Three Pillars for Business Transformation in the Digital Age

How Agile Organization, Product Lifecycle Management and Embedded Legal Compliance Engineering will shape successful products of the future

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Will your organization lead your industry in 10 years?

Re-inventing business models in the digital age requires companies to **move faster than ever**, while navigating an increasingly complex regulatory environment. Software, with AI as its most prominent manifestation, has become the **primary driver of this transformation**, reshaping how products are designed, delivered, and continuously adapted to customer needs in real time.

As software updates introduce new functionality and mitigate security risks, they increasingly **resemble new products rather than incremental changes**.

This acceleration is **collapsing technology cycles from years to mere months**. At the same time, regulatory requirements are expanding exponentially, forcing organizations to comply with more rules in less time. The resulting tension is not rooted in technology itself, but in the **ability to translate rapid product evolution into compliant, scalable, and mass-customized market offerings**.

Success in this environment depends on mastering **three interdependent capabilities:**

a) **End-to-end transparency of product data** across the entire product lifecycle,

b) **an Agile Organization** with the ability to convert these insights into market outcomes at speed and

c) **Embedded Legal Compliance Engineering**, tightly integrated into product development and operations, becoming a catalyst for innovation rather than a constraint.

Companies that excel at **aligning speed**, **software-driven innovation**, **and regulatory discipline** will redefine competitive advantage. Just as clear standards once enabled Bavarian beer to gain global recognition, organizations that **master today's regulatory complexity faster and more effectively than their peers** will not only keep pace with change, but they will also shape their markets.

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Agenda

1

Key Challenges for Business Transformation

CEOs worldwide see urgent need for transformation need amid regulatory barriers and technological disruption

42%

Believe their companies would **no longer be viable** in ten years' time, if they continue their current path[1]

#1

For these CEOs, regulatory environment ranks **no. 1 barrier for business model re-invention**[1]

57%

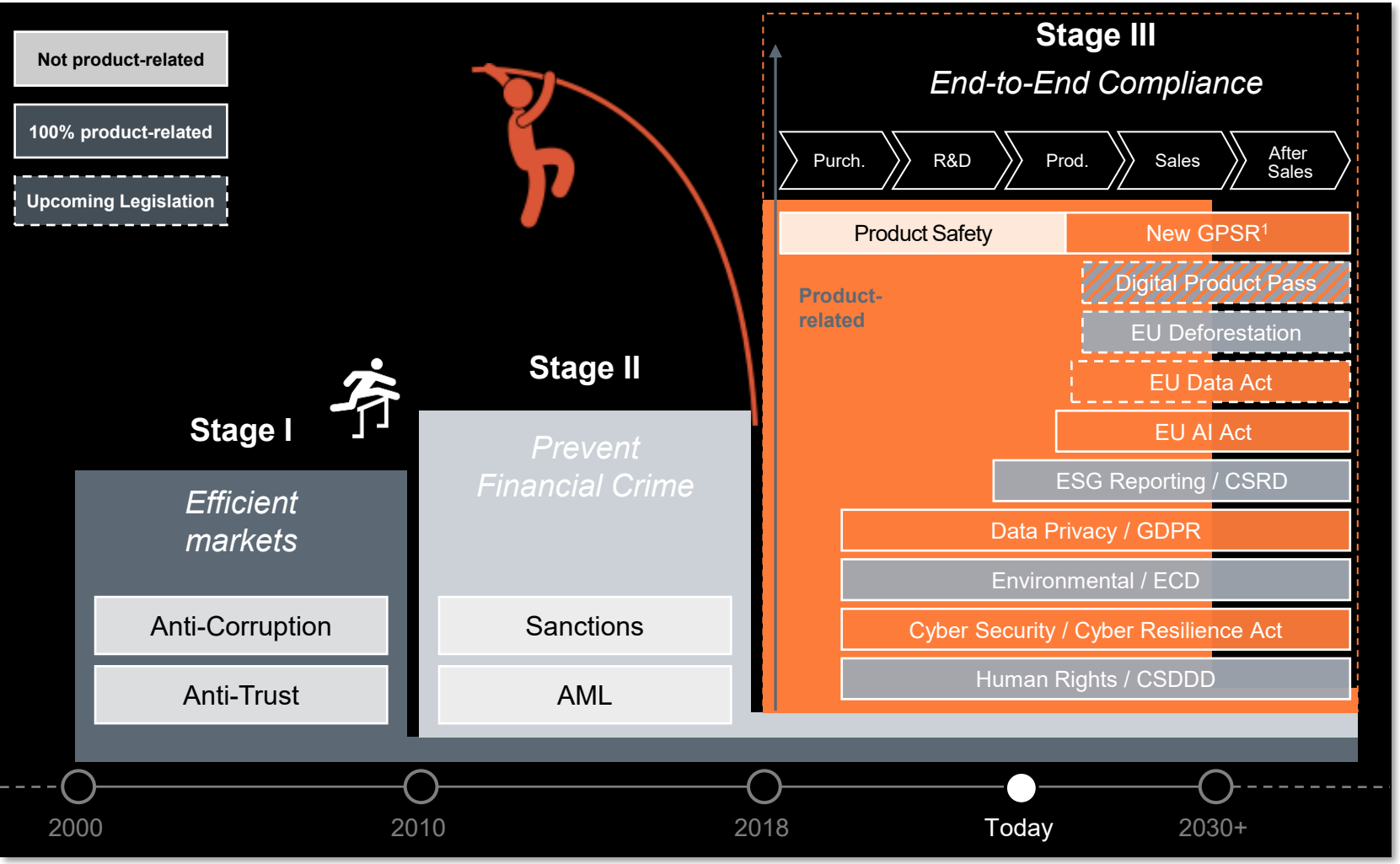
of German CEOs see **transformation speed as a top concern**, fearing they are not adapting fast enough to the pace and scale of technological change, especially AI[2]

[1] PwC's 28th Global CEO Survey | [2] PwC's 29th Global CEO Survey

How can this **major challenge be turned into a competitive advantage?**

Why is the regulatory environment so challenging?

“Follow the product” instead of “Follow the money” – regulation now addresses the entire value chain



Regulation is accelerating, shifting from "follow the money" (as in tracking financial flows and trans-actions) to "follow the product" (as in tracing goods, materials and their impact). This extends regulatory oversight **across the entire value chain**.

