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COMPLIANCE IN PRODUCT DEVELOPMENT

Revolutionizing Business: PLM & PCMS Tackle Regulatory Hurdles and Fuel Innovation

By Jochen-Thomas Morr, Kolja von Westerholt, Jens Rollenmüller, Dr. Tobias Zimmermann, Simon Thome

Increasingly stringent regulatory demands for product compliance and the growing number of sustainability requirements put companies under increasing pressure. How can development, production, and sales meet the rising expectations? Product Lifecycle Management (PLM) and Product Compliance Management Systems (PCMS) offer forward-looking solutions to master this complexity. The combination of PLM and PCMS breaks down information silos and enables close collaboration across departmental boundaries – the result: more innovation, efficiency and safety.

EU countries are serious about their commitment to consumer protection and sustainability and are holding companies accountable. Among other things, the EU has agreed on the introduction of a **digital product passport,** which provides strict standards for product quality, safety, and the environment. This provides companies with a framework for building environmental and resource protection requirements. Information commitments include information on durability, interchangeability of components, repairability, reusability, resource efficiency, and CO_2 footprint. This "transparency offensive" will be deployed gradually, with the first requirements introduced as early as 2027 for sectors that include textiles, electronics, plastics, and construction. Failure to comply can result in high penalties. Companies are, therefore, required to adapt to this at an early stage in order to secure competitive advantages and protect their brand reputation.

PLM is the most important, useful tool for companies to plan, control and map the entire lifecycle. The central retrieval and management option for all product information enables early integration into the development process, with optimizations that can be implemented faster and cost-effectively. In conjunction with a Product Compliance Management System (PCMS), conformity checks are also possible in real-time. Compliance with regulatory requirements can thus be ensured early in the product lifecycle during the development, procurement, production, or sales phases.

Compliance with regulatory requirements is a decisive factor for market success. It is, therefore, crucial for companies to master complexity and make data-based decisions. Through the comprehensive integration of PLM and PCMS solutions, it is possible to efficiently manage the regulatory flood of requirements and maintain product compliance. The article provides recommendations for an investment-safe introduction and optimization of corresponding systems. Using successful case studies, It shows the tangible benefits of early implementation and describes how companies can achieve a significant ROI in the long term.

Product Compliance: Mastering Current Regulatory Challenges with Confidence

Compliance with regulatory requirements is one of the biggest challenges for management. Requirements have become more stringent in recent years due to the increasing complexity of regulations and development dynamics. This is reflected in surveys like the PwC Global CEO Survey and the PwC Global Risk Survey. In addition, the regulatory environment is subject to ongoing adaptation, which means that companies are faced with the task of adopting instruments such as product compliance man-

This article covers, among other things:

- **Compliance with regulatory requirements with the help of a PCMS.** The systematic management of product-related regulatory requirements through a dedicated PCMS enables companies to adequately identify and implement increasingly complex legal requirements. Shorter and more secure development cycles provide a significant competitive advantage over the competition.
- **The transformative potential of PLM.** Improved data visibility enables frictionless collaboration and makes it easier for cross-functional teams to access critical compliance information. This also fosters a culture of accountability and informed decision-making.
- **The benefits of integrating AI and ML into PLM.** The integration of artificial intelligence (AI) or machine learning (ML) allows companies to analyze regulatory changes and their potential impact on product compliance in advance. This proactive approach makes it possible to anticipate challenges, identify compliance gaps, and take effective remedial action promptly.
- **A digital thread supports sustainability goals.** Companies receive a dynamically adaptable view of a product's data in a PLM system. The product-related information flow is continuously fed with all relevant data to ensure end-to-end traceability and control. This achieves a link between the digital and physical worlds.
- **Practical example: Introduction of a technical compliance management system – an interplay of compliance, R&D, and quality.** A technical compliance management system is intended to help reduce risks associated with compliance requirements. When introducing such a system, there are various success factors to consider. This includes a clear understanding of the interfaces to compliance, legal, quality, and research & development (R&D), as well as the risk-based approach to defining the focus of the TCMS. In the practical article, Dr. Christian Gabriel and Dr. Jörg Metzger go into more detail about these two points and show how companies can benefit from a well-implemented tCMS.

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agement systems for risk minimization and liability avoidance.

Compliance management systems have proven themselves in the past to ensure legal conformity and avoid rule violations. They help companies fulfill their duty of care and to protect themselves legally. A central aspect of this is the well-known motto "Follow the Money." Payment flows are tracked to detect corruption or price fixing, or the origin of funds is determined in order to track down money laundering or sanctions violations. However, new regulatory requirements and the increasing number of high fines due to defective products have led to a realignment in compliance management. In recent years, there has been a significant shift towards stronger monitoring and safeguarding of the product area. Companies today are much more focused on implementing compliance structures along the entire value chain to minimize the risk of product defects and associated compliance violations.

This development marks a paradigm shift. Companies are recognizing that a comprehensive and preventive compliance strategy goes far beyond the integrity of finance-related processes and also affects the product itself. Compliance must be understood as an integral part of the product lifecycle in order to meet regulatory requirements, maintain consumer trust, and ensure the long-term success of the company. In this era of change, an agile and future-oriented compliance strategy is essential to meet ever-growing demands and secure competitive advantages.

