



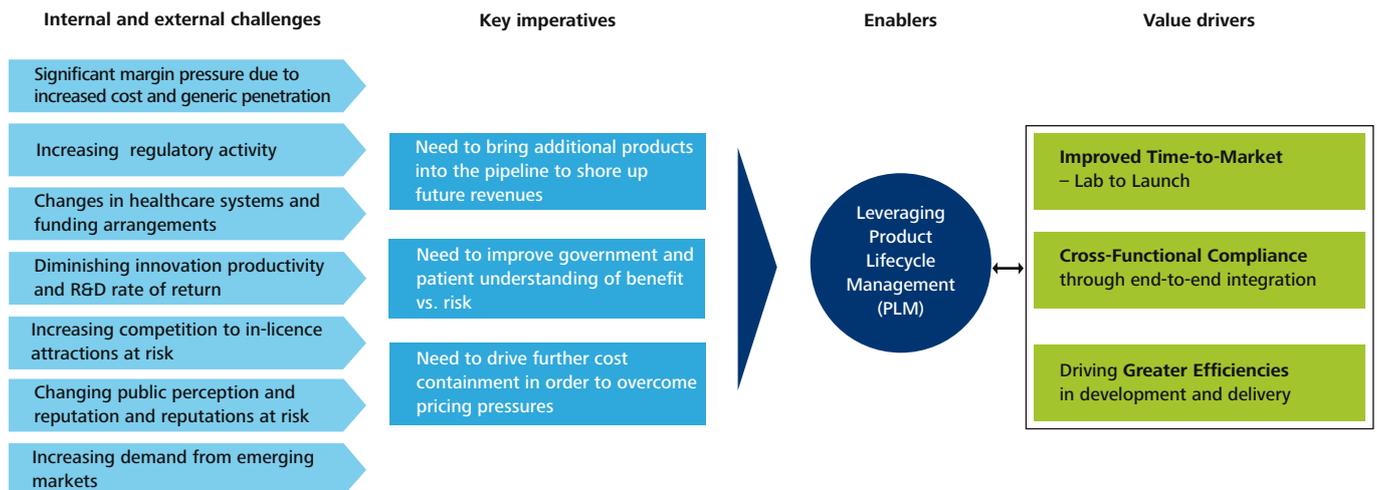
Product Life Cycle Management in Life Sciences Industry

Evolving from siloed to
cross-functional management



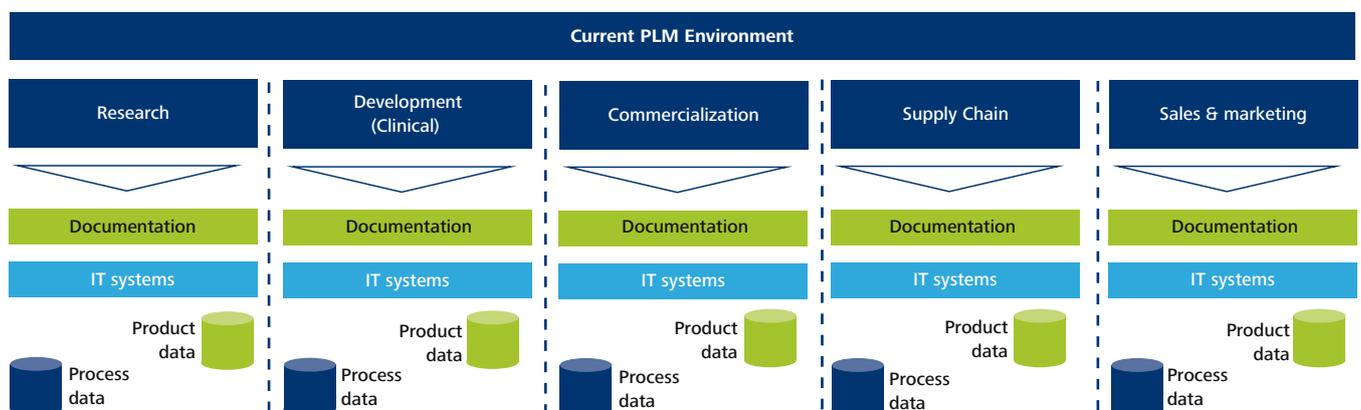
A need for Product Lifecycle Management

Life Sciences companies are currently experiencing a period of unprecedented change. Driven by shifts in age and demographics, disease, the entry of new technologies, increased government regulations and user requirements, and the pace of health care inflation, Life Sciences companies will have to dramatically change in order to cope with the future industry environment.



