Veeva MedTech

WHITE PAPER

Building a Strategic Enterprise Architecture for Medtech

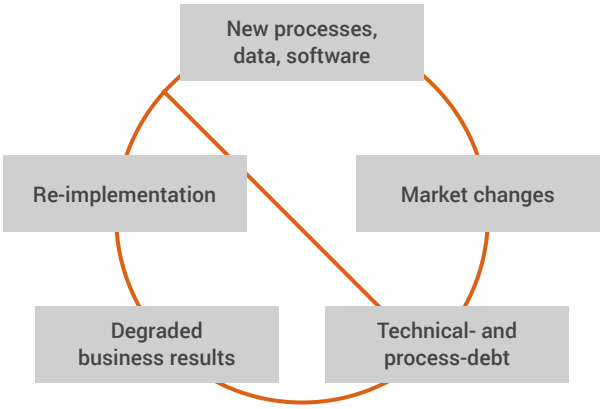
Enterprise architecture often focuses primarily on selecting pillar platforms. The guiding principle is to establish a core set of high-capability pillar platforms and to drive transformation to that end state.

Yet standing up pillar applications for maximum benefit depends on understanding the interactions among these applications and other key aspects of broader enterprise architecture like organizational design, legal entity structure, process capabilities, and market geographies.

Pillar application architecture also depends on key adjacent technical decisions, like integration standards, data strategy, and cloud strategy. Cloud-native SaaS applications can help cut through the complexity of these decision factors by streamlining deployment and future proofing through cloud application partners' commitment to innovation.

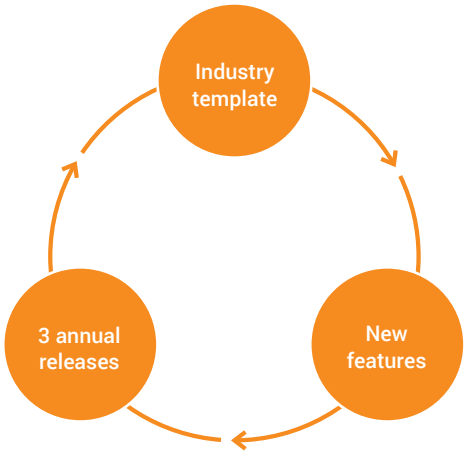
For life sciences and medtech companies in particular, selecting applications purpose-built for the industry drives simplification, standardization, and scalability versus products that are force-fit and generally require heavy configuration or customization to meet industry needs.

ON PREM AND **NON-NATIVE** CLOUD



INEFFICIENT CAPITAL RE-INVESTMENT CYCLE

NATIVE MULTI-TENANT CLOUD



EVERGREEN, APPRECIATING ASSET

Multi-tenant SaaS investments based on purpose-built applications are in effect appreciating assets that evolve as industry regulations and requirements evolve, rather than depreciating assets that entail a 5-to-7-year capital refresh cycle.

This white paper explores how these components fit together to optimize enterprise value, scale, and flexibility through mission-critical application architecture decisions.

A strategic perspective on enterprise application architecture through strategic, multi-faceted enterprise design is of particular importance for medtech enterprises, which commonly have a high degree of complexity both organizationally and technically, and thus can drive significant benefits from a thoughtful and systematic approach accelerated by cloud.

This simplifying approach is especially critical for medtech, which typically has complex legacy systems and data; heavy merger, acquisition, and divestiture activity requiring continuous integration and separation; and often is decentralized in business unit structure and governance.

GROWTH STAGE IMPLICATIONS

M&A and customized legacy processes are both key drivers for medtech technology, process, and data complexity. Both of these factors scale with size, ultimately turning a manageably complex enterprise design at revenues under $1 billion into an exponentially greater challenge in larger enterprises.

On the growth journey, attaining a simplified and standardized architecture sooner than later provides a solid foundation for growth without overbuilding capabilities and capacity. Conversely, under-investment in foundational capabilities and systems while medtech firms are smaller tends to result in excess process and application complexity that is difficult to unwind.

