

Chapter 11: Industry case studies on intelligent compliance implementation and smart manufacturing

11.1. Introduction

Intelligent compliance is a new digital transformation concept introduced to solve the leading questions of compliance in the intelligentized world. Understanding intelligent compliance, its multidisciplinary knowledge base from compliance science, engineering and theory of digitalization, autonomy and self-organization of complex sociotechnical systems with smart digitized agents, digital economy and intelligentized value-added chain of contributions, next industrial revolution, is important for its needs, aims and purposes on guaranteeing coordinated development of compliance and digitalization and risk and benefits of product and service processes in a new phase of digital economy. Intelligent compliance is a new intelligent compliance theory propelled by the intelligentization of the fourth industrial revolution with the development of data economy, coming from the theory of responsibility in sociology and self-organization of complex systems in theoretical physics.

The advent of intelligent compliance opens a new methodological way for the solution of many novel problems of intelligent compliance in the intelligentized world, new economic and social problems for the new stage of economic and social development. Intelligent compliance disciplines are composed of subjects from the compliance science and engineering as well as the theory of digitalization, autonomy and self-organization of complex sociotechnical systems with smart digitized agents. Intelligent compliance concepts are principles and rules, both generalized and specific, allowing a certain level of intelligence. General rules, allowing compliance with high intelligence, are derived from the basic principles of intelligent compliance. General intelligent compliance services include the services which follow development outlines of scientific schools, as derivative disciplines and subjects and branches of study, that offer experiences and methodologies for novel intelligent compliance solutions (Mittal et al., 2018; Cioffi et al., 2020; Maggi et al., 2021).

It aims to radically innovate the design of products, change the mode of manufacturing organization adaptive to customer demand, and improve production flexibility, efficiency, quality, and security, as well as for the service and environment response and finally realize the full life cycle optimization such as product cost and quality, as to promote the transformation and upgrading of the manufacturing industry, as well as the innovative development (Odważny et al., 2018; Shan et al., 2020; Pfeifer, 2021).



Fig 11.1: Industry Case Studies on Intelligent Compliance Implementation

11.2. Overview of Smart Manufacturing

Currently, the general naming of the new industrial revolution of the manufacturing industry has been discussed widely in the world. For example, the advanced manufacturing partnership proposed in response to its industrial downturn proposes “Advanced manufacturing,” while the Industrial Internet initiative proposes “Industrial Internet,” and governments and industrial circles focused on “Industrie 4.0” and “Connected Industries” respectively, i.e., intelligent networked system for the core. In addition, there is advocacy for “Smart Industry” and “Factory of Things.” There is promotion of the “Made in China 2025” and the “Industry 4.0” supported by economic development reform and innovation, while there is support for the “Manufacturing Innovation 3.0.” Other countries are committed to the construction of the “Smart Factory.” Currently, the mainstream naming of the new industrial revolution is pivoted by smart product design, product efficient and flexible manufacturing, and product logistics. The whole chain is the “Smart Manufacturing.”

Smart manufacturing is the future direction of the sustainable and innovative development of the manufacturing industry. It utilizes a series of modern science and technology such as new generation networks, Internet of Things, Cloud Computing, Big Data, and Artificial Intelligence, as well as the interconnection of the design, production and management of the physical and digital system of the manufacturing industry to carry out the intelligent integration and process reengineering.

11.3. The Intersection of Compliance and Smart Manufacturing

Smart manufacturing simultaneously increases the achievement of quality standards and the automatic verification of these standards, covering not only quality devices but also the entire production process. Therefore, considering the particular characteristics of the new generation of the Industry 4.0 paradigm, such as collaborative, connectivity and sustainability, there is a focus on the extension of the computability component interconnecting the physical and cyber organizations and working as a “service provider” of the second one. Thus, this extension of computability moving from a physical environment to a cyber environment guarantees the compliance of both environments. In this way, based on an Industry 4.0 digital twin applied to compliance, it is possible to have explicit models of regulations or standards that have to be followed by physical environments and the automatic enforcement by the cyber environment of any rule violations.