One meaningful way to address current challenges in today's complex Life Sciences environment is to focus on **Product Lifecycle Management (PLM)**, which is an integrated approach to manage products and related knowledge in a transparent way in order to improve **product time-to-market**, **cross-functional compliance** while ensuring **end-to-end integration** and driving **greater efficiencies**. By combining product and process data PLM provides visibility and traceability as well as the link between the regulatory and manufacturing world.

In our experience, the traditional functional PLM organization of a Life Sciences company suffers from virtual walls between the functional silos, product and process data being separated making it difficult for cross-functional information to flow quickly and securely.



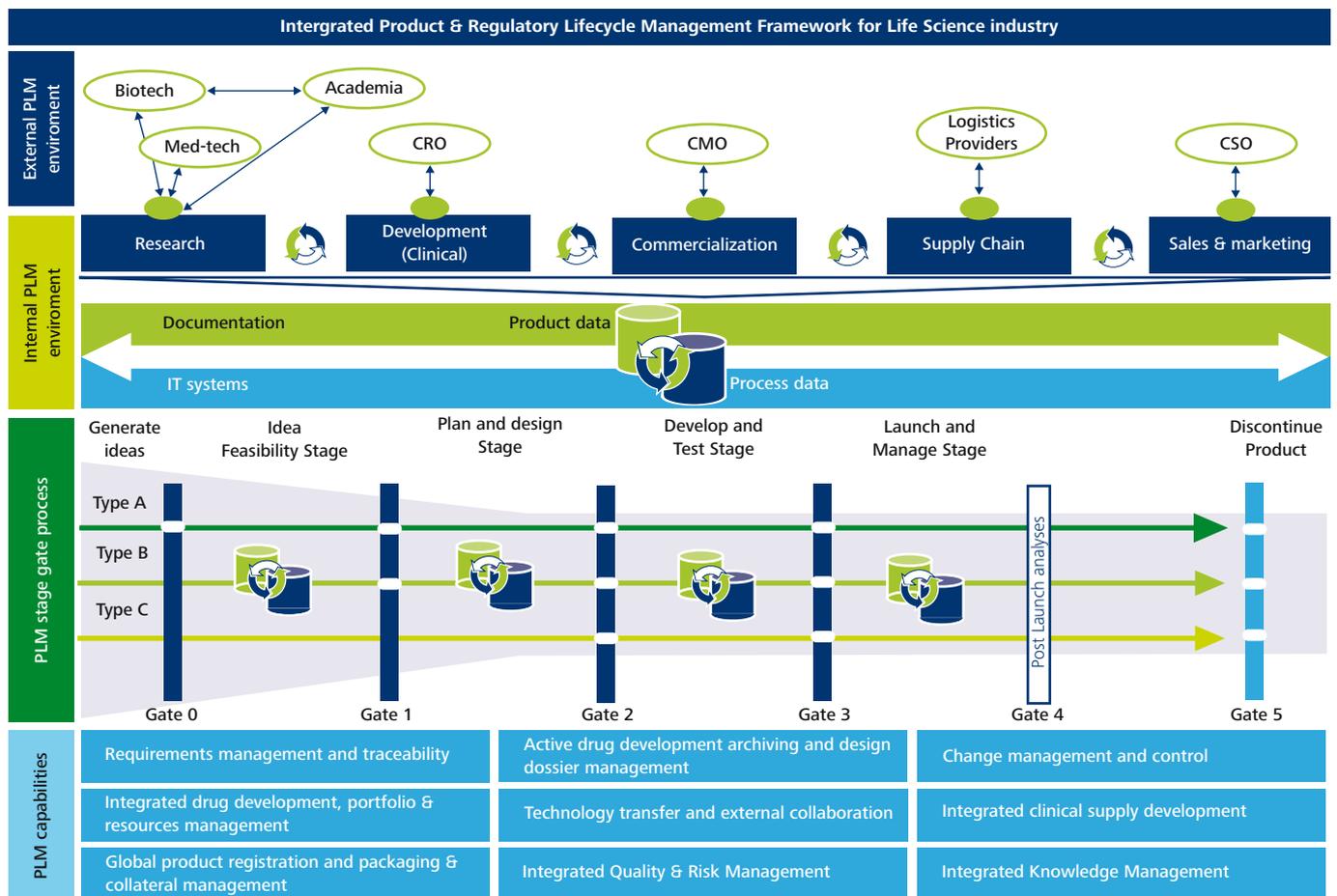
The most common issues within PLM in Life Sciences industries impacting profitability, risk and growth are listed below:

<p>Time-to-Market</p> <ul style="list-style-type: none"> • Delays in launch schedule impacting the planned volumes. • Delays in technology transfer to cope with the volume growth in commercialization phase. • Complications in pipeline execution for the multiple indication products – phased development products. 	<p>Compliance</p> <ul style="list-style-type: none"> • Isolated functional silos preventing cross functional integration for compliance and facilitate Quality by Design. • Failure to coordinate external capacities, i.e. CROs, CMOs, etc. • Difficulty in rapid and accurate document product changes (Change Control) causing compliance failures. 	<p>Efficiencies</p> <ul style="list-style-type: none"> • Multiplication of effort in documentation due to lack of platform to capture all the knowledge. • Multiple knowledge repositories across functions. • Huge effort in gathering data from different systems for KPI reporting.
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Deloitte’s Integrated Product & Regulatory Lifecycle Management Framework

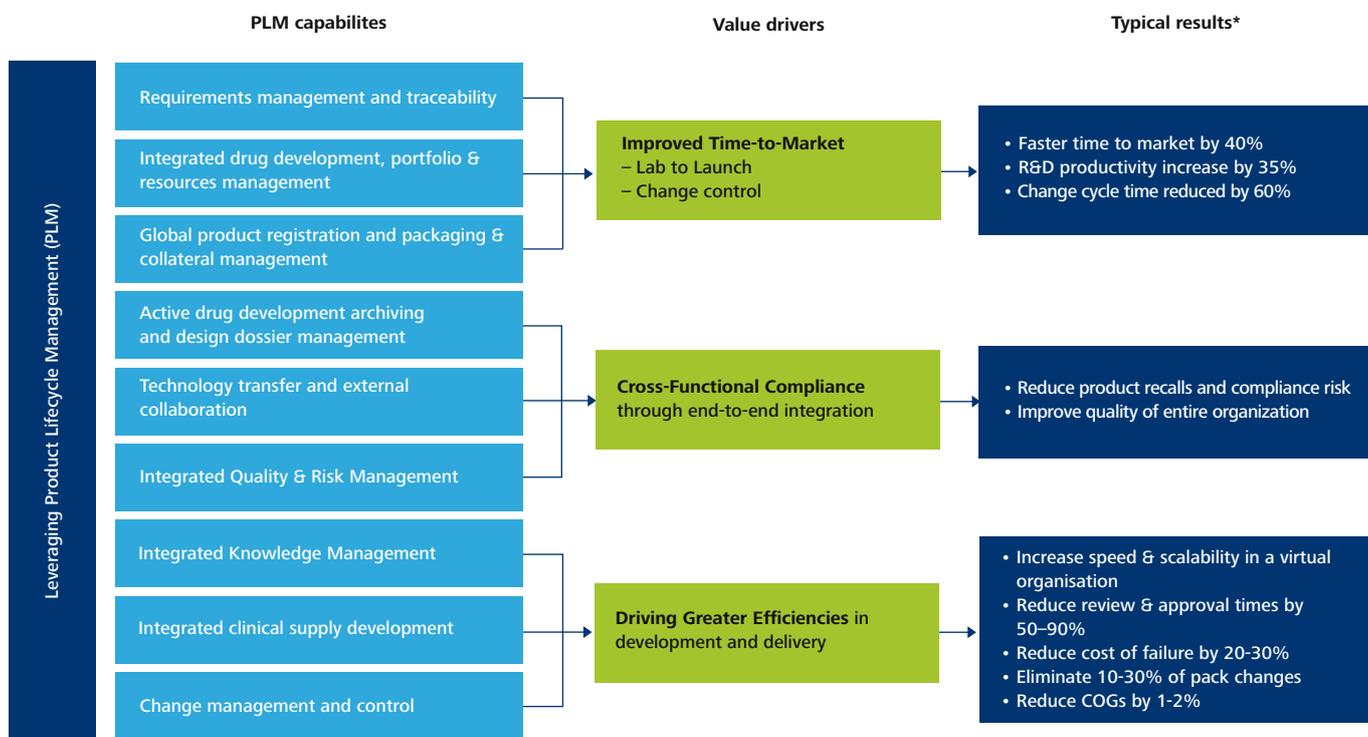
In order to respond to internal and external market challenges in the Life Sciences industry, Deloitte delivers to its clients a comprehensive and **integrated Product & Regulatory Lifecycle Management Framework**. Deloitte believes a business-driven approach enabled by technology will drive greater efficiencies in the development to commercialization process and contribute significantly to improved growth and profitability.