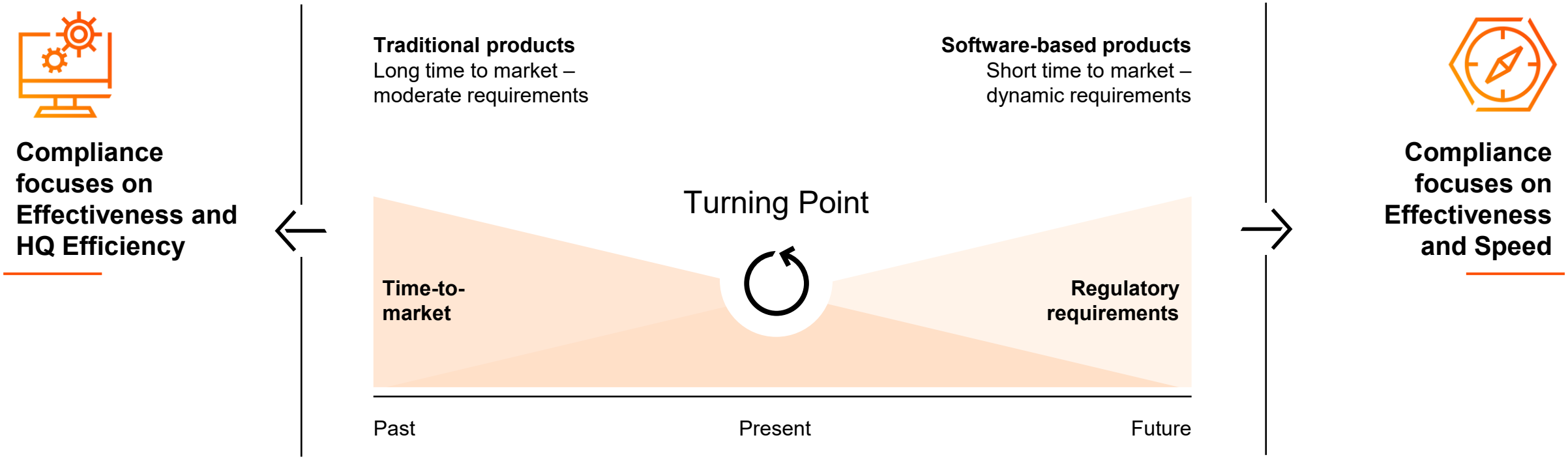
As requirements grow more complex and interconnected, **traditional compliance structures prove too slow and fragmented**. Innovation stalls, decision-making slows down, and market opportunities are missed.

Forward-looking organizations respond by embedding compliance into **end-to-end, agile workflows and leveraging automation and AI to keep pace**.

As corporate fines are increasingly linked to revenue and product responsibility, compliance requirements add **growing complexity to product development**. And those who master these requirements move faster, turning compliance **from a safeguard into a decisive driver of competitiveness and sustainable growth**.

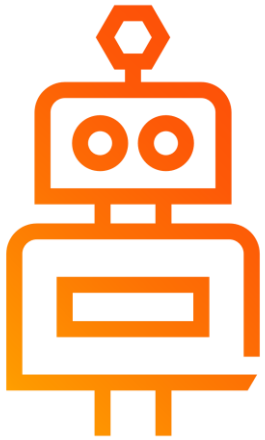
[1] General Product Safety Regulation

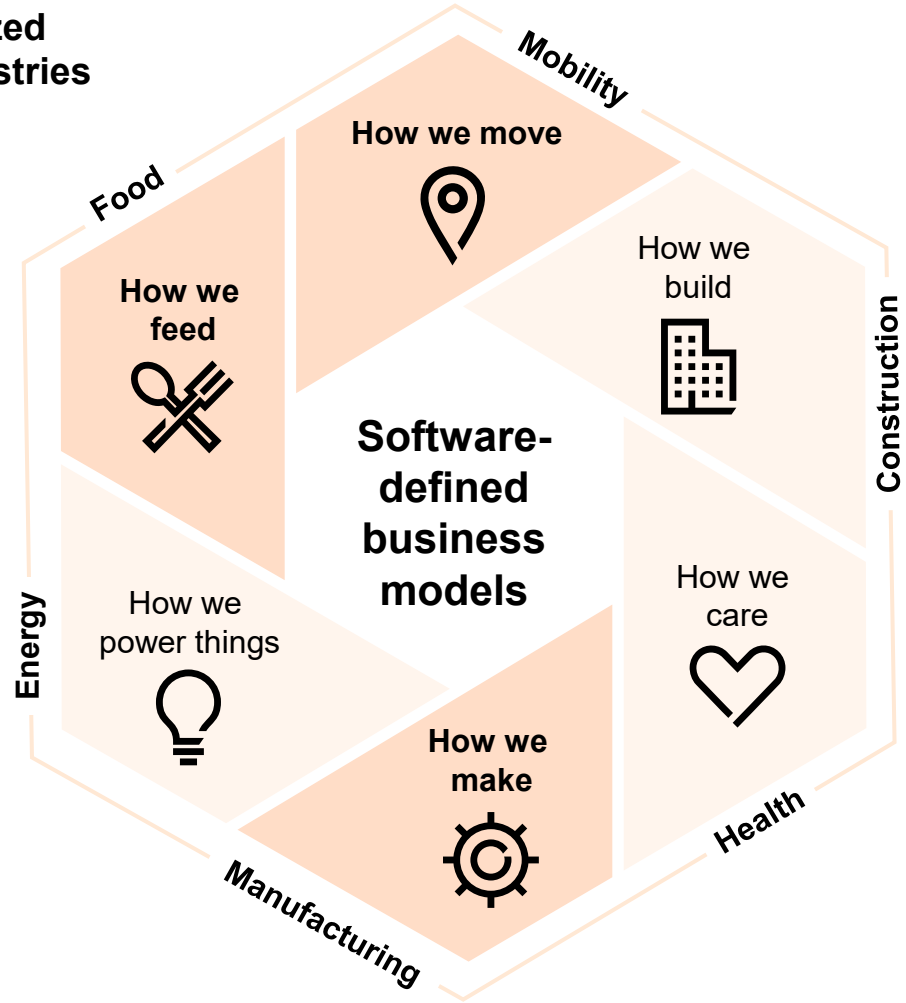
Software-based and AI-enhanced products require a new Compliance perspective



Software-defined and AI-enhanced business models re-shape all industries and require a new perspective on Compliance

Software & AI push individualized products that re-shape all industries





Software is reshaping every industry, because it allows companies to **capture customer behavior**, **respond to preferences within days** rather than months, and **individualize products at scale**.

Combined with automated manufacturing, **this enables true mass customization**: global scalability with local relevance.