For smaller medtechs, choosing software that embeds industry best practices is an excellent way to defend against encroaching process complexity while maintaining key competitive, differentiating capabilities.

Larger medtechs can benefit by establishing a small business unit or geography as a lighthouse design to prove out the application architecture to the broader enterprise.

To drive a holistic strategic enterprise architecture design, consider the following major dimensions:

Strategic Elements

- Organizational
- Financial
- Geographical/market

Capability Elements

- Process
- Physical flow of materials
- Risk

Technical Elements

- Application
- Data & Analytics
- Integration
- Technical infrastructure & cloud

Underlying each major dimension are several sub-dimensions, as depicted in the following table, that represent key elements of analysis indicated to drive a holistic enterprise design.

Strategic capability mapping is typically the first step in application selection and design, but taken in isolation tends to sub-optimize the opportunities, challenges, and hard constraints consequential to deriving benefits from a holistic design approach.

Each major dimension is thus shown below with one or more key questions to inform pillar application architecture design and decisions important to medtech companies.

Strategic Elements

Organizational 	• **Business units, shared services, service placement** • **Governance** • **Third party distributors** • **Large partners/strategic partnerships** *Do you have a key user census with clarity on organizational requirements, including access for partners and contractors?* *Are there any large strategic partnerships that are using separate or captive applications that affect your capability maps, data standards, or integration needs?*
Financial 	• **Legal entity structure** • **Tax** • **Treasury** *Are legal manufacturers clearly mapped to legal entities to applications, including required buy/sell and financial inventory transactions?* *Note: This is potentially consequential for tax strategy execution.*

Strategic Elements

Geographical/ Market

- People
- Channels
- Market entry/exit

How will sales execution and sales operations function within differing go-to-market models and channels, especially for new market/product entry?

Are capability and application requirements clear – both to operate in and to serve emerging markets?

THE CENTRALITY OF REGISTRATIONS

The ability to register and re-register products is frequently a gating factor for medtech enterprise transformation roadmaps. Re-registration is often mandated by change control, shared services strategy, tax strategy, and so on. This process can take up to several years, depending on the market and the Health Authorities (HA) involved. Because registrations drive revenue for medtech companies, ability to inventory registrations, assess change impacts, and orchestrate registration/re-registration timing is an especially crucial capability to drive transformation and growth. Conversely, errors in executing this process can create significant compliance risk and financial exposure, as well as slowing down transformations.

Not only are regulatory applications critical to growth and compliance, but they underscore the importance of integrated design. For example, maintaining local market compliance requires ERP integrations and common data standards, which can be automated in publishing to global Health Authorities.

Regulatory as a key integrated capability thus both enables and drives growth and speed of new market entry and market expansion.

Capability Elements

Process

- Definitions for pre- to post- market: Clinical/R&D, commercialization, sales, manufacturing, distribution, post-market
- Supply chain
- Major insource/outsource considerations

Does your overall business and competitive strategy align to which capabilities are table stakes versus differentiating?

For medtech sub-verticals, have industry-specific sub-process capabilities been cataloged (e.g., HA interactions, medtech-specific clinical trial stages, field inventory, etc.)?

How are partners harvesting evolving customer, industry, and HA requirements to expand table-stakes and improve differentiating capabilities?

M&A Spotlight

A core set of rationalized pillar applications speeds execution and time to value for mergers, acquisitions, and divestitures, while reducing cost and risk. Cloud SaaS enables this preferentially over both traditional on-premise and cloud "hosted" applications by better scalability and elasticity. Reduced customization in solutions purpose-built for the medtech industry helps provide a simplified "docking station" for M&A transactions and enables simplified carve-outs for divestitures. As well, speed reduces intrinsic integration/separation costs in addition to avoiding punitive transition service agreement extensions.