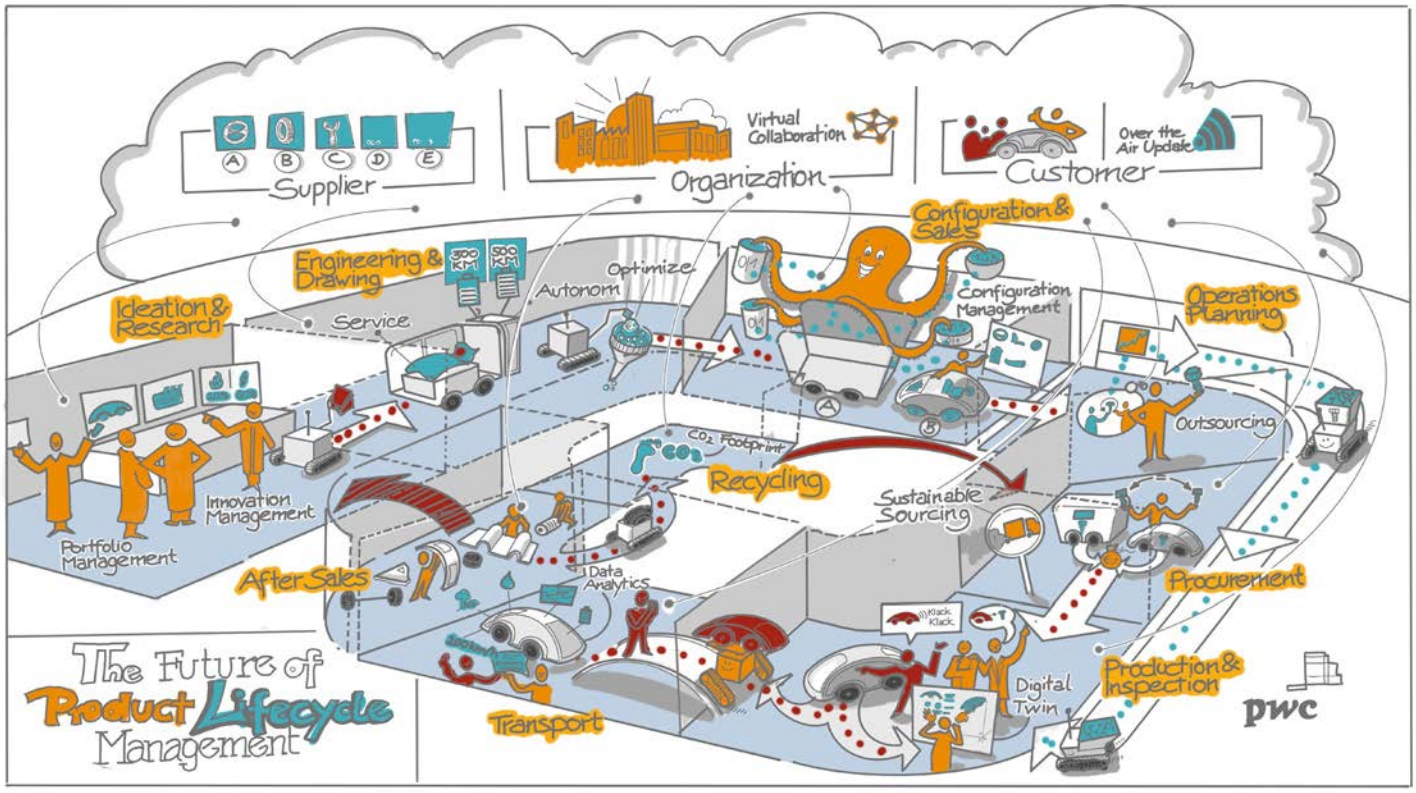
Definition of product compliance and differentiation from quality management

The technical term product compliance does not yet have a uniform legal or generally applicable definition. Companies, industry associations, and consultancies have defined or explained the term in a similar way, although there are certain industry-specific nuances. It is only since 2016 that the increased use of the term has been observed in German-language literature. Based on various published definitions, product compliance can be described as follows: *It is the adherence to product-related regulations that are binding on a company over the entire lifecycle of a product. In the German-speaking world, the term "technical compliance" is also used.*

For decades, the focus of product compliance has been on safety compliance. This focus had the decisive advantage that customer requirements and regulatory requirements were usually congruent. This allowed quality management to concentrate strongly on meeting customer requirements. There are now a large number of product-related legal requirements focused on, for example, environmental and health. These new requirements can quickly lead to conflicting goals, not only between time, cost, and compliance but also between key quality criteria such as the shelf life of the product or the fulfillment of the requirements from the PFAS regulation (more on this later).

