WHITE PAPER

MODERNIZING MEDICAL DEVICE ENGINEERING

A ROADMAP FOR REGULATED DIGITAL TRANSFORMATION

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Executive Summary

Medical device engineering is entering a new phase. Cloud-native PLM and ALM platforms, agentic AI for software delivery, composable digital QMS and PMS solutions, modern MES with industrial data fabrics, and virtual verification are converging to reduce time-to-market while strengthening regulatory compliance. Recent advancements from Siemens, PTC, Oracle, Atlassian, ComplianceQuest, Veeva, Harness, Microsoft, AVEVA, Tulip, Ansys, COMSOL, and others indicate that these capabilities have matured from experimentation to enterprise-scale adoption across Life Sciences.

For MedTech and Pharma leaders, this convergence creates an opportunity to move beyond point solutions toward an integrated, regulated digital backbone that spans requirements, design, verification, release, manufacturing, and post-market surveillance. This white paper outlines the market drivers, technology landscape, Infosys point of view, and a practical adoption roadmap to help organizations realize speed with safety.

Industry Context and Drivers

> "Life sciences organizations are accelerating adoption of cloud-native platforms as these technologies mature to support compliance, scalability, and enterprisegrade operations across regulated environments."

Medical device and life sciences engineering is undergoing a structural shift driven by the convergence of digital engineering, manufacturing, and quality technologies. Software intensity, connected devices, and continuous post-market obligations have expanded regulatory scope while compressing development timelines. Regulatory frameworks such as **IEC 62304, ISO 14971, FDA 21 CFR Parts 11 and 820, and EU MDR and IVDR** increasingly require end-to-end lifecycle traceability, continuous risk management, and demonstrable process control across development, manufacturing, and post-market activities.

At the same time, many organizations remain constrained by legacy, on-premise point solutions and document-centric workflows that evolved in isolation. These environments are commonly characterized by:

- Fragmented PLM, ALM, QMS, MES, and PMS systems
- Manual handoffs between engineering, quality, regulatory, and manufacturing teams
- Limited continuity of the digital thread from requirements through post-market evidence
- High effort to demonstrate compliance at scale, particularly during audits, inspections, and regulatory change

As software content grows and portfolios span multiple regions and device classes, these constraints increasingly impact time-to-market, scalability, and operational efficiency—not just compliance.

> "Organizations are pivoting from AI experimentation toward production-grade deployments, with governance, transparency, and compliance becoming foundational to scaling AI in regulated industries."
>
> — IDC, MarketScape: Unified AI

In parallel, the enabling technology landscape has matured decisively. Cloud-native PLM and ALM platforms, composable digital QMS and PMS solutions, modern MES platforms with industrial data fabrics, virtual verification environments, and agentic AI for software delivery are now being deployed across regulated environments at enterprise scale. Validation-ready SaaS platforms, zero-trust security architectures, and enterprisegrade AI governance have substantially lowered historical adoption barriers.

Recent advancements from Siemens, PTC, Oracle, Atlassian, ComplianceQuest, Veeva, Harness, Microsoft, AVEVA, Tulip, Ansys, COMSOL, and others demonstrate that these capabilities have moved from pilot use into production-critical adoption across Life Sciences engineering, quality, and manufacturing operations.

For MedTech and Pharma leaders, this convergence represents a clear strategic inflection point:

- Compliance and speed are no longer opposing forces
- Quality is shifting from a downstream control function to an embedded operating model
- Digital continuity across engineering, manufacturing, and postmarket data is becoming a competitive differentiator

Organizations that move beyond isolated point solutions toward an integrated, regulated digital backbone are better positioned to scale innovation, strengthen regulatory confidence, and operationalize AI safely across the product lifecycle—delivering speed with safety as a sustained capability rather than a tradeoff.

Technology Landscape

Cloud PLM and ALM for Design Controls

Modern **cloud-enabled PLM and ALM platforms** form the backbone of digital product development in regulated Life Sciences environments. Solutions such as **Siemens Teamcenter X** and **PTC Windchill** provide enterprisescale product lifecycle management to support **Design History File (DHF)** management, **Bills of Materials (BOM)**, configuration control, and formal change management across mechanical, electrical, and software domains.

