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NovintiX — Industry GTM & Capability Roadmap

An industry-prioritized GTM for NovintiX — Pharma & Healthcare as Priority-1, MedTech/Diagnostics as the core, and a reach-out motion into Aerospace & Defense, Automotive, Consumer Electronics and Industrial — plus the capabilities to build to sell better.

Company NovintiX

Scope Industry-prioritized GTM + capability roadmap

Priority-1 Pharma · Healthcare

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How to read this

One engineering muscle, sequenced across industries by fit and speed-to-revenue. NovintiX already sells regulated product engineering into MedTech; Pharma and Healthcare are the fastest adjacent expansions, and the safety-critical industries are a longer reach-out that reuses the same rigor.

NovintiX's transferable asset is **evidence-grade engineering for regulated products** — design controls, risk management, verification & validation, requirements traceability, and the compliance data regulators and auditors demand. That muscle is industry-agnostic; only the standard changes (FDA/MDR → GxP/GAMP5 → DO-178C → ISO 26262 → IEC 61508).

So the GTM is not "pick an industry" — it's **sequence the same capability** into the markets where the fit is tightest and the buying trigger is loudest, priced as fixed-scope offers that a team can buy without a bespoke program.

Industry prioritization

Priority-1 is where the regulatory pain is sharpest and the adjacency to today's MedTech work is shortest. The reach-out industries reuse the same safety-critical engineering discipline but need proof and, in some cases, a hire or partner.

PRIORITY 1 Pharma & Healthcare — fastest revenue, tightest adjacency

- **Pharma:** GxP/GAMP5 computer-system validation, data integrity (ALCOA+), manufacturing & quality analytics, combination-product (drug-device) design controls, PV & regulatory data engineering.
- **Healthcare:** SaMD & digital-health V&V, HL7/FHIR interoperability engineering, connected-health / remote-monitoring device integration, health-data platform engineering.
- **Why now:** EUDAMED/IVDR, GxP data-integrity enforcement, AI-in-clinical and digital-health scaling — all deadline-driven with a named owner.

CORE MedTech & Diagnostics (defend & deepen) — today's strength — the proof engine

- **Play:** Device product engineering, design controls & DHF, ISO 14971 risk, UDI/EUDAMED enablement, SaMD/IEC 62304 V&V, IVDR for diagnostics.
- **Role in GTM:** This is where the reference logos and case studies come from — every P1 and reach-out deal is sold on MedTech proof.

REACH-OUT Aerospace & Defense · Automotive · Consumer Electronics · Industrial — same rigor, needs proof + a hire/partner

- **Thesis:** Safety-critical & regulated engineering transfers: DO-178C/DO-254, ISO 26262/SOTIF/ASPICE, IEC 61508 all demand the traceability and V&V evidence NovintiX already builds.
- **Approach:** Warm, opportunistic reach-out — one lighthouse account per industry, an adapted offer, and a domain hire or partner before scaling.

Priority-1 · Pharma

Sell the same evidence discipline into GxP-regulated software, data and manufacturing — where the audit stakes are as high as MedTech and the specialist bandwidth is just as short.

ICP Who to target

Pharma R&D, manufacturing IT/OT, quality, PV & regulatory — in-house teams and their India GCCs (500–5,000 seats).

- Economic buyer: Head of Quality/IT/Manufacturing Systems or R&D Engineering
- Champion: QA/CSV lead or data-integrity owner
- Trigger: audit finding, GAMP5/CSV backlog, ALCOA+ data-integrity remediation, manufacturing digitalization, PV automation

OFFERS What to lead with

- **CSV / GAMP5 Validation Sprint** — validate one GxP system, audit-ready evidence in weeks
- **Data-Integrity Remediation** — close ALCOA+ gaps flagged in audit
- **Manufacturing-Quality Analytics** — batch-record / deviation analytics
- **Combination-Product Design Controls** — drug-device DHF & risk file

MESSAGING The line that lands

"We build the validation evidence, not just the SOP — audit-ready, on a fixed scope, without pulling your validation team off the line."

- Against big SIs: MedTech-grade rigor, not generalist staff-aug
- Against QA consultancies: we build & validate, they advise

PROOF TO BUILD What unlocks the sale

- One CSV/GAMP5 case study with a named outcome
- A sample validation-evidence package
- GAMP5 / 21 CFR Part 11 mapping accelerator

Priority-1 · Healthcare

Where devices become software and data — SaMD, digital health, interoperability and connected care. NovintiX's SaMD V&V muscle is the wedge; data engineering is the expansion.

ICP Who to target

Digital-health & health-tech companies, health systems' innovation/IT, payers' data platforms, and their India GCCs.