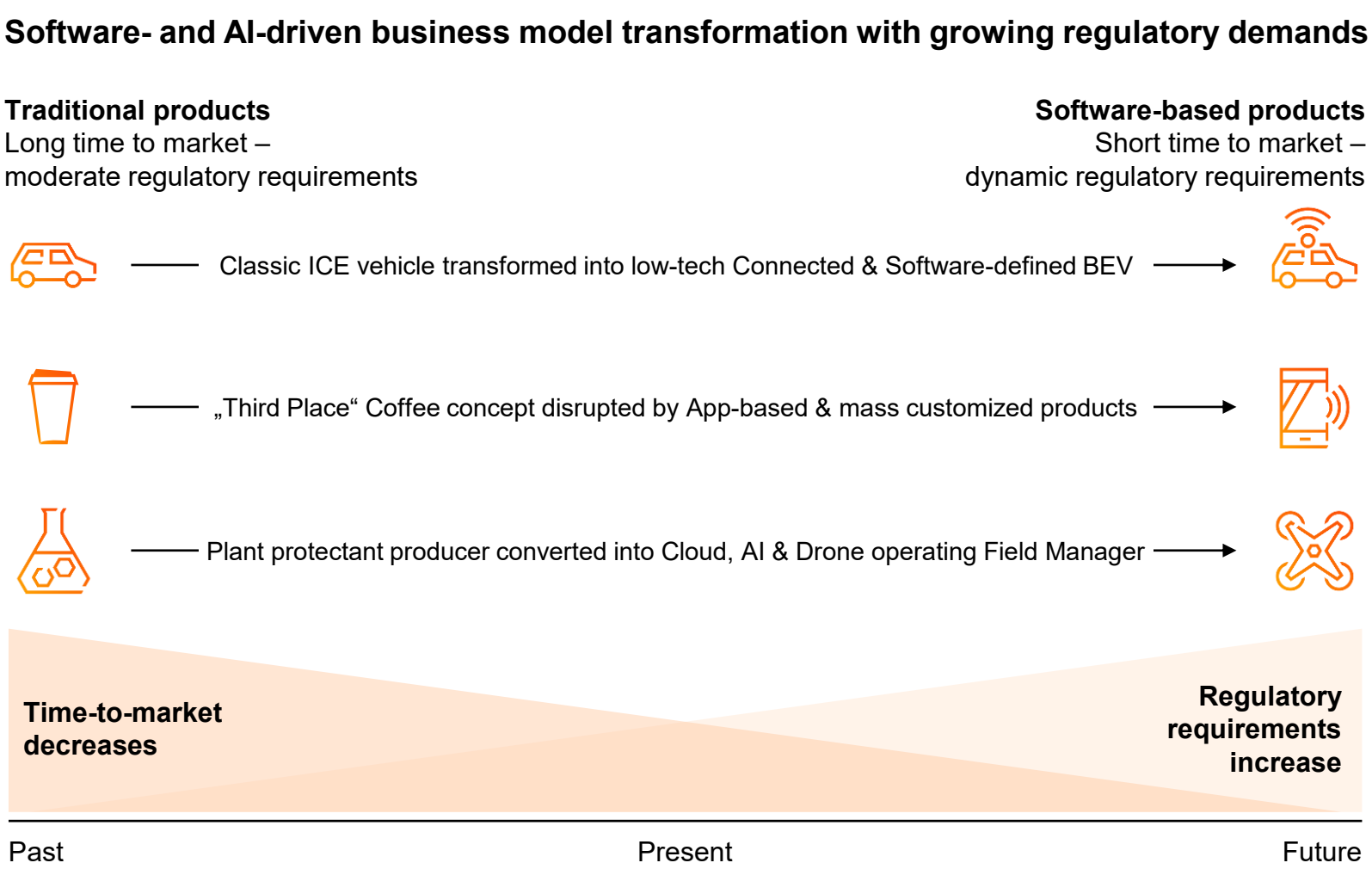
AI is now amplifying this shift, enhancing and eventually disrupting established business models.

Compliance must adapt at the same pace. Traditional structures struggle to keep up, while agile, software-defined compliance breaks down silos, improves efficiency, and enables innovation at scale.

Embedded directly into operations, it helps organizations **navigate regulatory change and drive transformation across industries simultaneously**.

Transformation to software- and AI-enabled business models drives innovation while facing increasing regulatory complexity

Software- and AI-driven business model transformation with growing regulatory demands



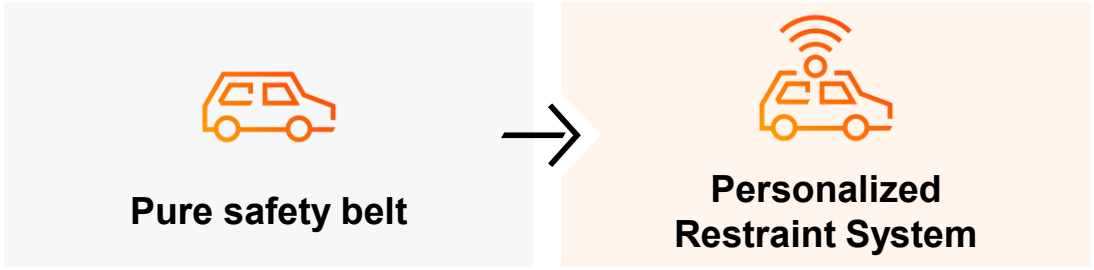
As conventional products become increasingly software-driven and AI-enhanced, **product regulation complexity is increasing rapidly**. The more digital innovation a product includes, the more it is shaped by emerging regulatory demands.

Yet innovative products are expected to **reach the market faster than ever** to be competitive.

This growing tension — **more product regulation with less available time-to-market** — is redefining how companies have to approach compliance.

Embedding compliance into the 1st line and bridging law & tech are essential for speeding-up product-related processes and time-to-market of innovations.

How the regulatory landscape is changing: Example #1 – Safety Belt



		Criteria	Hardware defined	Software defined
1	Product Compliance	**Regulatory requirements**	Complex but static	Highly complex, highly dynamic
2		**Key topics**	Safety	Safety, GDPR, AI, FOSS, SUMS, EUDR, Cyber Security, Supply Chain Law
3		**Scalability**	High (global)	Limited (unique product) High (business model)
4	PLM[1]	**Data amount**	Low	Very high
5	Agile	**R&D approach**	V-Model	Agile software development (e.g., SAFe)

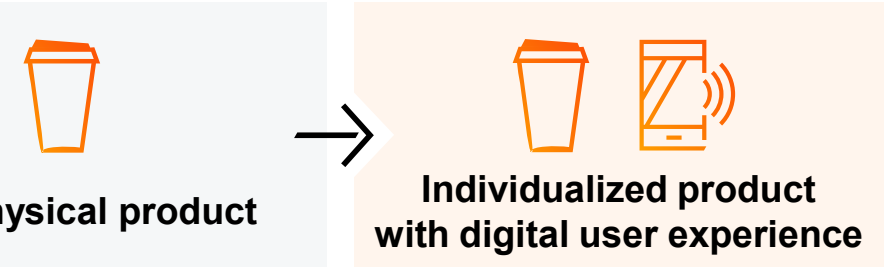
Safety belts have been regulated under UN/ECE R16 since the 1970s, with well-defined requirements for mechanical performance such as **tensile strength, durability tests and standardized crash test setups** to ensure occupant protection.