Fig 11.2: The Intersection of Compliance and Smart Manufacturing

In this context of Industry 4.0 regulatory compliance, smart manufacturing volume flexibility, production cycle time and operational and assessment costs might increase as compared to traditional approaches. However, the investment in the technology needed to monitor physical environments and ensure the computation of rules in an automatic way is compensated by the increase in the confidence of shareholders, suppliers and customers. Moreover, it is also important to highlight that the level of digital maturity of an industry, considering different characteristics such as the level of connectivity and integration through the whole production chain, automation of production, efficient use of resources, innovative capacity and use of new technologies contribute to the height of compliance investments to be adopted.

11.4. Case Study Methodology

A case study, in its simplest form, is a research strategy that focuses on understanding the dynamics present within single settings. The caveat is that case studies cannot be dismissed lightly. Case studies are complex entities. Cases need to be argued for and against, and convincingly and sensitively made. Their rationale needs to be understood and woven into the logic of the research. The choice of case is paramount. Choices and actions shape the case. Case studies need to be constructed. The outcome of a case study is convincing stories supported by convincing evidence. Such stories and the evidence that supports them provide the foundation for intuitive and/or theoretically rooted conclusions and/or explanations.

A qualitative research approach, and especially a case study approach, can be useful in the early phase of exploring a domain, and we believe that this kind of research is useful in the operationalization of the intelligent compliance concept. This is unfortunate because many of the questions raised by the intelligent compliance perspective, for example “what is intelligent compliance?”, “what does it mean for organizations to be intelligently compliant?”, and “how is intelligent compliance achieved?” require careful scrutiny. Given that intelligent compliance is a relatively new concept, using case studies in this manner would not provide us with sufficient prior conceptualization of intelligent compliance to give these research questions the focus they require.

11.5. Case Study 1: Automotive Industry

This Section outlines the results of an automotive case study that implemented an Intelligent Compliance System and achieved returns of over \$17 million in reduced accounting costs while increasing the level of service to Presidents and senior executives. This organization, a US-based automotive firm with \$2.5 billion in revenues, 9 worldwide manufacturing facilities, and 4,000 employees, asked to work with its

Corporate Regulations Compliance Group to identify business processes that could be improved by implementing intelligent business-to-business and business-to-government compliance systems. While many of the recommended changes applied to multiple departments at the corporate head office, the departments undergoing the most significant sensitivity analysis, design, development, testing, and implementation initiative were the Corporate Regulations Compliance department and the Compliance and Risk Management Area.

Intelligent compliance process and system implementation reduced the cost of complying with regulations by enabling the cornerstone of the required internal control taxonomies to be tied directly to the business processes that generated or failed to generate the corporate financial reports. The ability to collapse and expand the hierarchy and access its reports was also disclosed. The act required organizations to prove that their internal financial reporting control system was in compliance, using the judgmental implementation methodology. This act was a major event in business history because it established for the first time an explicit relationship between budget and direct cost center disclosure requirements and the internal financial reporting control and compliance internal business process and external business systems.

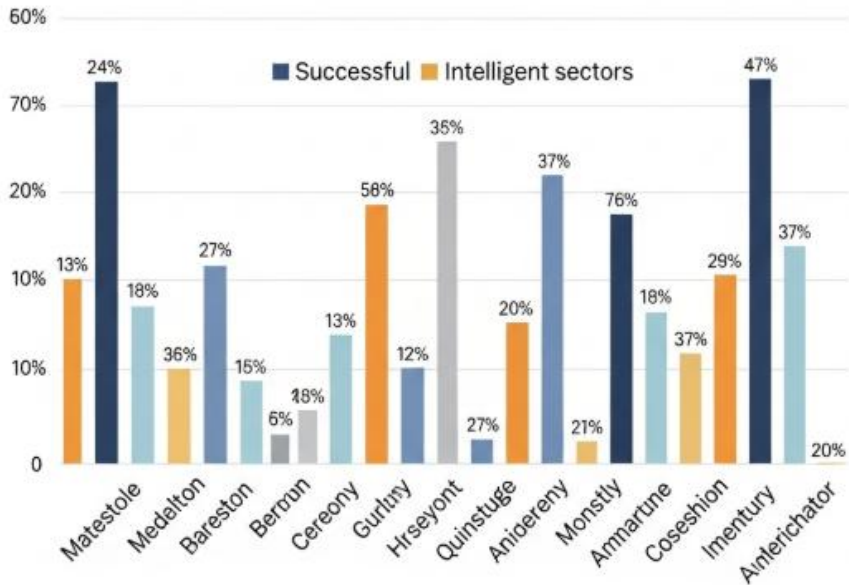


Fig 11.3: case Studies on Intelligent Compliance Implementation and Smart Manufacturing