- Economic buyer: VP Digital Health / Head of Product Engineering / CMIO-adjacent IT
- Champion: Regulatory/quality lead for SaMD or an interoperability owner
- Trigger: SaMD/AI feature entering review, FHIR interoperability mandate, remote-monitoring launch, health-data platform build

OFFERS What to lead with

- **SaMD Assurance Pack** — IEC 62304 V&V evidence a notified body accepts
- **FHIR / HL7 Interoperability Engineering** — conformant integration + validation
- **Connected-Health Integration** — device-to-cloud data pipelines with quality controls
- **AI-in-Clinical Validation** — model validation & change-control for clinical AI

MESSAGING The line that lands

"Digital health only ships when the evidence is ready — we make SaMD and health-data features audit-ready and interoperable."

- Against pure dev shops: we bring the regulatory & V&V evidence
- Against advisory: we build the pipelines and the proof

PROOF TO BUILD What unlocks the sale

- A SaMD V&V reference + sample evidence file
- A FHIR conformance demo
- An AI-in-clinical model-validation template

Reach-out industries — same rigor, adapted

The safety-critical industries buy the identical discipline under a different standard. Reach out opportunistically to one lighthouse account each; win it, then decide whether to hire/partner and scale.

Industry	Why NovintiX can play	Entry wedge (adapted offer)	Needs first
Aerospace & Defense	DO-178C / DO-254 demand the same requirements-to-test traceability & V&V evidence NovintiX builds for devices	Safety-critical V&V & certification-evidence pod for one avionics software/hardware item	A DO-178C-literate engineer or partner; a security/ITAR-aware posture
Automotive	ISO 26262 functional safety, SOTIF and ASPICE mirror device risk-management & V&V — surging with ADAS/EV software	Functional-safety V&V pod for one ADAS/EV software component	An ISO 26262 lead; an automotive reference
Consumer Electronics	Connected/wearable devices increasingly cross into regulated (medical-adjacent) territory — NovintiX's regulatory edge is the differentiator	Wearable / connected-device engineering + regulatory-adjacency review (is this a medical device?)	A consumer-hardware reference; speed/cost-tuned delivery
Industrial & Heavy Equipment	IEC 61508 functional safety + industrial IoT + predictive-maintenance data engineering reuse the safety & data muscle	Functional-safety + industrial-data engineering for one line/asset class	An IEC 61508 reference; OT-data literacy

Rule for reach-out: **do not lead generation-scale outreach here yet**. One scoped lighthouse per industry, sold on MedTech proof and the transferable rigor. Only after a win do you invest in the domain hire, the certification, or the partner that makes the industry a real line of business.

Cross-industry positioning

Category: "The regulated & safety-critical product-engineering specialist — we build the evidence." One identity across every industry; the standard is a footnote, the discipline is the brand.

The through-line: design controls · risk management · verification & validation · requirements traceability · compliance data. Whether it's a 62304 file, a GAMP5 validation, a DO-178C artefact or an ISO 26262 safety case, it's the same craft.

Why a specialist beats the SI and the boutique: the SI is generalist and priced for transformation; the boutique advises but doesn't build. NovintiX lands fast on one scoped thing and hands back audit-ready evidence — under the client's existing vendor framework.

Capabilities to build to sell better

Selling better is less about more outreach and more about assets that shorten every evaluation: productized offers, proof, reusable IP, and — the compounding move — turning the highest-repeat service into an AI-native product.

NOW · 0–6 MONTHS Package & prove

- **Fixed-scope offer catalogue** with published price bands (UDI Sprint, Design-Control Accelerator, SaMD Assurance, CSV Validation Sprint, Engineering Health Check) — so buyers say yes without a bespoke SOW
- **3–5 written case studies** + reference customers + sample artefacts (a redacted DHF, a V&V evidence set, a UDI record pack) to hand a technical evaluator
- **Accelerator IP:** template libraries, validation harnesses, compliance-mapping checklists (MDR, IVDR, 62304, GAMP5)
- **Per-industry capability decks + ROI one-pagers** and an outbound cadence per ICP

NOW · 0–6 MONTHS Credibility & access

- **Own ISO 13485 / a quality system** for NovintiX itself — proof you live the discipline
- **Notified-body & UDI-platform relationships;** cloud/tooling partnerships for co-sell
- **Thought-leadership engine:** a regulatory-intelligence newsletter + executive roundtables (the convener channel)

NEXT · 6–18 MONTHS Productize & scale delivery

- **AI-native product from the most-repeated service** — test-proof / V&V-evidence management → *ProofX* (see the ProofX launch plan)
- **Domain accelerators:** pre-built compliance frameworks & mappings per standard, sold as IP
- **Delivery playbooks + associate-engineer enablement** so standardized offers run without founder time
- **Data & analytics capability** for manufacturing-quality and PV

LATER · 18 MONTHS+ Platform & footprint

- **A small product portfolio** (ProofX + one adjacent tool) — recurring revenue alongside services
- **Retained-pod / managed-service model** at scale as base-load revenue
- **Onshore regulatory presence (US/EU)** and multi-geo delivery for global GCC buyers
- **Ecosystem positioning:** integrate with eQMS/ALM vendors; selective hire/partner/M&A for automotive & aerospace adjacency

Channels & motion

Land in the core (MedTech), expand into P1. Every MedTech win is a reference that opens a Pharma or Healthcare conversation about the same evidence problem under a different standard.