While the regulation itself has changed only incrementally, the product has evolved substantially: from a purely mechanical, globally standardized component to a **vehicle- and market-specific, highly integrated restraint system**.

Software-supported and adaptive restraint functions introduce additional regulatory dimensions beyond classical product safety, including cybersecurity, data protection and software lifecycle governance. As a result, **compliance shifts from a one-time approval to a continuous lifecycle challenge**, becoming a key bottleneck for development speed in software-defined products.

[1] Product Lifecycle Management

How the regulatory landscape is changing: Example #2 – Coffee retail



		Criteria	Hardware defined	Software defined
1	Product Compliance	**Regulatory requirements**	Complex but relatively stable, focused on food safety and labeling	Highly complex, highly dynamic
2		**Key topics**	Product safety, quality control, traceability	GDPR, AI, FOSS, Cyber Security, Supply Chain Law, IP
3		**Scalability**	High (global)	Limited (unique product), High (business model)
4	PLM[1]	**Data amount**	Low, batch testing and quality data	Very high, consumer data and personalization metrics
5	Agile	**R&D approach**	Classical food science and regulatory R&D	Agile software development (e.g., SAFe)

[1] Product Lifecycle Management

Coffee retail products have traditionally been regulated as **purely physical consumer goods**, with relatively stable regulatory requirements focused on food safety, quality control and labelling within well-established approval frameworks.

With the shift towards **individualized products combined with digital user experience**, coffee retail increasingly becomes software-defined. Mobile apps, digital ordering, personalized offers and data-driven customer interaction fundamentally change how products are designed, delivered and scaled.

This development has already **disrupted the domestic coffee retail market** in China with successful players moving to western markets.

The use of consumer data, digital platforms and AI-supported personalization triggers obligations related to data protection, cybersecurity and digital compliance, while food regulation remains relevant. As a result, compliance shifts from a stable, product-centric model to a **dynamic, lifecycle-oriented challenge** for retail business models.

How the regulatory landscape is changing: Example #3 – Agriculture

Pure physical product

Individual products via AI-based platforms

		Criteria	Hardware defined	Software defined
1	Product Compliance	**Regulatory requirements**	Complex but static (~10 years validity)	Highly complex, highly dynamic
2		**Key topics**	Safety (e.g., compliance with plant protection laws), Environmental impact, Chemical composition, Storage and transport regulations	Export Regulation / Dual Use, GDPR, AI, FOSS, Cyber Security, Supply Chain Law, IP
3		**Scalability**	High (global)	Limited (unique product), High (business model)
4	PLM[1]	**Data amount**	Low, mostly batch and quality control data	Very high
5	Agile	**R&D approach**	Classical agricultural R&D including agronomy, chemical/biological testing, regulatory field trials, product formulation optimization	Agile software development (e.g., SAFe)

[1] Product Lifecycle Management

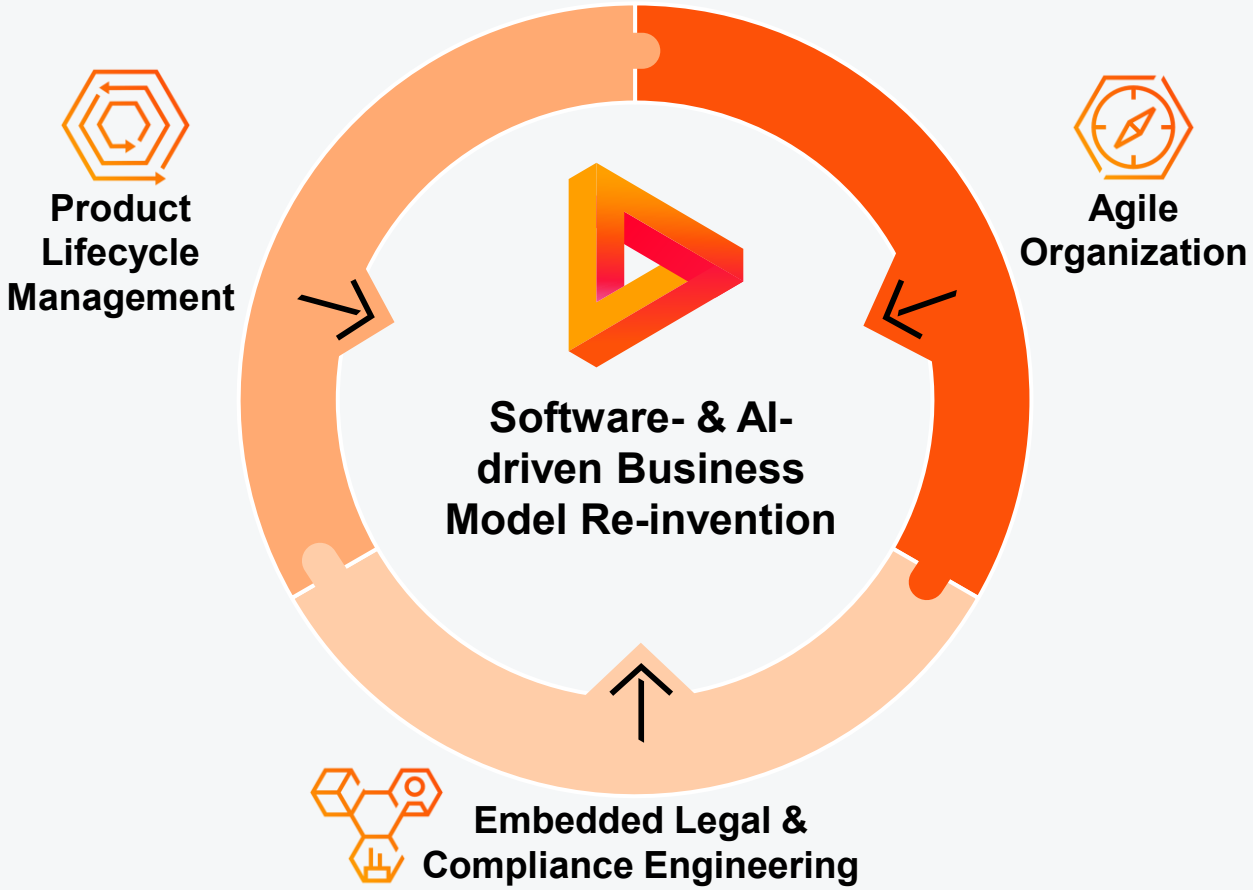
Agricultural products such as seeds, fertilizers and crop protection products have traditionally been regulated as **purely physical products**, with long-term approval cycles focused on safety, environmental impact and chemical composition.

With the introduction of **software- and AI-based platforms**, agricultural solutions are shifting towards **highly individualized, data-driven applications**. Instead of treating entire fields uniformly, digital technologies enable plant-level decisions on treatment needs, reducing input volumes while increasing yield and efficiency.