11.5.1. Background

Before diving into an implementation of intelligent compliance within a specific case study, we would like to briefly revisit the basic characteristics of the automotive sector. The American automobile industry helped to pioneer modern mass production of consumer goods. The initial mapping of the automotive sector characteristics below serves to highlight how intelligent compliance implementation and smart manufacturing affects what earlier research has identified as a production paradox. Mass customization favors smaller batch sizes creating an apparent conflict between a need for flexibility and a need for efficiency. Flexible manufacturing systems provided a solution that allowed for both, but the relatively recent emergence of intelligent factories has made possible, in theory, a far greater level of flexibility without sacrificing efficiency than previously existed. To what extent intelligent compliance implementation and smart manufacturing shift the production paradox is the empirical question our case study, in part, is seeking to highlight.

On the one hand the automotive sector is characterized by high levels of global interdependence due to its well-established Global Value Chains. On the other hand, Production technology is highly advanced and begins to change emphasizing the use of robotic technology and advanced technologies. Product design is at the center of the creativity and R&D, which means that within GVCs design requirements flow to the local assigned for production mainly by means of contracts and through an infrastructure of training and consultancy undertaken by the lead firm. As a consequence, relationship specific investments are made by DTV in plants which are generally located in economies with forces such as skilled labor and R&D, design, training and infrastructure support, etc. are co-located in the same region. These strategic and production reasons explain the comparative resilience of the sector against cyclical fluctuations in demand. In addition, local plants are also sensitive to pressures for improvements in terms of labor wages, work conditions, health and safety, and environmental standards.

11.5.2. Implementation Strategy

The greatest challenge during the implementation of a smart compliance system is to develop the potential contribution offered by an intelligent integration of System Administration capabilities, going beyond centralization of data management, and Security Operation Center technology, going beyond centralization and automation of incident detection and management. The Application Layer must leverage the tools already used for the internal trustworthiness definition and control, violation and incident management, and risk analytics. The entire spectrum of verification and detection activities is based on digital resources that Environment Layer controls through operation security and mission assurance methods, as risk analytics is based on relational

evaluation and trustworthiness matrices defined in the Patch and RBS Layers. Integrating the Application Layer with the Environment Layer, and with the Patch and RBS Layers is the cornerstone for achieving the goals, which point to reducing the burden of compliance on business processes, by means of automatic violation detection, and risk analytics. These two elements are also the key to developing a systematic approach, rather than a point-in-time set of activities, as the building of an organization's supporting infrastructure for Authority, Configuration, and Activity Allowability is in fact a continuous process, which cannot be reduced to just a point-in-time auditing of trustworthiness. The systematic approach needs to be integrated into the ordinary Adaptive Business Processes life cycle – monitoring and continuous improvement.

11.5.3. Outcomes and Benefits

The study proposed a structured methodology to achieve compliance and enable intelligent implementation of industry 4.0 technologies to enable smart factories. This paper was successful in achieving Qualifiable Outcomes while enhancing Quality of existing Implementation Processes. It proposed a novel SCOM for Industry 4.0 to achieve compliance and enable intelligent implementation of Industry 4.0 technologies to enable smart factories. It also proposed a Simplified Checklist Model to enable SMEs with limited resources available for Industry 4.0 Implementation. Based on the detailed quantitative study, based on the various levels of 4.0 and 4.0 principles applied, the compliance deficits were identified and steps were suggested to achieve compliance. The entire Industry 4.0 principle categorization and their mapping with SCOM was based on the existing literature. The detailed data collection and FDM were performed with an extensive sample size of the Indian manufacturing sector which together achieved the desired validity and reliability of the factors analyzed in detail with ANOVA test and F-Test. The successfully verified SCOM can be used as a valid and reliable model for assessing the compliance status of Indian Manufacturing with respect to Industry 4.0 principles. The SCOM also extends itself as an Implementation Guide by proposing Design Steps and Implementation Steps for various elements of the industry 4.0 principles.