Founder-led + convener. Peer-to-peer outreach to the economic buyer and champion, plus small standards-themed roundtables ("Design Controls & UDI", "GxP Data Integrity", "SaMD V&V") to earn access across several accounts at once.

GCC corridor as a force multiplier. The India MedTech/pharma/healthcare GCCs concentrate the buyers — the flagship GCC-penetration motion (see the NovintiX GCC example) is the account-selection and buying-center engine for all three P1 segments.

Reference-led expansion. Case studies do the selling in a risk-averse market — invest in capturing and publishing them from day one.

The plans — 30, 90, 180 days and 1 year

30 days Package the core, open Pharma & Healthcare

Goal. Turn today's MedTech capability into a sellable catalogue and open the two Priority-1 segments.

- **Offer catalogue.** Publish fixed-scope offers with price bands for MedTech + a CSV/GAMP5 Sprint (Pharma) and a SaMD Assurance Pack (Healthcare).
- **Proof kit.** Draft the first MedTech case study and assemble sample artefacts (redacted DHF, V&V evidence, UDI records).
- **Target lists.** Build P1 account lists — pharma quality/manufacturing GCCs and digital-health/health-system targets — with buying-center roles.
- **First touches.** Launch founder-led cadences into 3 Pharma + 3 Healthcare accounts, each on a specific trigger (audit, EUDAMED, SaMD review, FHIR mandate).
- **Convener.** Date a "GxP Data Integrity & SaMD V&V" roundtable.

Exit. Offer catalogue live, 6 P1 accounts in active cadence, first case study drafted, roundtable dated.

90 days First P1 wins + credibility assets

Goal. Land the first Pharma and Healthcare micro-pilots and stand up the credibility assets that shorten the next sale.

- **Land P1.** Close 1 Pharma (CSV/GAMP5) and 1 Healthcare (SaMD/FHIR) micro-pilot on a fixed scope.
- **Proof engine.** Publish 2–3 case studies; capture references; ship the per-industry capability decks + ROI one-pagers.
- **IP.** Package the first accelerators (GAMP5 & 62304 mapping checklists, validation harness) as reusable assets.
- **Quality system.** Kick off ISO 13485 / internal QMS and open notified-body + UDI-platform partner conversations.
- **Reach-out probe.** Warm-intro one Aerospace or Automotive lighthouse to test the safety-critical adjacency.

Exit. 2 P1 pilots delivered/closed, 3 case studies live, accelerators packaged, QMS underway, 1 reach-out probe open.

180 days Expand P1 + start productizing

Goal. Grow P1 into repeatable revenue and begin turning the most-repeated service into a product.

- **Expand.** Convert the first P1 wins into device-family / system-wide engagements; open retained-pod conversations.
- **Repeatability.** Standardize the top offers with delivery playbooks so associate engineers run them without founder time.
- **Productize.** Scope the AI-native product (ProofX) from the V&V/test-proof service; start the MVP (see ProofX plan).
- **Roadmap the reach-out.** If the lighthouse probe landed, hire/partner for that domain (ISO 26262 or DO-178C) and build one adapted offer.
- **Thought leadership.** Run the roundtable series; ship the regulatory-intelligence newsletter monthly.

Exit. P1 expansions in motion, 2+ offers productized, ProofX MVP started, 1 reach-out offer defined, content cadence live.

1 year Multi-industry specialist with a product edge

Goal. Establish NovintiX as the go-to regulated-engineering specialist across MedTech + Pharma + Healthcare, with a productized edge and a foothold in one reach-out industry.

- **Balanced book.** Revenue across MedTech (core), Pharma and Healthcare; 1–2 retained pods as base load.
- **Product.** ProofX in market with early customers — recurring revenue alongside services.
- **Reach-out.** One safety-critical industry (automotive or aerospace) with a first reference and an adapted offer.
- **IP & brand.** A published accelerator/framework library; a recognized voice on regulated-product evidence.
- **Delivery engine.** Playbooks + associates run standardized offers; founders focus on new-logo landing, product and expansion.

2
(Pharma+Healthcare)
Priority-1 segments live

5+
Productized offers

5–7
Case studies /
references

1–2
Retained pods

1 (ProofX)
AI-native products

1
Reach-out references

Exit. 3-segment revenue balance, ProofX live with customers, 1 reach-out reference, retained pods, a scalable delivery engine.

Directional GTM research aid built on public information about NovintiX and its stated industries (medical devices, life sciences & healthcare, aerospace & defense, automotive, consumer electronics, industrial & heavy equipment). Prioritization and sequencing are recommendations, not commitments; validate against NovintiX's actual capacity, references and appetite before acting. Not affiliated with any named company.