Basically, PLM encompasses the Lab-to-Launch and Post-Launch **stage gate processes** and applies to **all functions** within the Life Sciences ecosystem covering organizational, process, data and technology aspects. PLM is about improving the **capabilities** of the product development, change and regulatory cycle to enable product and process information to flow as one through the stage gates and functions.



- **A broad perspective enables cooperation with the external environment**, e.g. third party research, manufacturing, sales and logistics organizations.
- **A cross-functional view facilitates integration and synchronization within internal environment** – in order to break up relatively independent functional silos of internal research, development, commercialization, supply chain and sales & marketing disciplines.
- **A consolidated IT platform enables integrated knowledge and data management** – provides the master source for product related information along with supporting processes for knowledge and data exchange within internal and external environments.
- **A strong focus reinforces integrated quality and risk management** – due to stronger cross functional collaboration covering product, quality, risk and compliance issues.

Deloitte’s integrated PLM Framework focuses on improving PLM capabilities, which results in major business benefits realized in a range of improvement areas.



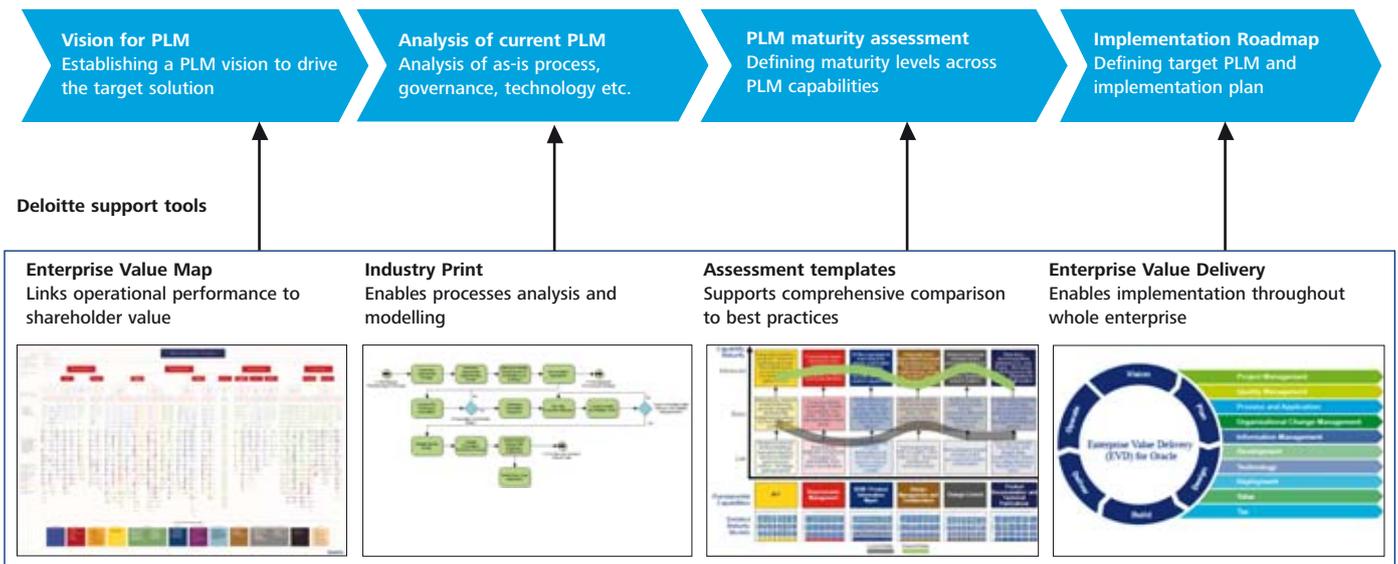
*Deloitte/Agile experiences

Deloitte's approach

Deloitte's unique value driven approach to the PLM implementation looks beyond technology by ensuring that business vision and benefits comes first, and that implementation follows business priorities to deliver full PLM capabilities over time.

Our tools and accelerators from implementing PLM in multiple industries differentiates Deloitte clearly from technology driven approaches.

Deloitte phased approach



A strong set of key design principles and a systematic approach makes Deloitte's PLM approach ultimately more successful:

- **Standards** set the guidelines and rules for creating and maintaining product data. This includes rule sets for data architecture, data modelling, and the creation of data domains and elements.
- **Governance** specifies the policies and procedures maintaining the product and the process data, it establishes accountability, sets goals for the organization, and defines monitoring and enforcement for both – product and process.