The distinction between product compliance management and quality management systems (QMS) is crucial to making the most of the advantages of both systems. While quality management traditionally focuses on compliance with functional requirements to meet customer requirements, compliance focuses on regulatory requirements. The latter contain a large number of non-functional requirements, for example with regard to environmental or data protection. Another key difference is that compliance includes not only compliance with regulations but also the risk of deliberate manipulation. This is less present in quality management. It is thus focusing more on controls, necessary segregation of duties and the involvement of the company's legal representatives. Consequently, QMS and PCMS complement each other, ideally both to ensure product quality and, at the same time, to control liability management.

This extended approach to product compliance management becomes more important as the complexity of products increases. A current example of this is software integration into products, as is the case with modern car keys. In the past, a simple metal key stored in a case



Productlife Cycle Management is a holistic strategy across all domains. *Source: PwC*

was sufficient. In total, these used perhaps three materials, manageable production steps, and a transparent process chain from A to Z. Today, the key is often no longer recognizable as such but as a card with a chip or an electronic module. More and more materials, integrated circuits, and software components are being used. These innovations increase complexity and represent an additional hurdle for compliance with regulatory requirements and for product compliance management. Compliance with the increasing regulatory requirements is determined not only by the physical properties of the product but also by the integrated software. This requires a holistic and flexible compliance strategy.

The Product Compliance Management System continues to be a young discipline with varying distribution. While 52% of the 21 companies surveyed as part of the PwC Compliance Transformation Study of the automotive industry currently have an independent PCMS, this proportion is only 17% in other sectors.

New legal requirements for companies

The European Union has set ambitious goals for a sustainable future. These include promoting the circular economy, protecting the environment and habitats, and strengthening consumer rights. To achieve these goals, various initiatives and legislation are being launched, including:

Digital Product Passport

The Digital Product Passport originates in the European Circular Economy Strategy and is closely linked to the Ecodesign Regulation. The Digital Product Passport creates a basic digital infrastructure for the recycling of products. In the future, many products will be provided with clearly identifiable markers in order to make information such as their CO_2 footprint, repairability, or toxic ingredients easily accessible. Corresponding laws and projects are currently expected by 2027. The starting point was formed by traction batteries over 2 kWh. The use of the product passport is anchored in the EU Battery Regulation and will be mandatory from February 2027.

PFAS

Per- and polyfluorinated alkyl compounds (PFAS) are a group of chemicals used in many everyday products. These include packaging, medicines, surface coatings, cosmetics, and electronic devices. They can have significant harmful effects on human health and the environment and are now found everywhere, from the lowest point on earth to breast milk. The EU has, therefore, taken measures to regulate PFAS to reduce the risk. The latest proposal is being revised and will be explored by various economic sectors by September 2024.

EU Data Act

The EU Data Act is a new legislative project that aims to strengthen the governance of data in the EU. The Data Ordinance regulates the use of AI and data sharing, among other things. The focus is on individual access and the rights of users while at the same time ensuring the protection of personal data. In November 2023, the Council of the European Union adopted the EU Data Act, which will officially become enforceable in 2025.

Product Safety Regulation

The Product Safety Regulation (ProdSV) defines the requirements for the safety of products on the EU market. The Council of the EU adopted the ProdSV in April 2023. It ensured the safety of new consumer products, especially against the background of the digitization of products and the challenges of new business models. Due to advancing digitization and numerous different sales channels, the legislature has provided many changes that challenge economic actors in ensuring product compliance.

EU Deforestation Regulation

The EU Deforestation Regulation (EUDR) aims to stop global deforestation. The regulation prohibits importing products associated with illegal logging into the EU. This includes not only wood but also raw materials such as rubber, coffee, beef, palm oil, or soy. The EUDR was finally adopted in June 2023 and will become enforceable at the end of 2024 with a transitional period of 18 months.

Vision

- Define an overall vision for digital transformation as enabler for business development

Governance

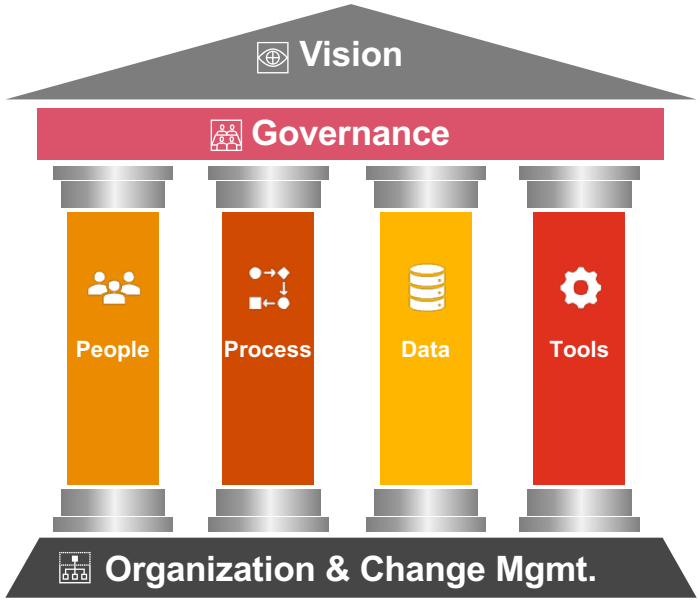
- Establish a robust governance structure for strategic, operational, and tactical decision-making

