery discussion to ensure regulatory, technical, and organisational fit.

About Transvolve

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Transvolve provides senior engineering leadership across medical devices, digital health, and regulated healthcare platforms, specialising in architecture, risk, verification, and evidence-driven delivery.