This transformation introduces **regulatory requirements beyond classical Product Compliance**. The use of AI, sensor data and geo-data triggers obligations related to data protection, cybersecurity and digital compliance, alongside highly relevant ESG requirements. As a result, compliance evolves into a **dynamic, lifecycle-oriented challenge** for software-defined agricultural business models.

Building new business models through Agile Organization, Product Lifecycle Management and Unified Compliance Services

Integrated Operating Model for Software- and AI-driven Business Model Re-invention



The epic challenge of super-fast innovation cycles in software- and AI-based business models with increasing regulatory complexity requires **a radical response and a break-out of compliance** from its silos.

A **Three Pillar Approach** is key for every future business model re-invention

Embedded Legal & Compliance Engineering is bringing functions together on shared platforms, while **Agile Organizational Design** embeds compliance directly into day-to-day operations.
With comprehensive **Product Lifecycle Management** providing end-to-end visibility of product data, organizations can maintain control, meet regulatory demands, and innovate confidently across the value chain.

2

Three Pillars for Business Transformation

2.1

Product Lifecycle Management

Companies perceive a growing complexity of regulatory requirements along their entire value chain

Growing **regulatory requirements** for products are becoming **increasingly difficult** for companies to **oversee, implement** and **document.**

Legal Requirements
- Execute an efficient CMS[1]/Product CMS
- Product Safety Regulations
- Environmental Criminal Law
- Ecodesign

Corporate Responsibilities
- Ensure complete product transparency along entire Product Lifecycle
- Combine pre-existing Data Management tools with Product Lifecycle Management

Supplier Obligations
- Supply Chain Act
- Material Compliance/Conflict Materials
- EUDR

Customer rights
- Right to repair
- Product information
- Data Subject Rights

The integration of product-specific data into a comprehensive PLM system **enables organizations to manage regulatory requirements and documentation** with greater efficiency and consistency.

As regulatory complexity increases, **compliance can no longer be addressed within isolated functions**.

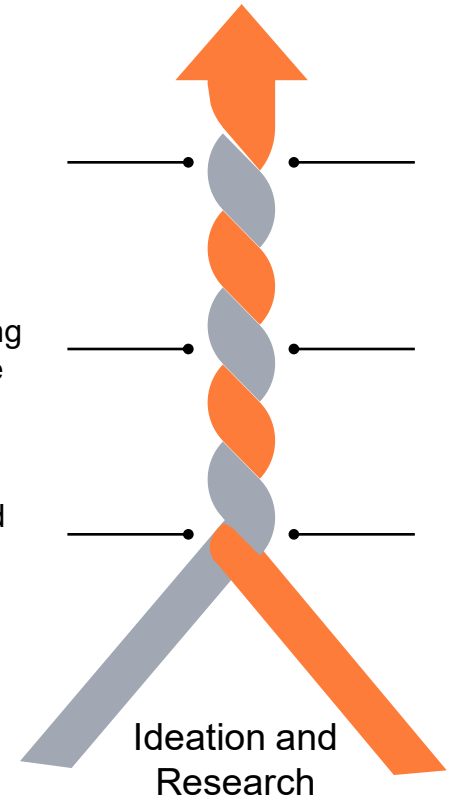
A holistic PLM approach creates a **centralized and transparent information base** that supports legal, internal, supplier, and customer requirements while ensuring a compliant data management throughout the product lifecycle.

Exemplary Value Chain

Ideation and Research — Development — Sales and Marketing — Procurement — Manufacturing — Logistics and Warehousing — Service/ Maintenance — Return/Reuse/ Recycle

[1] Compliance Management System

Compliant products are the result of having PLM associated with Technical Data Management



Technical Data Management

- Legal regulations and regulatory standards
- Process requirements along the entire product life cycle
- Continuous monitoring and improvement

Product Life Cycle Management with Product Architecture

- Connection of internal and external stakeholders
- Data collection and traceability along the entire value chain
- Defined Product Architecture & Product Hierarchy

Compliant products are achieved by integrating Product Lifecycle Management with Technical Data Management, ensuring **adherence to regulations and continuous monitoring throughout the product lifecycle**.

PLM supports collaboration, data tracking, and traceability, helping companies **manage complexity and embed compliance from the start**, leading to more efficient and transparent product delivery.

Full technical Product Compliance can be ensured by tackling the three Data Management Dimensions

Product Lifecycle Management

Functional Data Management
Product Architecture & Functional Mapping

Material Data Management
Specifications & BoM[1] Approach

Product Lifecycle Data Management
Product Compliance System

Full technical Product Compliance is **achieved through a holistic, lifecycle-driven approach**.

By **embedding compliance early** into product design, material selection, and manufacturing planning, **organizations proactively reduce regulatory risk and rework**.

Material Data Management ensures adherence to global standards through controlled specifications, certifications, and substance management.

Functional Data Management completes the framework by validating product architecture and software against safety, performance, and regulatory requirements.

Together, these dimensions **establish a scalable Data Management Model** that increases transparency, accelerates time-to-market, and safeguards regulatory approval across the product portfolio.

[1] Bill of Materials

2.2

Agile Organization

Scaled Agility has become the blueprint for the way of working in digital teams, requiring Compliance to be agile in the age of AI

Scaled Agility enables organizations to adapt at scale, align strategy and execution, and deliver value faster in complex environments.

What Scaled Agility enables in R&D

Managing complexity while accelerating innovation

Reliable strategy-to-product execution

Earlier value delivery with reduced risk

Built-in quality, compliance, and governance

Management-level transparency and control

Agility matters because it **enables organizations to bring products to market faster while continuously improving product quality** through rapid feedback and iteration.

At the same time, **it strengthens organizational resilience** by allowing companies to adapt more effectively to change and uncertainty. Agile ways of working also contribute to **higher employee satisfaction and engagement**, as teams are empowered with greater ownership and collaboration.

Finally, agility **increases transparency and supports stronger governance**, since progress, decisions, and responsibilities are clearly visible at all times.

Why Compliance must be integrated into Scaled Agile Operating Models

Why
compliance must be evolved in Scaled Agility

- **Shift from reactive control to built-in compliance** → Compliance is embedded into day-to-day work, not added at the end.
- **Speed and scale require early compliance integration** → Traditional downstream controls cannot keep pace with agile delivery at scale.