Of course, a strategic integrated design reduces integration friction as well, since new business units generally arrive with their own footprint across all ten core dimensions. A well thought-out sales execution approach, distribution network, and global regulatory strategic capabilities, for example, will help maximize the growth synergy proposition that motivates most M&A transactions.

Capability Elements

Physical Flow of Materials

- Physical network, plants, property, equipment
- Manufacturing, distribution/hubs, sterilization
- Field and consigned inventory

What is the financial inventory accounting system of record for each network node and major type of inventory?

Which facilities in which entities are insourced/outsourced legal manufacturers?

Note: This decision impacts integration design and financial inventory risk controls, as well as gross profit elimination and reporting by region and entity.

Risk

- HA, statutory, and regulatory compliance
- Cyber security
- Financial (controls, commodity/input, currency, sovereign)

Have you experienced quality or compliance risks and costs due to outdated legacy applications with inadequate controls?

Note: It's critical to consider overall risk management as a macro-capability.

Technical Elements

Applications

- ERP, PLM, CRM, R&D
- Capability mapping to pillar applications
- Instance strategy / logical architecture of major applications

Are there clearly documented current, interim, and future state application architectures, including capability overlap and deconfliction mapping, and the identification of any un/underserved areas?

Can you avoid customization by using applications that are purpose-built for medtech?

Do your cloud partners have underserved areas on their development roadmaps?

Data & Analytics

- System of record for transactional, master, and reference data
- Data/records retention
- BI/AI/reporting
- Access requirements and security
- Privacy & sovereignty
- Data sourcing: Third party/market/government data vs. internal enterprise data

For critical data, is the source of truth understood, as well as where core data will be passed to other applications and data lakes/EDWs?

Can cloud SaaS partners address data sovereignty requirements for these markets?

Are trusted third party sources used where available (e.g., for HCP data)?

Note: This assessment frequently impacts the boundary definitions of applications.

What about AI?

AI is top of mind for IT and business leaders, with significant promise of innovation and efficiencies. Successful AI strategy and execution needs a *horizontal* combination of key dimensions of strategic enterprise design, rather than a separate, standalone design dimension. In particular, all of the technical components of a sound architecture are essential for AI:

- Pillar **applications** are key for digitized processes and trusted transactional and master data.
- **Integration** design is crucial for data interoperability and refresh.
- **Data & analytics** are paramount since AI is largely "made of" data, external and internal data sourcing, data engineering, and data management capabilities
- **Technical infrastructure & cloud** is foundational for AI & ML production technology, automation, and hosting models and data sets.

In addition, **risk** considerations ground security, privacy, and AI ethics/ transparency, while a sound process architecture allows targeted augmentation and automation of business workflows, which will ultimately drive AI speed, strategic innovation, and efficiencies.

Technical Elements

Integration 	• How applications communicate, both internally and externally • Pub/sub model with hub/spoke; integration standards • Partner communications (suppliers, customers, technical partners) • Government, regulatory, HA communications and filings *What are the emerging automated filing requirements by regulators?* *Are the appropriate data standards, applications, and integration components in place to support required automated reporting, for example for regulatory filings or post-market surveillance?*
Technical Infrastructure & Cloud 	• Cloud • Data center • Hybrid *Have cloud/data center buy/make/hybrid decisions been carefully evaluated? How stable are these decisions?* *Is there a high switching cost among providers and options?* *Note: This will impact storage and compute financials vis-à-vis retention, archiving, and data security; flexibility of deployment and TCO tends to favor cloud software providers significantly.*

A few integrated examples that touch on multiple core architectural dimensions illustrate the importance of holistic analysis supporting enterprise design and execution.

Governance

Logical (or "instance") design of applications in the architecture critically depends on companies' governance capabilities across multiple business units, shared services, or geographies. From a technical standpoint, application architects generally want to minimize logical instances, as having fewer instances tends to reduce cost and complexity. This is particularly true for cloud native SaaS where disaster recovery, failover, and performance are largely solved problems when using trusted partners.