Product-centric integration

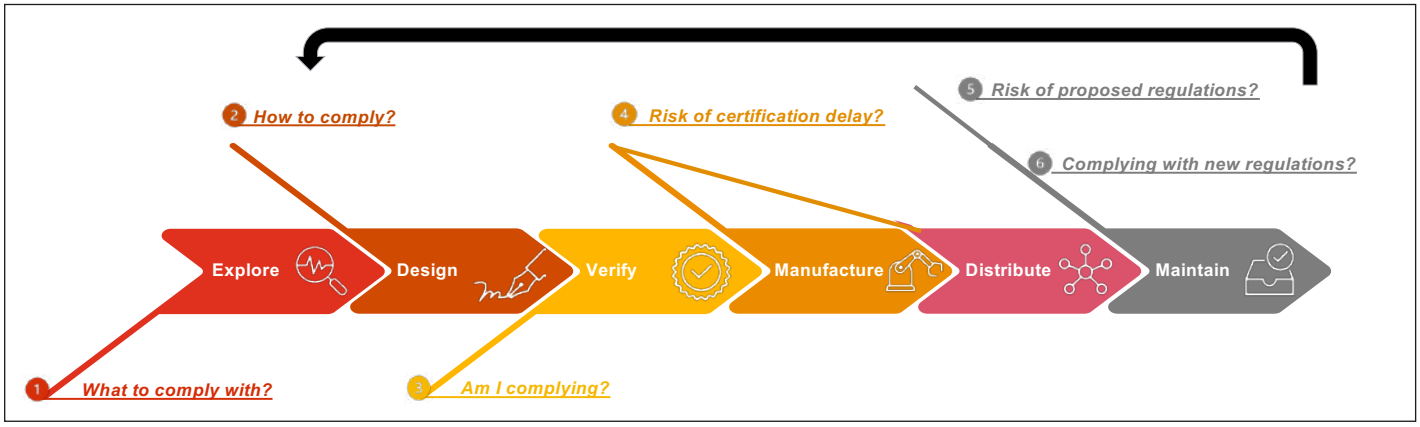
- Integrate people, E2E processes, data and tools based on a holistic product data model

Organization & Change Mgmt.

- Plan and drive change and communication
- Align cultural change with agile delivery models
- Allocate capacity based on necessary scope



Successful PLM story requires board commitment, a clear vision and harmonization driven E2E processes. *Source: PwC*



PwC offers a variety of different services around the topics of Compliance and PLM, which ideally complement each other. *Source: PwC*

These examples show that the EU legislature is taking a comprehensive approach to sustainable products. The focus is on the entire lifecycle of a product, from raw materials to the use of data and AI to market surveillance and product updates.

The aim is always:

- to reduce ecological and social burdens,
- strengthen the circular economy,
- protect consumer rights.

Risk of sanctions and damage to the brand

Companies have to react accordingly to the new regulations, also because, in the global economic environment, there is a clear trend from the voluntary commitment of companies to criminally sanctioned regulations. This development can be observed in particular in the US, where violations of compliance regulations can have significant financial consequences.

A fictitious case illustrates the possible consequences of compliance violations in the US. If a company causes damage of 50 million US dollars, this can result in a penalty of 500 million US dollars, depending on the severity of the incident. The calculation of such penalties is based on US Sentencing Guidelines, which take into account the company's offense level and culpability score. The Offense Level is a numerical value that reflects the severity of the crime, while the Culpability Score measures the offender's culpability to determine an appropriate penalty. Multiplying these factors can quickly lead to a substantial fine. In addition to the fines, other costs may arise, such as compensation payments, buyback obligations, court costs, and legal sanctions, as well as loss of market share and reputational damage. **A real-life case** illustrates the importance of brand reputation and the potential consequences of compliance violations. A cycling gear manufacturer ran into trouble when a new, 2022 version of the equipment experienced software issues. After a local television report on possible risks, the EU country's consumer protection authority stepped in. It imposed a ban on sales in the domestic market in early November 2023, which quickly expanded from international retailers to a global ban. As a consequence, the affected dealers not only had to stop selling the products but also had to recall equipment already sold. Although the manufacturer criticized the investigation methods of the consumer protection authority and successfully sued to stop the sales ban, the decision came too late. On the day the ban was lifted by the administrative court, the company filed for bankruptcy. This underlines the importance of effective product compliance, close cooperation with market supervisory authorities, and coordinated crisis communication to protect a company's brand reputation.

Consistent compliance with regulatory standards

Due to cross-industry digitization and the use of agile development methods, technology cycles are becoming shorter and shorter. At the same time, the regulatory requirements applicable to a product are increasing rapidly. As a result of these two opposing forces, product compliance is increasingly becoming a central factor for the time-to-market of products.