What
changes in scaled agile environments

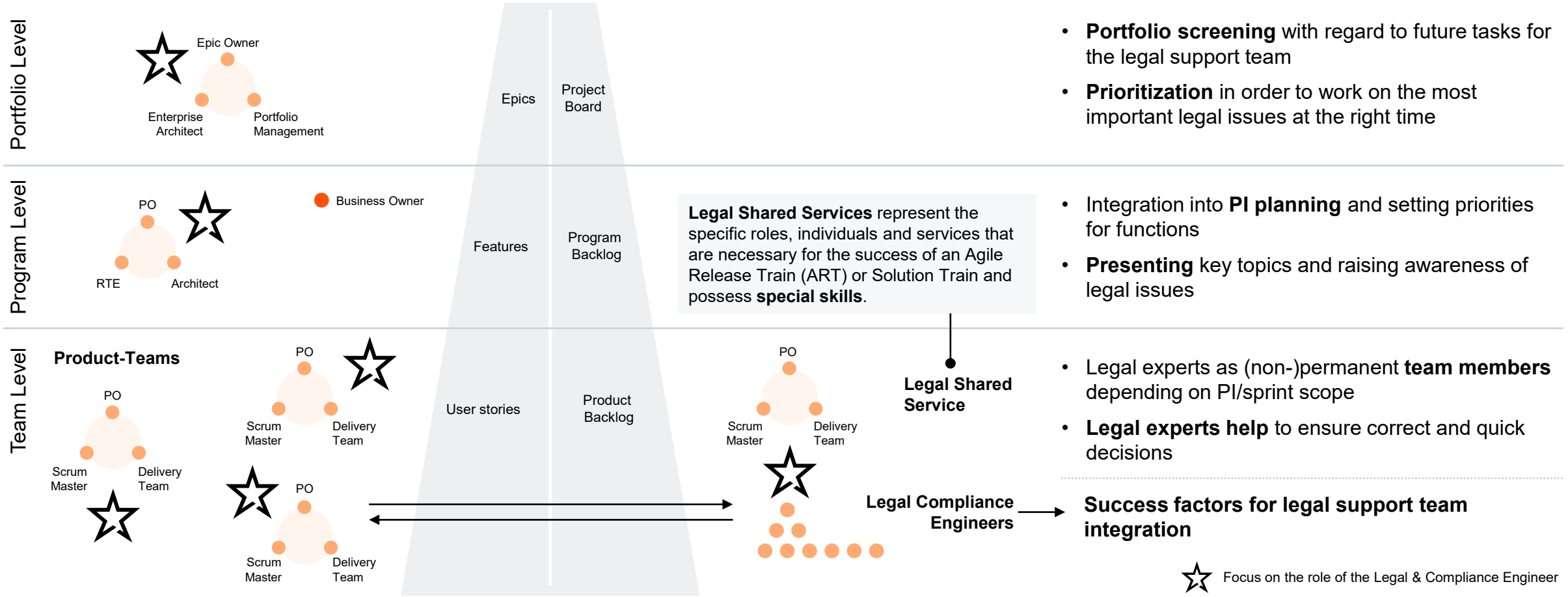
- **Early involvement enables speed and better decisions** → Legal input happens where priorities and design decisions are made.
- **Compliance becomes part of value creation** → Legal considerations are addressed continuously rather than through late-stage reviews.

How
compliance is embedded in scale

- **Scalability requires clear roles and integration models** → Agile scale demands structured, repeatable involvement of support functions.
- **Transparency replaces approval loops** → Governance is achieved through visibility, not manual sign-offs.

The integration of the Legal Compliance Engineering Team can be seamlessly embedded at all levels in the agile operating model

Agile Operating Model



Legal Shared Services represent the specific roles, individuals and services that are necessary for the success of an Agile Release Train (ART) or Solution Train and possess **special skills**.

- **Portfolio screening** with regard to future tasks for the legal support team
- **Prioritization** in order to work on the most important legal issues at the right time
- Integration into **PI planning** and setting priorities for functions
- **Presenting** key topics and raising awareness of legal issues
- Legal experts as (non-)permanent **team members** depending on PI/sprint scope
- **Legal experts help** to ensure correct and quick decisions

Success factors for legal support team integration

☆ Focus on the role of the Legal & Compliance Engineer

Agile teams succeed when Compliance & Legal is built in from the start – not added at the end

01	02	03	04	05
Priorities and focus	**Stakeholder involvement**	**Cross-functional**	**Transparency and trust**	**Compliance and built-in quality**
Ordinary agile teams				
Clear priorities and focus • Transparent goals and priorities aligned across teams and stakeholders • Clear decision boundaries to enable fast execution	Early and continuous stakeholder involvement • Business, Legal, and other support functions involved from the start • Decisions are prepared where knowledge and context are present	Empowered, cross-functional teams • Teams have end-to-end responsibility for delivery and outcomes • Skills and authority are close to the work	Transparency and trust-based governance • Progress, risks, and dependencies are visible at all levels • Steering is based on features, facts and outcomes, not control mechanisms	Built-in quality and compliance • Quality, risk, and compliance are integral parts of daily work • Issues are addressed continuously, not escalated late
Compliance & Legal focus				
Clearly defined non-negotiables and decision boundaries	From “review & stop” to “co-create & safeguard”	Standardized guardrails instead of individual approvals	From full upfront assurance to risk-based decision-making	Compliance by design instead of compliance by audit

2.3

Embedded Legal Compliance Engineering

To effectively address new regulatory complexity an Embedded Legal & Compliance Engineering Approach is key

The Task

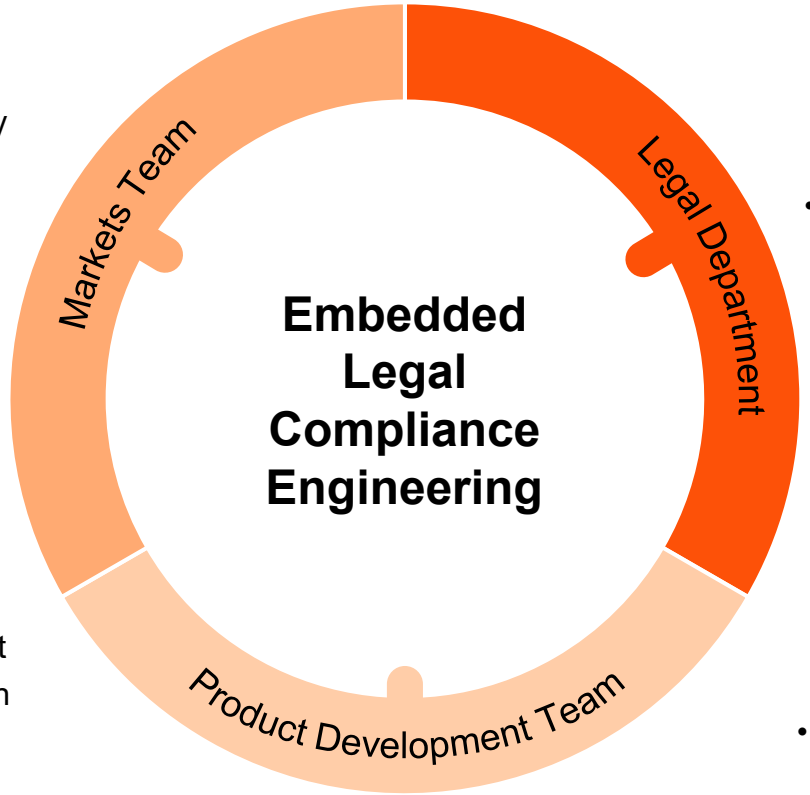
Bridging Law, Tech & Product

- Identify, analyze & manage product-relevant regulatory requirements during entire product lifecycle
- Translate regulation into technically adoptable requirements, processes and guidance
- Align compliance requirements between product development teams, markets and legal department
- Maintain documentation and traceability