Complementing PLM, **application lifecycle management (ALM)** platforms such as **Siemens Polarion** and **PTC Codebeamer** provide endtoend traceability across requirements, risks, tests, defects, and releases in alignment with **IEC 62304, ISO 14971**, and FDA design control expectations. Together, PLM and ALM anchor the **digital thread**, enabling:

- Closedloop traceability from user needs and requirements through implementation, verification, and release
- Impact analysis for changes across requirements, risks, software, and documentation
- Consistent, inspectionready evidence generation across development lifecycles

Cloud deployment models further improve collaboration across distributed teams, suppliers, and partners while maintaining access control, audit trails, and validation readiness.

Digital QMS and PostMarket Surveillance

Next-generation **digital QMS and PMS platforms** are redefining how quality and post-market operations are executed. Platforms such as **ComplianceQuest** and **Veeva MedTech** support core quality processes including **complaints handling, CAPA, nonconformance management, audits, training, and regulatory submissions,** while providing structured data models and workflow automation.

Increasingly, these platforms embed **analytics and governed AI capabilities** to move beyond reactive quality management toward proactive risk detection and regulatory readiness. Key capabilities include:

- Faster complaint intake and triage through guided workflows
- Trend detection across complaints, deviations, and field data
- Closedloop linkage from complaint → investigation → CAPA → effectiveness verification

In postmarket surveillance, **governed AI** can accelerate high-effort activities such as **signal intake, similarity and de-duplication, narrative drafting, and reportability pre-checks,** while preserving full traceability and human oversight. When properly governed, AI augments — rather than replaces — quality judgment, enabling scalable PMS operations without compromising auditability.

AI-Native SDLC and DevOps

AI-native software delivery platforms are reshaping the "after code" stages of regulated software engineering. Solutions such as **Harness AI, Azure DevOps with Copilot, GitHub Copilot, and Atlassian Jira with Rovo AI** increasingly act as **controlled execution agents** across testing, CI/CD pipelines, security scanning, documentation generation, and release orchestration.

In regulated environments, these capabilities are most impactful when applied to **structured, repeatable, non discretionary tasks**—and operated under explicit governance models aligned with **IEC 62304, GAMP 5, and FDA 21 CFR Part 11**. When coupled with human-in-the-loop approvals and audit trails, AI native DevOps enables:

- Accelerated validation and regression testing cycles
- Consistent enforcement of quality gates and security controls
- Automated generation of traceable evidence and documentation artifacts

For Life Sciences organizations, this translates to faster iteration cycles without sacrificing engineering judgment, as AI augments delivery discipline while maintaining traceability, accountability, and inspection readiness.

Manufacturing and Industrial Data Platforms

On the manufacturing floor, **MES and industrial data platforms** provide the foundation for digitally integrated, regulated operations. **Siemens Opcenter** supports electronic DHR/eBR, genealogy, and review by exception workflows, while **AVEVA PI System** delivers high fidelity time series data and analytics across equipment, processes, and facilities. Tulip enables low code, validated applications that digitize frontline operations while integrating with MES and quality systems.

Together, MES and a **hybrid industrial data fabric (edge → plant → cloud)** underpin:

- Electronic batch and device history records
- Genealogy and lot traceability across complex supply chains
- Continuous Process Verification (CPV) and OEE analytics

Where **Lab Informatics (ELN, LIMS, CDS)** platforms are in scope, interoperability with QMS and MES accelerates deviation investigations, root cause analysis, and regulatory evidence packaging—shortening cycle times for both operations and audits.

Simulation and Digital Twins

Advanced **simulation and digital twin platforms** such as **Siemens Simcenter, Ansys**, and **COMSOL** enable virtual verification and validation through multiphysics modeling and in-silico testing. These tools allow organizations to explore design alternatives, assess risk scenarios, and validate performance earlier in the development lifecycle.

When integrated with PLM and ALM systems, simulation outputs strengthen the digital thread by linking computational evidence directly to requirements, risks, and verification activities. Key benefits include:

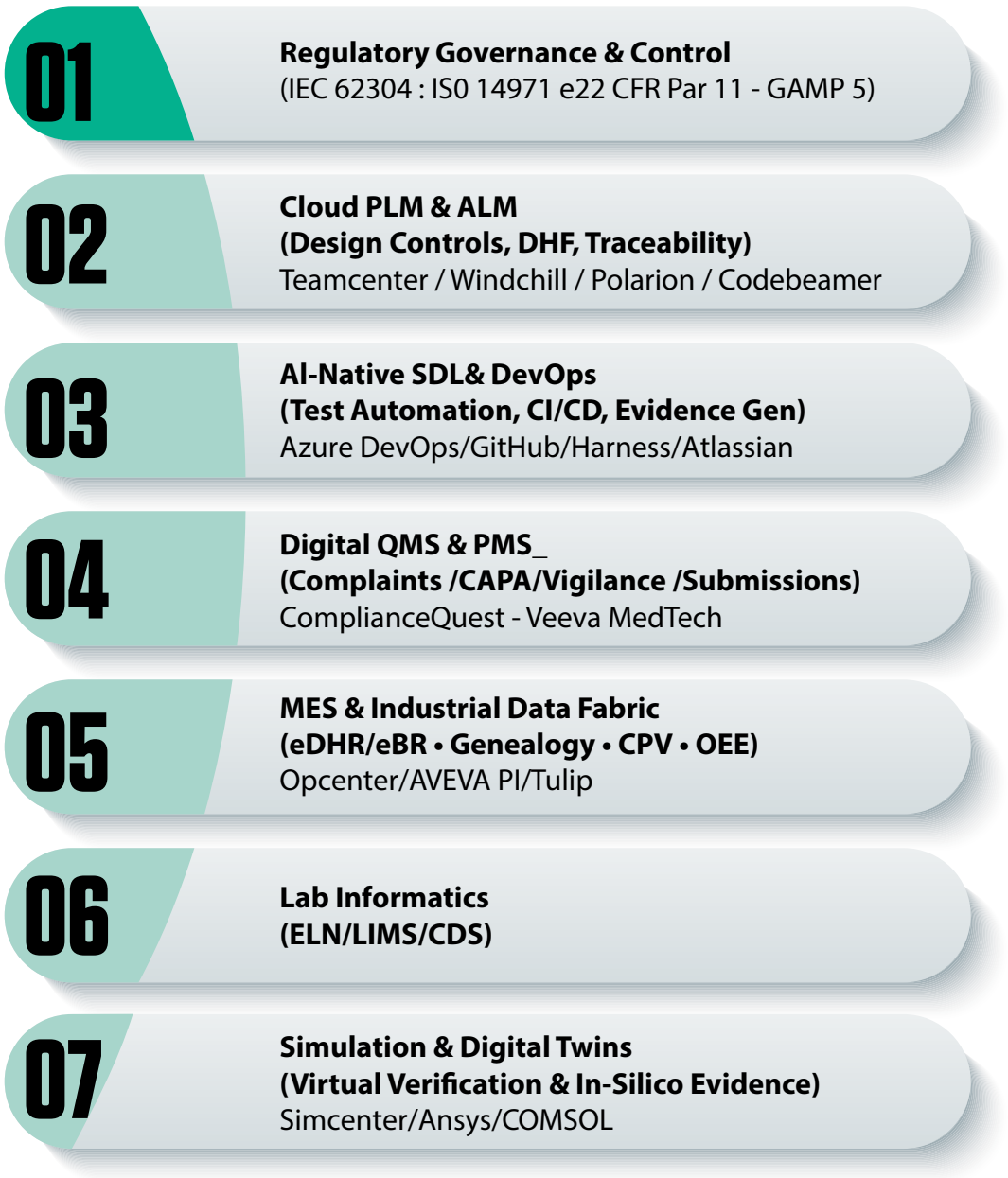
- Reduced reliance on costly physical prototypes
- Faster design iterations and design freeze decisions
- Support for regulatory submissions with computational and virtual evidence

As regulatory acceptance of modeling and simulation continues to advance, digital twins are becoming a practical lever for improving both **development speed and regulatory confidence.**

Infosys Point of View

Infosys recommends adopting an **Integrated Regulated Engineering Backbone** to address the growing complexity of medical device and life sciences product development. Rather than optimizing individual tools or functions in isolation, this approach establishes a cohesive, end-to-end digital foundation that connects engineering, quality, manufacturing, and post-market processes through a governed digital thread.

The Integrated Regulated Engineering Backbone combines **cloud-enabled PLM and ALM, AI-native SDLC and DevOps, digital QMS and PMS, MES with industrial data fabrics, and simulation-driven verification** into a unified architecture. Each layer is implemented with explicit regulatory intent, enabling traceability, auditability, and validation readiness by design—not through after the fact reconciliation.