The early consideration of regulatory requirements over the entire product lifecycle is essential to stay ahead of the competition. This starts in the ideation phase, in which possible compliance requirements for a product must be identified. During development, these requirements must be continuously reviewed, tracked, and, if necessary, adapted. The advantages of integrating compliance into this process at an early stage are manifold:

- **Reduction of development times**: By considering regulatory requirements early, delays and rework in later development phases can be avoided.
- **Lower costs**: Early integration can help avoid additional costs arising from adapting the product to regulatory requirements after development is complete.
- **Increased market safety**: A compliant product reduces the risk of fines, product recalls, and other legal consequences.
- **Improved brand image**: A company that makes the best possible effort to comply with regulatory standards is held in higher regard by customers and business partners.

A structured PCMS allows companies to manage compliance requirements sustainably. Effective product compliance management should include all essential processes and methods required to comply with regulatory requirements. In addition, it is important that all employees in all relevant departments are informed and trained on the applicable regulatory requirements. This helps ensure that compliance requirements are taken into account throughout the organization. The standardization that goes hand in hand with the systematic approach of a management system also enables a significant reduction in additional effort.

What are the benefits of a PLM?

PLM for enterprise-wide data transparency

Originally, PLM was used as a digital tool to manage product-related documents and CAD data and to enable collaborative work through "check-in" / "check-out." However, thanks to further developments and flexible integration

options, a modern PLM system can now map complex process chains in order to better understand and control them. A product-centric approach enables the tracking of data and information about the product over the entire lifecycle, including the respective areas of design through recycling. An ideal basis for sustainability, as the product cannot be viewed in isolation but holistically with the involvement of users, manufacturers, the economy, and the environment.

PLM thus offers a strategic approach to managing the product lifecycle. It involves a mix of processes, systems, and people with the goal of optimizing product-related data and workflows within an organization. It is important that business processes are first optimized and harmonized before the digital transformation begins. PLM is a comprehensive framework that enables companies to efficiently manage product information. It is a central point of contact where data from different sources and departments converges. This unified platform improves collaboration, drives better decision-making, and ensures consistency in product development and management. Adopting PLM is not only an IT project and requires the attention of senior management to be successful.

By collecting and evaluating relevant data from the manufacturing process and use phase, also with regard to environmental impacts and performance, sustainability, and product information can be optimally linked, and dependencies and relationships can be identified. In addition, the technical basis for the definition and measurement of sustainability goals is created. The often abstract concept of sustainability is now filled with content.

In this way, not only meaningful, data-based sustainability indicators can be created but also orientation for the entire industry. This is necessary because only a comparable and measurable assessment of environmental impacts will lead to an industry-wide boost for sustainable product development, production, service, and recycling. PLM is destined to provide the data basis for these KPIs (Key Performance Indicators) in order to comply with and enable global benchmarks.

This can be achieved with PLM ecosystems that go beyond a linear view, i.e., are flexible and adaptable to meet product and compliance changes at any time. This is because companies have to adapt to permanent changes and new regulations in the long term. This is particularly true for companies that operate internationally.

Comply with the EU product passport with PLM

The imminent introduction of the EU product passport is a major challenge for companies that have to comply with strict quality, safety, and environmental standards. PLM is proving to be a critical enabler in managing this complexity, making it easier to meet requirements by providing a structured approach to managing product data. It centralizes information relevant to meeting requirements and allows real-time assessments and validations to be performed throughout the product lifecycle. This real-time monitoring ensures that products comply with regulatory standards from the design phase to market launch. In addition, PLM promotes collaboration between different organizational stakeholders by enabling interdisciplinary teams to work harmoniously to achieve compliance goals. PLM minimizes errors and discrepancies by providing a single source of compliance data, reducing compliance risks.

Data Management with PLM

A key benefit of PLM is the simplification of data management at different stages of the product lifecycle. Consolidating product-related data into a central repository allows PLM systems to easily access, share, and retrieve critical information. In addition, communication rules can be applied to avoid loss of information, e.g. through email communication. This centralized approach improves data quality and integrity while reducing the risks of fragmented or distributed data. It enables consistent documentation of compliance-relevant information and ensures that regulatory requirements are consistently met throughout the product lifecycle. PLM also simplifies workflows by automating repetitive tasks, increasing operational efficiency. Through standardized processes and automated workflows, PLM minimizes manual errors, accelerates time to market, and ensures compliance measures are seamlessly integrated into product development and manufacturing processes.

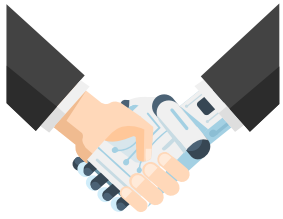
Respond proactively to change with PLM

In addition to data management, PLM systems offer a proactive approach to identifying and addressing regulatory issues. The integration of artificial intelligence (AI) and machine learning (ML) enables PLM systems to perform predictive analysis. AI and ML algorithms integrated with PLM solutions enable the analysis of historical compliance data and regulatory trends. This allows organizations to anticipate potential changes, identify compliance gaps, and proactively initiate corrective actions.