Executed by

A new role: Legal Requirements Engineer/ Legal Compliance Engineer

- Combination of legal compliance and technical skill-set
- (para) Legal-grade or compliance-grade combined with deep product, process and markets know-how
- Expert in agile working methods, high communication skills, cross-discipline minded



Way of working

Embedded in the 1st line product organization

- Legal Compliance Engineers are integrated into Product Development and Markets Team
- Integration into project rituals, data flows and delivery timelines
- Supporting & Relieving 2nd line functions, NOT replacing in-house legal department
- Shared Service or Managed Service increases efficiency and speed

The Benefit

From Complexity to Structured Compliance

- Generate savings by eliminating/reducing friction losses between product development, markets and legal function
- Product Risks are effectively managed and minimized without compliance affecting time-to-market
- Scaling modular and reusable compliance results across different product portfolios and jurisdictions
- Relieving both product functions and legal function from “non-core” tasks while speeding-up results

How the Embedded Legal Compliance Engineering delivers value

What Legal Compliance Engineers do – bridging law & tech

Understand & map

- Analysis of product set-up, data lifecycle and existing controls
- Clear mapping between business processes and legal/regulatory requirements

Identify & prioritize

- Detection of regulatory gaps with risk-based prioritization
- Focus on issues that really matter for regulators, customers and your board

Co-design & enable

- Joint working sessions with product teams to shape compliant-by-design solutions
- Creation of templates, checklists and playbooks that teams can reuse at scale

Align & document

- Structured alignment with inhouse legal and data protection function
- Preparation of documentation to support audits, DPIAs[1] and regulatory inquiries

By embedding a Legal Compliance Engineer directly into the product teams, organizations gain **a single, structured interface between product, tech and legal/privacy**.

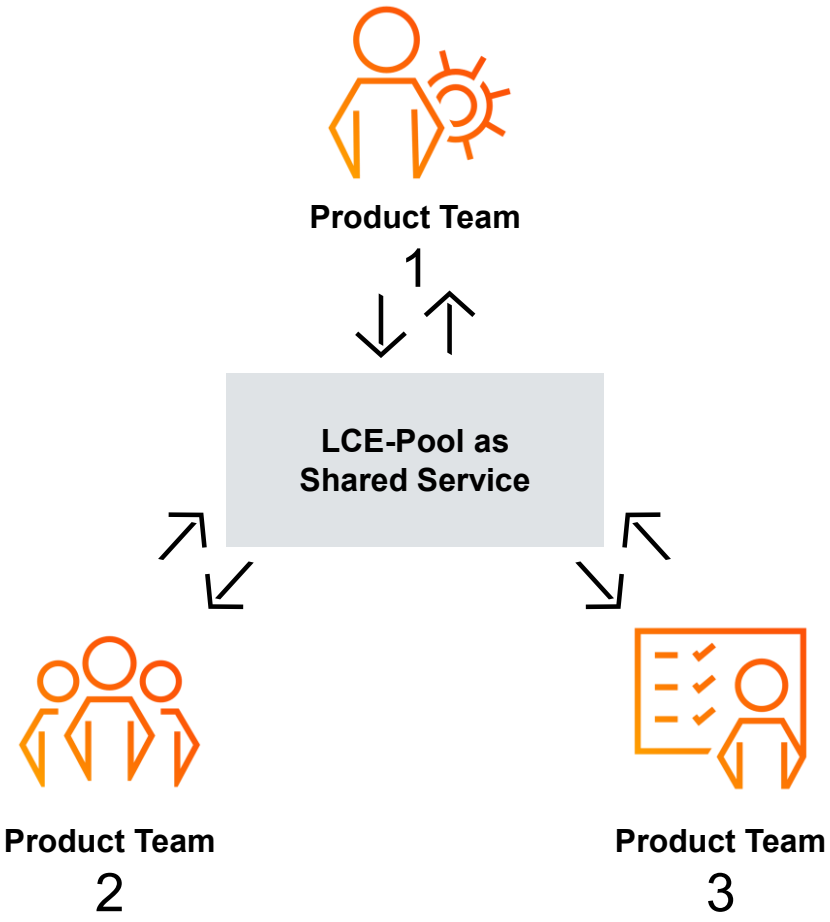
Regulatory risks are identified and addressed early in the product lifecycle, **enabling faster and safer go-to-market** while reducing friction and misunderstandings between stakeholders.

Compliance obligations are translated into reusable processes, templates and documentation, allowing organizations **to move from ad-hoc legal reviews to scalable Compliance-by-Design** – backed by regulatory-grade legal expertise combined with practical product and risk experience.

[1] Data Privacy Impact Assessments

Legal Compliance Engineering is most effective if organized as a Shared Service of pooled experts

Legal Compliance Engineering (LCE) organized as Shared Service



Unified standards, shared knowledge

Standards, methods & templates
Layer 1

Central knowledge base
requirements, interpretation guidance, lessons learned
Layer 2

Requirements management tools
unified taxonomies, traceability matrices
Layer 3

Knowledge is developed once and reused across the entire organization

By organizing Legal Compliance Engineering as a Shared Service of pooled expertise, a neutral, cross-functional and skilled service provider is established and can **effectively respond to changing demand-requests**.

This enables both solid **integration of the Legal Compliance Engineering expertise** into project teams and adaptation of resources.

Standards, methods and templates are developed once, **maintained in a central knowledge base** and ready for reuse organization-wide.

Harmonized requirements management tools ensure traceability, consistent compliance quality and knowledge transfer across BU boundaries.

The Shared Service Function provides **central compliance oversight and early-warning capabilities** for all participating projects.

