Inspection-ready quality records.

NeoAssure is the documented Neodrics quality operating system for pharmaceutical manufacturers: pre-build, source-bound and designed for regulated records.

GXP SAAS | QUALITY YOU CAN TRUST | A NEODRICS PRODUCT

NEO ASSURE

QUALITY YOU CAN TRUST

The product was renamed to NEO ASSURE on 2026-09-18. This brochure uses only facts recorded in the NeoAssure documentation and keeps draft guardrails visible.

THE GAP NEOASSURE TARGETS

Pharma quality needs linked, inspectable records.

The source docs frame the customer problem as silos, slow inspection retrieval, paper and Excel persistence, data-integrity risk and expensive validation. NeoAssure targets this gap with one inspection-grade quality platform for pharma manufacturers.

QUALITY GRAPH

Linked records across modules

Every record is linked across modules so impact analysis is a first-class capability rather than a manual search exercise.

PROOF LEDGER

Records that can be verified

Hash-chained audit trail and signatures, anchored daily to WORM storage, with a public verifier in the documented differentiators.

CONTINUOUS VALIDATION

Evidence with every release

The supplier validation evidence package is planned to be generated with every release, aligned to GAMP 5 and FDA CSA principles.

CONFIGURATION PACKS

Signed, locked minimums

Configuration as signed packages, jurisdiction packs and industry packs let tenants configure without uncontrolled custom code.

Source wording to preserve: NeoAssure is pre-build design and documentation. Do not present it as already built.

ONE PLATFORM

20 modules. 10 core engines.

The documented scope is broad, but shared engines keep the architecture coherent. Each business module inherits the same controls for identity, audit trail, signatures, workflow, files, reports, configuration and AI hooks.

DMS
DEVIATION/CAPA/CHANGE
TRAINING
DIGITAL LOGBOOKS
AUDITS
SUPPLIER QUALITY
EQUIPMENT
RISK
PQR
LICENCE REGISTER
PORTAL
COMPLAINTS
RECALL
INVENTORY
EBR
QC-LIMS LITE
VALIDATION
STABILITY
EM
PV/E2B
SERIALIZATION

M1-M4	2A	3	4-5
PHASE 1 CORE RECORDS	COMPLIANCE SUITE CORE	MANUFACTURING AFTER G2	PLANNING-LEVEL EXTENSIONS

Phase labels and sequencing follow the NeoAssure roadmap summary and module catalogue.

PHASE 1 SLICE

Start with the daily records that make quality visible.

Phase 1 is documented as the Schedule M core record slice: DMS, QMS, Training, Digital Logbooks and Audit-lite, with a Starter Pack and controlled legacy SOP import.

M1

Document Management

Controlled documents, effective versions, read-and-acknowledge and legacy SOP import.

M2

Deviation, CAPA, Change

Quality events and controlled change records tied back to affected records and workflows.

M3

Training and Competency

Training records, acknowledgements and operator-facing screens, with Hindi planned for Phase 1 operator flows.

M17 + M4 LITE

Logbooks and audit-lite

Digital logbooks, checklists, equipment-lite and audit/inspection support with exported copy verification hash.

> The source docs say no Risk or Management Review module lite in Phase 1; templates only. Keep that limit explicit.

ARCHITECTURE AND INTEGRITY

Compliance is treated as shared infrastructure.

The architecture is documented as a FastAPI modular monolith backed by PostgreSQL, Keycloak identity, PyCasbin authorization and row-level security. The Proof Ledger and electronic signature engine are common services, not per-module afterthoughts.

RECORD	WORKFLOW	SIGNATURE	AUDIT	ANCHOR	EXPORT
module action	configured lifecycle	meaning + step-up	hash chain	S3 Object Lock	verifiable evidence

E-SIGNATURE

Part 11 model by default

The e-signature engine records meaning, user, time, record, version and content hash through a controlled signing path.

AUDIT TRAIL

Tamper-evident events

Audit records are designed as a chained ledger with retained integrity evidence.

TENANCY

Database-layer isolation

Tenants are isolated with row-level security and server-side identity controls.

DATA RESIDENCY

India-first records

Quality records, files, backups and search index are stored and processed in India per the current architecture note.

SHOP-FLOOR UX

Built for operators, reviewers and inspection days.

The UX standard defines status semantics, GxP dialogs, controlled downloads, inspection view, density modes, Indic typography and accessibility checks. The intent is a consistent meaning model across every module and device.

OPERATORS

Large, labelled controls

Shop-floor mode avoids icon-only actions and gesture-only paths. It uses larger targets, visible text labels and high-contrast semantics.

QA REVIEWERS

Review by exception

Audit trail review, batch record review and logbook review are documented as review-by-exception differentiators.

INSPECTORS

Presenter and copy paths

Phase 1 uses exported copy with verification hash and optional read-only inspector account. Full Inspection Mode is planned later.

LANGUAGE

Hindi operator screens

Phase 1 covers Hindi operator screens for logbooks, training acknowledgement, e-sign and reason dialogs.

ROADMAP

Planned in gates. Sold only when shipped.

The roadmap is provisional until the recorded gates and ratifications clear. Plans are sold only when their contents ship.

OCT 2026 - MAR 2027

Foundation build

Core engines, validation pipeline and UI shell are planned for Phase 0b.

JAN - JUN 2027

MVP core records

DMS, Deviation/CAPA, Training and Logbooks with shadow non-GxP pilots in the plan.

15 NOV 2027

India GA target

Essentials and Start are orderable at India GA in the current roadmap summary.

2028+

Compliance suite and extensions

Risk, PQR, Supplier, Equipment, Complaints, Licences, AI Assist Basic and conditional US/UK packs.

AFTER G2

Manufacturing and full suite

Manufacturing starts only after G2; later phases remain planning-level until gated.

WHY NEODRICS

Connected intelligence, applied to pharma quality.

NeoAssure follows the Neodrics blue-teal identity and connected-node visual language with an assurance-graph A mark for quality records.

SAME FAMILY

Shared palette and mark logic

Blue, teal, navy and mint mirror the Neodrics product family for consistency.

STRICT SOURCING

No invented claims

This brochure avoids live-product claims, customer proof, uptime and certifications unless present in the source docs.

DRAFT GUARDRAILS

Clear status

Trademark clearance and claims review are called out before any external use.

NEXT STEP

Review against source docs

Use this as a design-ready draft, then route through counsel and QA claims review before outreach.

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- Vadodara and Gandhinagar | Gujarat | India
- info@neodrics.com
- Draft review pack | September 2026

NeoAssure | Quality You Can Trust

A NEODRICS PRODUCT | SOURCE-BOUND DRAFT

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