This Research-Based Example and Framework for the verification or validation of industry 4.0 Technology which has been developed can be utilized by research centers, universities, and institutes to conduct further detailed study and verification in the area of Smart Industry 4.0 Implementation. Future researchers can use this study to study a different aspect of these Technologies among Industry 4.0 elements or Parameters. The SCOM can help various Policy Planning Bodies by aiding policy creation and support for the enhancement of compliance of Companies with Industry 4.0 Initiatives. It could additionally also be effectively utilized by Regulatory Bodies, Advisory Bodies,

Consultancy Firms, and Industry-Specific Industry 4.0 Guidelines to draw Templates/Models for compliance guidelines and to further product-specific checklists for Industry Classification.

11.6. Case Study 2: Pharmaceutical Industry

Background As a regulated highly sensitive industry, pharmaceutical manufacturing is now under pressure to automate and digitalize their factories. Compliance requirements hold back innovative investments in Industry 4.0 components including IIoT, Cloud, AI. Current validation processes rely heavily on manual efforts. Existing computer validation life cycle processes require huge investment of time, money and effort. They require early and excessive detail to be spent on topics that are difficult to understand. Compliance personnel get bogged down with long and cumbersome documentation and hope to rely on them if they ever needed to prove compliance. Data integrity, which is not requested by regulators, is responsible for a lot of failures. Smart compliance concepts apply innovative intelligent automation and scripting techniques as well as intelligent enterprise methods to address the needs of the pharmaceutical industry.

Implementation Strategy The Intelligent Compliance approach recommends designing an intelligent globally integrated template factory without country or region specific requirements. The template should be implemented to the highest degree with no workarounds that apply during production. These templates offer the capability of intelligent automation and integration of all intelligent automation capabilities and optimally utilize employee competency. The script should include a test automation layer that is broken down by phase and should be reusable. The purpose of an Intelligent Compliance approach is to pure 100% trustworthy compliance. “You must be on vacation and far from your computer to be warned about an emergency. Your system will automatically advise all factory employees from top to bottom in the vertical process visible hierarchy, from top to bottom in the business visible hierarchy, plus all knowledge workers when this happens. Your system will prepare and send the appropriate media into all languages.”

11.6.1. Background

In this chapter, we present an Intelligent Compliance Implementation in the case of a pharmaceutical company. The pharmaceutical industry is characterized by a high number of regulations from health authorities to ensure that national health systems are supplied with safe medicines. Thus, the pharmaceutical sector invests a lot of resources to comply with the applicable regulations. In particular, these regulations apply to the procedures used by the company while producing drugs and, in the majority of cases,

data must be generated for validation purposes. Compliance Departments are in charge of analyzing Company trends to suggest corrective actions whenever the data trend exceeds the threshold values. These threshold values are defined according to regulations or to what must be achieved to ensure that medicines meet the characteristics explained into the specifications. For example, regulations suggest that stability studies must be performed to ensure that the quality of medicines over time does not exceed the threshold values.

People have to prepare a lot of data to comply with the regulations, and the approval of documents may take weeks due to the fact that the content is sometimes complex, difficult to understand, and often assessed with skepticism. This is a slow process that obliges Companies to maintain high levels of raw materials and finished product stocks, immobilizing important economic resources. Furthermore, Companies may be opaque. Indeed, it is sometimes difficult to understand why a product is not within the specifications; what corrective actions must be adopted?