Corporate Compliance

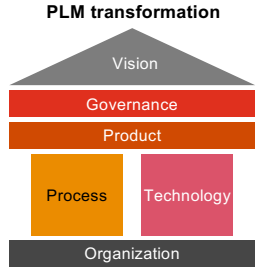
PwC's Compliance methodology is based on a proven framework incorporating requirements of the IDW AsS 980. A 3-phase project approach supports an efficient and sustainable reduction of compliance risks:

1. Relevance analysis, scoping and organizational set-up
2. High-level Gap Analysis according to defined scope
3. Optimization through closing of identified gaps



The **product-specific data** and **analytics** provided by a **PLM** provide the ideal **input** to **track** and **document** the adherence to all product-related **binding obligations** of a **company**.

Product Life Cycle Management



PwC's strong business focus enables our clients to break future state vision down into epics & use cases for implementation:

1. Future state vision
2. Processes
3. Capabilities
4. Solution architecture
5. Functional breakdown

Various compliance requirements must be met along the different phases of the product life cycle. *Source: PwC*

PLM represents a forward-looking approach to compliance management, helping organizations keep pace with changing regulations. Essentially, PLM is not only used for data management, but also for proactively dealing with regulatory subtleties. It plays a critical role in navigating the complexities of the European Product Passport, helping organizations ensure compliance, mitigate risk and foster innovation as they grapple with the changing regulatory landscape.

Integrating AI and ML into PLM Systems

New analytical methods

With AI and ML support, PLM systems can analyze large amounts of regulatory data. This way, companies stay ahead of the ever-changing compliance requirements. The main strength of AI lies in the recognition of patterns and trends in large amounts of data. Using this approach, valuable insights can be gained for decision-making.

Know what's coming

AI and ML algorithms can predict regulatory changes and assess their potential impact on compliance. This proactive approach allows organizations to anticipate and prepare for regulatory developments.

In the context of compliance, the digital thread can be used in the following ways:

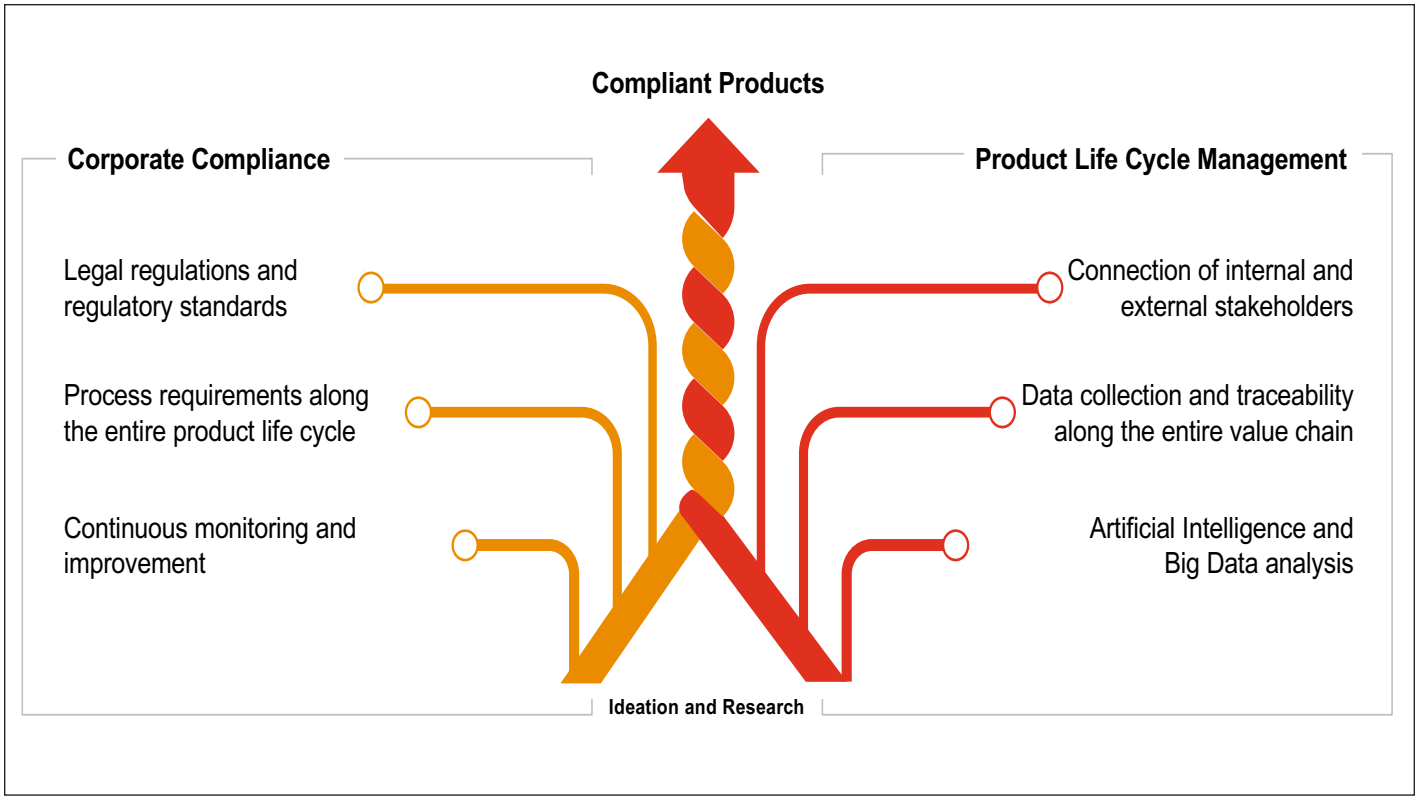
- Implement proactive product compliance management with a central platform to detect potential violations in advance.
- Create a digital thread for each individual product throughout its lifecycle with complete visibility across all systems.
- Develop a flexible PLM system that can be easily adapted to new regulations for existing products.
- Automate the creation of product-related documentation and the associated legal obligations to provide evidence.
- Implement improved variant management.
- Integrate with artificial intelligence (AI) for automated incorporation of regulatory information and changes.