This backbone enables organizations to:

- Embed compliance and quality directly into day-to-day engineering and operational workflows
- Scale software-intensive and data-driven products without disproportionate increases in validation effort
- Accelerate development, release, and manufacturing cycles while maintaining regulatory confidence

Critically, the objective is not tool consolidation, but **orchestration**—ensuring that data, workflows, and evidence flow seamlessly across systems, lifecycle stages, and organizational boundaries.

Governed AI as an Accelerator, Not a Risk Multiplier

Infosys views **AI as a force multiplier for regulated execution**, not an autonomous decision engine. Within the Integrated Regulated Engineering Backbone, AI is applied selectively to **structured, repeatable, non discretionary activities**—such as testing, documentation generation, signal triage, and analysis—under explicit governance and human oversight.

This "governed acceleration" model allows organizations to benefit from AI-native platforms while preserving:

- Clear accountability and role based approvals
- Immutable audit trails and version control
- Traceability across requirements, risks, and evidence artifacts

By aligning AI usage with IEC 62304, GAMP 5, and FDA 21 CFR Part 11 expectations, Infosys helps clients operationalize AI safely and at scale—without introducing validation debt or regulatory risk.

Enabling Value Through a Connected Partner Ecosystem

The Integrated Regulated Engineering Backbone is delivered through a **broad, partner-aligned ecosystem**, rather than a single vendor stack. Cloud PLM and ALM platforms, next-generation eQMS and PMS solutions, MES and industrial data platforms, lab informatics, simulation tools, and AI-native SDLC technologies are sourced from leading providers including **Siemens, PTC, Oracle, AVEVA, Veeva, ComplianceQuest, Atlassian, Microsoft, and others.**

Infosys partners deeply across this ecosystem, enabling organizations to benefit from:

- **Pre-validated and reusable integration patterns** across engineering, quality, manufacturing, and post market systems
- **Harmonized data models** that support traceability and impact analysis across lifecycle stages
- **Proven implementation accelerators** for regulated environments, reducing time to value

This partner-agnostic approach ensures that clients can build an interoperable, inspection-ready digital thread across design controls, quality, manufacturing, and post market processes—**without forcing consolidation onto a single vendor platform** or disrupting existing investments.

Outcome-Driven Transformation

By adopting an Integrated Regulated Engineering Backbone, Life Sciences organizations move beyond incremental digitalization toward **structural capability change**. Quality and compliance shift from downstream controls to embedded behaviors. Data transitions from siloed records to lifecycle-wide evidence. AI becomes a governed accelerator rather than a source of uncertainty.

Infosys' role is to design, orchestrate, and operationalize this backbone—helping clients achieve **faster innovation with safety**, at enterprise scale.

Infosys Point of View

Successfully implementing an Integrated Regulated Engineering Backbone requires a **phased, value-led adoption strategy** rather than a "big-bang" transformation. Infosys recommends a staged approach that balances speed with safety, allowing organizations to demonstrate value early while progressively expanding scope, integration, and automation under regulatory control.

Phase 1: Establish the Digital Foundation (PLM, ALM, and Data Readiness)

The journey begins by stabilizing and modernizing the **engineering system of record.** Organizations should prioritize targeted pilots in **cloud-enabled PLM and ALM,** focusing on design controls, requirements management, traceability, and change impact analysis. This phase establishes the digital thread that will anchor all subsequent capabilities.

Key objectives in this phase include:

- Migrating or modernizing PLM and ALM platforms to support DHF, requirements, risks, and verification artifacts
- Standardizing data models, naming conventions, and lifecycle states
- Establishing baseline traceability, audit trails, and validation practices

By starting with design and development, organizations minimize downstream risk and create a reference architecture that can be reused across products and programs.

Phase 2: Scale Quality and AI-Enabled Delivery Capabilities

Once the engineering backbone is in place, organizations can layer in digital QMS and PMS capabilities alongside AI-native SDLC and DevOps automation. This phase focuses on scaling execution while preserving regulatory rigor.

Key priorities include:

- Integrating QMS and PMS platforms to enable closed-loop quality, from complaints through CAPA and effectiveness verification
- Introducing governed AI for structured, repeatable activities such as test execution, documentation generation, and signal triage
- Implementing human-in-the-loop approval gates and inspection ready evidence generation

This phase delivers measurable benefits in cycle time, audit readiness, and operational efficiency, while maintaining clear accountability and traceability.