- **Processes** define the procedures for the creation of new elements, integration and harmonization of existing elements, and managing the change control processes. These processes are defined cross-functional instead of silo-ed.
- **The Organization** component addresses the people responsible for owning and maintaining the product information and the related process steps. It specifies the organization model, names data and process owners, and establishes the resources responsible for maintenance.
- **Technology** defines and creates the data architecture that enables a single source of data for PLM. This includes technologies for tasks such as data integration, traceability of progress, transparency across the entire process and performance monitoring.

About Deloitte's approach

"We are in the middle of a successful global PLM Program, which is designed to deliver value – time-to-market gains, increased sales, and efficiency improvements. The underpinning of [the project] from a technology perspective is the Oracle/Agile PLM suite. This project highlights a successful three-way relationship between us, Deloitte Consulting, and Oracle/Agile"

Client's personnel, Global Business Process Innovation

"Life Sciences businesses have a growing need to find solutions to integrate both with internal departments and partners as the commercial environments become more challenging. There are few alternatives for integration and some of them are simply too high risk for the large Life Sciences businesses to take. PLM is a subtle way of gaining visibility, control and connectivity"

Phil Symonds, Deloitte Partner, Life Sciences

About Deloitte's Life Sciences & Healthcare practice

Deloitte's Life Sciences & Healthcare industry comprises of over 5000 professionals in over 50 member firms.

Deloitte works with all of the top 10 largest medical equipment manufacturers, 8 out of the 10 largest biotechnology companies and all of the 15 largest pharmaceutical manufacturers.

Deloitte Life Sciences & Healthcare are lead sponsors of the FT's Pharmaceutical & Biotechnology conference, one of Europe's pre-eminent industry events attended by leading executives, government decision makers, investors, analysts and other specialists providers. Deloitte Life Sciences & Healthcare have a long standing relationship with the World Economics' Healthcare Governors Group looking at topics such as emerging markets and innovation in health care.

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