However, an inability to govern processes almost inevitably leads to excess uncontrolled customization or configuration variants. This is particularly the case in large, decentralized medtechs with diverse business units and therapeutic areas. Thus, organizational maturity needs to influence the logical application design, which has corresponding implications for the data, integration, and risk components of the overall enterprise design. And correspondingly, the transformation roadmap should lay out future governance evolution to support a more consolidated, simpler enterprise design.

Governance complexity can be managed—if not completely neutralized—through modern SaaS applications that are modularly deployable in an agile roadmap and have built-in innovation upgrades over time. Purpose-built SaaS applications maximize flexibility and scalability, both technically and organizationally, so that as larger medtechs build shared services or acquire new businesses, the technology landscape becomes an enabler rather than a constraint.

Seamless Upgrades	Data Backups	Disaster Recovery	Elastic Content Storage	>99.5% High Availability	Global HA Compliance Ready
Global Access Data Sovereignty	Penetration Testing Multilayer Security	Real-time Performance Monitoring	Point + Click Administration	Configuration Management	

Tax Strategy

Tax strategy execution depends on the interplay of several key design dimensions. For example, regional or country-specific incentives often require the local establishment of a new organization with statutory materiality requirements for (e.g.) planning, manufacturing or distribution hubs. These hubs frequently call for more advanced capabilities, but also can have a long lead time to operationalize and may require the establishment of new legal entities or change in existing legal entities. Any strategies that impact physical material flow will depend on fixed asset buy/make decisions. Data sovereignty and The goal of enterprise transformation is to create competitive advantage by driving profitable, compliant growth through bringing new therapies to market. Holistic strategic enterprise architecture design is a key enabler to creating both a blueprint and a roadmap for that transformation.

Sustainability

Emerging sustainability compliance requirements will likely necessitate full lifecycle carbon footprint reporting for products. This will require not only consideration and ultimately measurement across the physical flow of materials in the fixed asset network, but also capturing the landed carbon footprint of incoming materials from suppliers and additional footprint tracking of inter-network transport carbon emissions scope. Current ERP applications are likely inadequate to this task, underscoring the need for supplier management application capabilities for inbound carbon footprint as well as integration using approved data standards with regulators for automated compliance reporting.

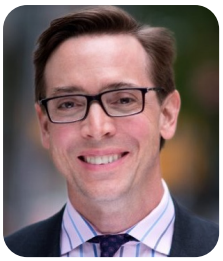
Conclusion

The goal of enterprise transformation is to create competitive advantage by driving profitable, compliant growth through bringing new therapies to market. Holistic strategic enterprise architecture design is a key enabler to creating both a blueprint and a roadmap for that transformation.

Speed is essential to this outcome. Not only speed of roadmap execution, but also speed of business decisions and orchestration based on metrics and data are paramount. Decision speed depends on key dimensions of the enterprise blueprint: having the right pillar applications that support key industry capabilities, along with a data and analytics strategy, and mapping these to the right analysts and leaders organizationally to drive execution based on facts and data.

While integrated strategic enterprise architecture is typically complex in medtech companies, cloud-native SaaS is a key vehicle for simplifying design and design-related decisions, particularly where cost-effective medtech industry-specific capabilities can be deployed at scale.

Author



Chris Knerr
Vice President, Technology Strategy, Veeva MedTech
chris.knerr@veeva.com

Chris Knerr is responsible for helping Veeva MedTech's CIO and IT leadership customers maximize the value of their digital transformation strategy and roadmap. He is a seasoned medtech executive and industry leader—both as a practitioner and an entrepreneur—whose experience and expertise spans from leading mega-programs at Johnson & Johnson to serving as the Chief Digital Officer for a PE portfolio firm, to co-founding and leading an AI/ML tech startup. Chris holds a BA in Philosophy from Columbia University and an MBA from Cornell University, where he has been a periodic guest lecturer in digital transformation, analytics strategy, and "real-world project management."