Phase 3: Extend into Manufacturing and Operations

With engineering and quality systems stabilized, organizations can then extend the digital backbone into **manufacturing and operations.** This phase connects design intent and quality controls directly to execution on the shop floor.

Key activities include:

- Deploying or modernizing MES to support eDHR/eBR, genealogy, and review-by-exception
- Establishing an industrial data fabric that connects edge, plant, and cloud systems
- Integrating MES, QMS, and lab informatics to accelerate deviations, root-cause analysis, and evidence packaging

By sequencing manufacturing after foundational systems, organizations avoid brittle integrations and ensure that production data becomes first class regulatory evidence rather than operational exhaust.

Phase 4: Introduce Virtual Verification and Digital Twins

In the final phase, organizations can unlock advanced capabilities through **simulation-driven verification and digital twins.** These capabilities are most effective once the digital thread and governance models are firmly established.

Key outcomes of this phase include:

- Earlier risk identification through virtual testing and in-silico validation
- Reduced dependence on physical prototypes and late-stage testing
- Stronger computational evidence linked directly to requirements and risks

This phase enables continuous improvement across design, manufacturing, and post-market activities—closing the loop across the full product lifecycle.

Guiding Principles for Adoption

Across all phases, Infosys emphasizes a common set of principles:

- **Value at every stage:** Each phase delivers measurable business and compliance outcomes
- **Governance by design:** Validation, traceability, and auditability are embedded, not added later
- **Orchestration over consolidation:** Integration across systems matters more than replacing them
- **AI as a controlled accelerator:** Automation augments expertise without replacing accountability

Outcome

By following this phased roadmap, Life Sciences organizations reduce transformation risk while progressively building toward a fully integrated, regulated digital backbone. The result is not just modernized tools, but a **sustainable operating model** that supports faster innovation, stronger quality, and regulatory confidence at scale.

Expected Outcomes and KPIs

Adoption of an Integrated Regulated Engineering Backbone is expected to deliver **measurable improvements across engineering efficiency, quality performance, regulatory readiness, and time-to-market.** Typical outcomes include stronger end to end traceability, shorter release and validation cycles, faster complaint triage, reduced audit preparation effort, and improved responsiveness in both manufacturing and post market activities. To demonstrate value realization, organizations should baseline key metrics before transformation and track a focused set of KPIs as capabilities are rolled out across phases, using them both to report progress and to guide ongoing optimization.

Representative Outcomes and KPIs

Lifecycle Area	Expected Outcomes	Representative KPIs
Engineering & Design Controls	Improved traceability and reduced rework	• % of requirements with bidirectional traceability (requirements ↔ risks ↔ tests ↔ releases) • Average time to complete design change impact analysis • Number of audit findings related to design controls
Software Delivery & Validation	Faster, more predictable releases with lower validation effort	• Release cycle time (code complete → production) • % of automated vs. manual test cases • Validation effort per release (hours/FTEs) • Defects escaping to post release
Quality Management & PMS	Faster issue resolution and improved regulatory responsiveness	• Average complaint triage time • Time from complaint receipt to investigation closure • CAPA cycle time and on time effectiveness verification rate • Late or corrected post market submissions
Manufacturing & Operations	Increased efficiency and stronger production evidence	• % of batches reviewed by exception • Deviation rate per batch or lot • Time to assemble audit ready manufacturing evidence • OEE and CPV trend stability
Verification, Validation & Simulation	Earlier risk detection and shorter V&V cycles	• Reduction in number of physical prototypes • Time spent in verification and validation phases • % of verification coverage supported by virtual or in silico testing

Conclusion

Path-breaking digital tools are fundamentally reshaping how medical devices are designed, built, validated, manufactured, and sustained across their lifecycle. Cloud-native engineering platforms, governed AI, digital quality systems, connected manufacturing, and virtual verification are no longer emerging capabilities—they are becoming essential enablers for operating at scale in a regulated, software intensive environment.

By aligning technology investments with regulatory expectations and a clear operating model—anchored by an **Integrated Regulated Engineering Backbone**—Life Sciences organizations can embed quality and compliance into everyday execution rather than treating them as downstream controls. This approach enables faster development and release cycles, stronger inspection readiness, and more resilient post-market operations without compromising patient safety or product integrity.

Organizations that act decisively now will be better positioned to manage regulatory complexity, scale innovation confidently, and sustain competitive advantage through FY27 and beyond—delivering **speed with safety** as a repeatable capability, not a trade off.

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