Call to Action – get your business ready for the digital age

PLM Quick Assessment

Creating fast transparency on PLM readiness, risks and priorities

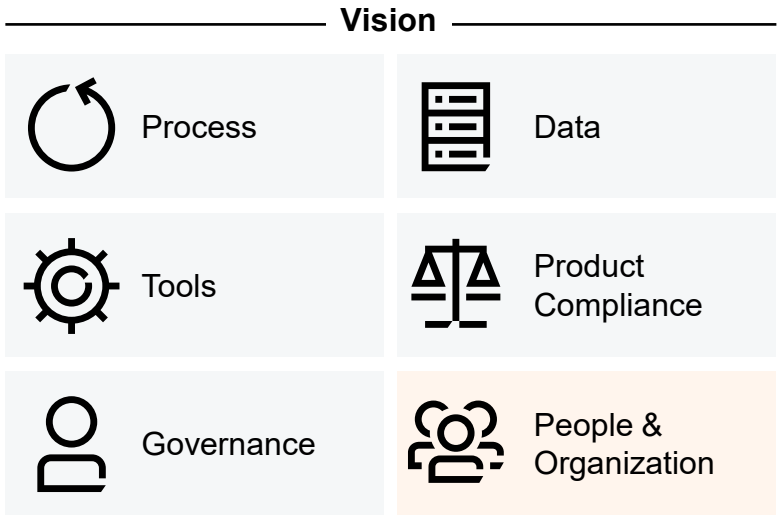
Objective

The PLM Quick Assessment is a short, structured diagnostic to rapidly evaluate an organization's readiness, risk management and improvement potential in the context of a PLM transformation.

It provides management with a **fact-based snapshot** of the current situation and **clear guidance on next steps** – without the effort of a full-scale assessment.

Scope & Assessment Dimensions

The assessment is framed along seven core PLM pillars, covering both organizational and technical aspects:



Resulting Value for our Clients

- Fast transparency without long assessment cycles
- Objective, structured view on PLM strengths and weaknesses
- Actionable recommendations instead of generic maturity statements
- Solid foundation for decision-making and prioritization

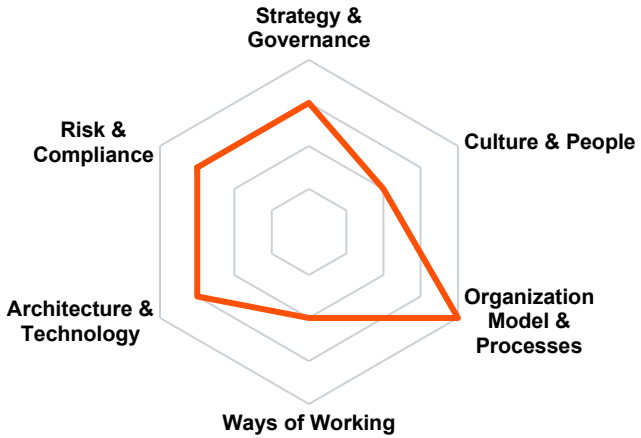
PLM Assessment → **PLM Vendor Selection** → **PLM Transformation Support**

Our PLM approach can be **applied flexibly** to **any situation** in the customer's **PLM transformation journey**

Kickstart your agile journey by measuring readiness for building your transformation path

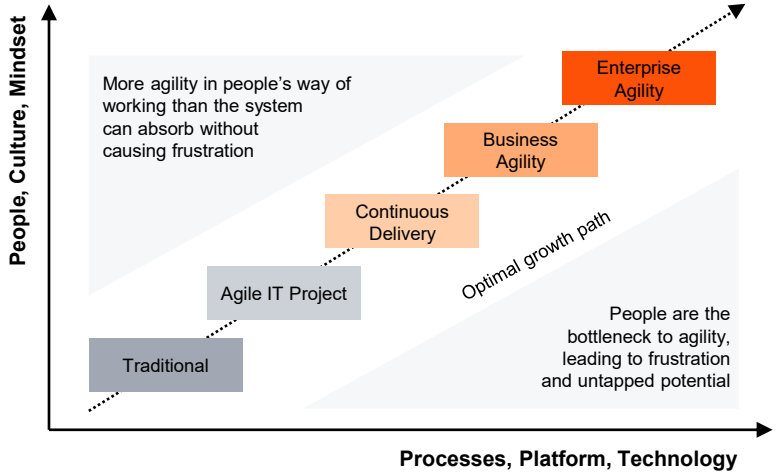
By combining Agile Maturity Assessment and a clear Ambition with a holistic agile view, we create transparency on the current state, align stakeholders on a shared and defined end-to-end path from strategy to execution. Turning agile readiness to measurable progress.

Agile Maturity Assessment



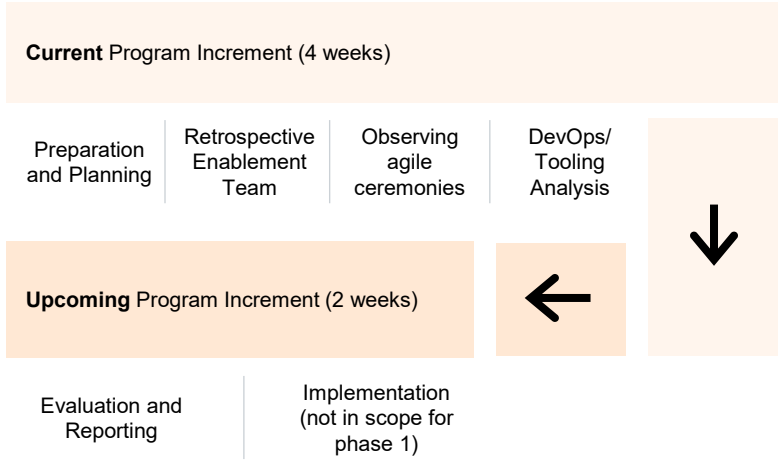
A structured, holistic instrument used within the context of an IT Transformation to assess, evaluate and transparently communicate the current level of agility of an organization. It equally considers agile methods, organization, culture, leadership, processes and technology.

Ambition Workshop



The workshop aligns leaders on a shared agile ambition by defining the target level of agility, clarifying focus areas across organization, ways of working, leadership and technology and setting the direction for the transformation journey.

Holistic Agile Transformation Workshop



Jointly discuss agile ambition, current maturity, target operating model, governance, leadership behaviors, culture and technology enablement with leaders and key stakeholders to concrete and steer agile transformation.

Start your Journey

Embedded Legal Compliance Engineering (LCE) Readiness Assessment

Station 1

Discovery Workshop

- Stakeholder interviews
- Pain Point mapping
- Regulatory landscape overview

Station 2

Maturity Assessment

Evaluation of current processes, tools, organization, and capability gaps

Station 3

Tailored Roadmap

Prioritized recommendations, quick wins, and implementation options

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Key Questions to be explored

Business Units
Which Business units have LCE needs?

KPIs & Compliance
How do KPIs align with compliance efforts

Regulations
Which regulations are most critical?

Tools & Methods
What tools and methods are in place?

Processes & Roles
What processes and roles exist today?

Pain Points
Where are the biggest pain points?

What you get

Clarity: Transparent view of your current LCE maturity and gaps
Prioritization: Actionable recommendations tailored to your context
Decision basis: Business case foundation for LCE Pool implementation

Duration

2–3 weeks

Investment

Contact us for a tailored proposal

Your Contacts

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Compliance Transformation 2030+

PwC insights into how the compliance function is being transformed