Detect errors before they occur

AI and ML identify compliance deviations by analyzing data from various sources, such as product specifications, regulations, and customer feedback. This allows companies to take proactive measures, such as implementing corrective actions and process improvements, to ensure compliance throughout the product lifecycle.

Improve product quality

An example from the automotive industry: Automotive SPICE v4.0 is a widely used framework for evaluating and improving software development processes in the automotive industry. The integration of AI and ML into PLM systems can improve the implementation of Automotive SPICE v4.0 and enable companies to achieve higher process maturity and product quality.



Compliant products are the result of having PLM associated with Corporate Compliance. *Source: PwC*

Implementation and optimization of PLM systems

The implementation of AI and ML in PLM systems can affect the complexity of the software solution and also affect costs. Careful planning – also in cooperation with partners – is therefore useful. Three points are in the foreground:

Keeping costs under control

Companies should carefully consider their specific requirements and consider working with experienced vendors who offer customized solutions. In addition, investing in employee training and change management initiatives can help alleviate concerns about complexity.

Create a roadmap

The successful adoption of AI and ML in PLM requires a well-defined strategy. Companies should define goals, coordinate stakeholders, and develop a roadmap for implementation. Working together in interdisciplinary teams and involving end-users in the decision-making process can foster a culture of innovation and ensure a successful rollout.

Achieve ROI

Early adopters of AI and ML in PLM can gain a significant competitive advantage. Organizations should focus on measuring and communicating their implementation efforts' return on investment (ROI). This can include quantifying compliance improvements, efficiency gains, and improved product quality.

PLM provides an opportunity for change and sustainability

The integration of AI and ML into PLM systems provides organizations with a transformative opportunity to improve regulatory analysis, compliance management, and optimization of the entire product lifecycle. By following implementation and optimization best practices, organizations can unlock the full potential of AI and ML, gain a competitive advantage, and drive both sustainable growth and sustainability.

Against the background of the increasing complexity of compliance and safety regulations in connection with the pressure to innovate on the part of manufacturers, it is becoming increasingly important to think about sustainability from the beginning of the product lifecycle. Manual systems reach their limits when it comes to overseeing the impact of changes on current and planned products, and because time dependencies are not recorded. PLM systems help to develop sustainable solutions by using insights from products already in use to better size new product generations and thus save material or reduce wear, for example.

> The earlier sustainability is considered, the better.

> The Digital Thread accelerates the time-to-market of products.

PLM also improves communication and coordination between stakeholders inside and outside the organization. It is possible to work from one platform, from the procurement and design of components to the disposal of hazardous materials and the reuse or recovery of other elements. The PLM application serves as a central control unit to ensure the consistency of the data, including the integration of modern technologies. The importance of this holistic view in terms of sustainability is also shown by calculations by the European Court of Auditors, according to which decisions in the design phase can account for up to 80 percent of the environmental impact of a product. This means that the earlier a company considers sustainability aspects in the product lifecycle, the better.

The advantages lie not only in the reduction of CO_2 emissions but also in an overall leaner and more efficient way of working. In addition, exchanging information enables the transfer of ideas and experiences. Systems and networks are emerging with cross-functional teams, third-party vendors, and geographically dispersed employees, leading to faster and more innovative product development. *By integrating different players, it is not only possible to better meet environmental requirements but also to improve production efficiency and product quality.* Sustainability does not take place in silos but requires cooperation, partnerships, and alliances. However, this networking can only succeed organizationally if technical integration is guaranteed.

Linking the digital and physical worlds

The digital thread is the ideal connecting element of the product lifecycle; in the PLM system, it enables the digital and physical worlds to be linked and provides a dynamically adaptable view of an asset's data, as the product-related information strand is continuously fed with all relevant data to ensure end-to-end traceability and control.

Conclusions

Flexible PLM systems form the basis for engaging all stakeholders, meeting regulatory requirements, and ensuring product compliance**.** Companies that understand and implement new requirements better than their competitors – whether from a compliance or competitive perspective – extend their advantage; they are more creative, profitable, and faster. They gain a deeper insight into their value chain, which can be used for both the past and the future. After all, possible cascade effects of small changes at the beginning of a process chain can only be understood and analyzed in complex systems with digital support – ultimately leading to a better, greener and legally compliant product.

The Authors

Jochen-Thomas Morr *is a partner at PwC Germany. He is responsible for research and development in the Operations Transformation Practice Group and is an expert on product development.*

Kolja von Westerholt *is a director at PwC Germany. Together with Dietrich Boß, he is responsible for Product Compliance Services in the Risk Practice Group and is an expert in product compliance management systems.*

Jens Rollenmüller *is vice president of Professional Service at Aras. He has been working in the PLM field for over 25 years and is responsible for Aras' German business and all Aras PLM services in EMEA.*

Dr. Tobias Zimmermann *is a senior manager at PwC Germany. He works in research and development in the Operations Transformation Practice Group and is an expert in PLM strategy and implementation.*

Simon Thome *is an associate at PwC Germany. He works in the field of governance, risk, and compliance and is an expert on the topic of product compliance.*

Introduction of a technical compliance system – an interplay of compliance, R&D, and quality

By Dr. Christian Gabriel, Dr. Jörg Metzger

A technical compliance management system can help to reduce the risk of product-related binding technical obligations. When introducing such a system, there are various points to consider that can be an essential lever to success. This includes, among other things, a clear understanding of the interfaces to compliance, legal, quality and R&D and the risk-based approach to defining the focus of the tCMS. The following article will go into these points in more detail.

Technical compliance is becoming increasingly important

Technical compliance or product compliance "means the adherence to the obligations binding on the company." [1] This topic has received increasing attention in recent years, especially in the automotive industry, partly because regulatory requirements and product complexity are constantly increasing. As a result, more companies are introducing a technical compliance management system [2] and recognizing its importance. The question arises as to how this can be implemented sensibly and in accordance with current standards. It helps that many companies already have compliance management systems. At the same time, the VDA (Verband der Automobilindustrie) also publishes recommendations specifically for the implementation of product compliance systems. [1] Furthermore, the publications of the US Department of Justice provide orientation.

Technical compliance is part of an overarching compliance management system

The Schaeffler Group has compliance management systems for business integrity, export control, taxes, human rights, and technical compliance, among other things. It makes for these systems to be uniform and aligned with industry and assurance standards. At the Schaeffler Group, responsibility for this lies with the Group Chief Compliance Officer. It should also be noted that integrity is a fundamental component of the Schaeffler Group's business practices. It is an essential element in all compliance systems and is enforced by uniform compliance management.

The Technical Compliance Management System (TCMS) at Schaeffler is established on the basis of the IDW PS 980 [3] auditing standard – analogous to the other compliance systems. It is an essential component of compliance management. This ensures a systematic approach of the overarching compliance management that utilizes the compliance competencies already available in the company. TCMS is also anchored within the Board of Management Department for Research and Development. This enables a good understanding of existing and new products and technologies. The organizational anchoring of a TCMS is company-specific and depends, among other things, on the respective responsibilities and organizational forms. It can be seen that technical compliance is often located in quality or compliance in addition to R&D [2].

When introducing a TCMS, which is a second-line responsibility, the connection to quality assurance should also be carefully considered. There are requirements to establish the product integrity of a product placed on the market [4].

A risk-based approach to a technical compliance system

Risk management is an essential part of any compliance management system. In order to develop an appropriate and effective TCMS, it is advisable to proceed in a risk-based manner, i.e. to systematically derive which topics the respective TCMS must focus on [1]. This is company-specific and depends on the respective products and markets. It should be noted that compliance with the binding obligations applies across the entire product lifecycle. From a process point of view, more than the respective product development process should be considered.

The assessment of technical compliance risks should be carried out regularly and systematically, so the main focus of a TCMS can adapt accordingly over time. This is an essential tool in the continuous development of a TCMS. For companies with a broad portfolio of different products, the TCMS risks of the product groups will vary. Accordingly, risk-based focal points must be identified in the TCMS.

The new version of the auditing standard IDW PS 980 explicitly addresses the fact that it is advisable to introduce a risk control matrix in order to identify and document the corresponding compliance risks [3]. With the help of the risk-based approach, i.e. identification of the relevant key topics, a risk-control matrix can be created in a structured manner. This is a helpful way to see if the identified risks are matched by sufficient measures and controls to reduce the risk. The effectiveness of the risk reduction must then still be tested in the application. In the next step, the risk-control matrix can be an essential factor in continuously improving and developing the TCMS.

Conclusion

As a result, the TCMS can reduce the corporate risk of TCMS incidents, take into account the due diligence of company management, and provide orientation for employees.

[1] Product Compliance, Volume 1: Product Compliance System; VDA QMC; 1st edition; November 2023
[2] Compliance Transformation 2025+, PwC study.
[3] IDW Auditing Standard: Principles of Proper Auditing of Compliance Management Systems (IDW PS 980 n.F. 09.2022)
[4] Product integrity; VDA QMC; 1st edition; November 2018

The authors

Dr. Christian Gabriel *is Head of Technical Compliance at Schaeffler AG. He holds a doctorate in physics and has been with the Schaeffler Group for 12 years in various functions.*

Dr. Jörg Metzger *is Head of Technical Compliance Management System at Schaeffler AG and has been with the Schaeffler Group for 25 years in various functions.*

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