11.6.2. Implementation Strategy

Implementation of the proposed artificial intelligence-based compliance implementation and management framework in the pharmaceutical industry is done by formulating a research question that addresses the need of compliance-aviation in the structural design of the used DQ framework. Understanding the regulatory guidelines and existing compliance framework required to be smart enough to differentiate between expert knowledge and user-defined DQ variables is essential for initiation of the process. The study employs the expertise-DQ modules related to respective phases of a typical business process, adopted solution design methodologies, regulatory com-domain adoptions, and factors guaranteeing conformance to regulatory guidelines to show compliance with specific attributes of DQ. A typical query is also presented whose output is an overview of the DQ attributes related to the monitoring of the respective phases of any business unit whose implementation strategy is defined in the data monitoring specification. The second stage evaluates the DQ module at the data collection and transmission phase. The proposed AI-based compliance tools leverage the design automation engineering's digital thread to integrate digital twin technologies into product lifecycle management for easy connectivity and compliance monitoring of product data throughout the product life cycle. The fourth phase evaluates the metadata related to the data collected at the execution level third phase. User query-based output of the specific DQ attribute, concerning track and trace data collected by the track and trace system, makes it easy to monitor the data to be conformed. A proposed set of use cases is developed at each step to test the defined strategies and framework on a

manufacturing system at a proposed duration parameter allowed for running the compliance monitoring and decision-making mechanism.

11.6.3. Outcomes and Benefits

Profound effects of implementing intelligent compliance and smart manufacturing to the pharma industry: a.. Saves time and resources through accelerated product development and launch. b.. Less number of manual operations and increased traceability. c.. Fewer paperwork and system resistance. d.. Provides valuable business insights for improving product quality and reducing risk. e.. Continuous validation, leading to less than 0.5% deviation for validated processes. f.. Comprehensive training and help. The Application Intelligence allows the products compliant with the current patent regulations to come into the market early and make more money for the concerned organizations. The validation-related heat maps give priority to which process requires validation more urgently and which system users need training on process execution. The Application Intelligence allows early detection of the companies/processes which do not comply with the set metrics. General users of the system can view the dashboards and ascertain the state of the process execution immediately.

11.7. Case Study 3: Food and Beverage Industry

Fast food and beverage industry is one of the fastest growing sectors in Vietnam. High consumption growth and foreign capital contribution are the two most noticeable trends in the growth of the fast food market in Vietnam during the last five years. There are many factors contributing to the success of fast food in Vietnam, the most important being the cafe culture which creates a wave of shopping habits among the Vietnamese community. Fast food chains have been appearing in most urban areas and the majority of their sales come from take away. At first, they were the highest qualified foreign brands, but rising GDP and the demand of local citizens have made room for local suppliers. Not only making our experienced chains meet the regulation, but also attracting a considerable number of new suppliers to join the industry is not an easy task for the Company.

Therefore, the need for embarking on compliance implementation towards the fast food and beverage supplying chains amongst stakeholders is more favorable than ever. Complying with a design strategy which ensures the required quality dealing with their wished price. The bakery imported materials containing the same composition as the local suppliers but at lower cost. The past behavior showed that the global market is volatile and often lacks transparency. In order to prevent product blocking issues, local facilities have to follow local statutes and internal compliance registers. The key thing

is to design adequate compliance requirements that can be understood as either a complete restriction limit or a sliding scale limit for qualification. The second part is the message sharing with the other stakeholders providing ingredients who can validate and check if ingredients are coming from a registered checked supplier/project.

11.7.1. Background

To make operations profitable, food companies must adopt an intelligent compliance implementation strategy in the product management unit in order to make the product marketable. Product compliance has become a warranty not only of quality but also of economy for a successful company. The rules to be considered during Food Contact Plastic compliance processes strongly depend on the target countries, because they can set different requirements. Obviously, to protect the public health, countries must afford a strong control on imported products, but this means an additional burden to those companies that are a model of excellent execution, or at least bring their know-how abroad all that permits to increase returns.

Leveling with the cheapest companies by applying low-quality standards in order to favor price competition increases the number of fake products. This means putting at risk people's health and undermining the image and reliability of any country, causing long-lasting damage. In the brief paper, the Intelligent Check Point (I.C.P) to be realized in Formex s.r.l to make compliance rules a profitable instrument, not an additional cost, is described. The Center's strategic objective continues to assist companies in overcoming the market barriers that are the cause of an increasing number of fake products. Moreover, it provides laboratory support, to which the real SME would have a cost due to the small volumes of requests.

The framework of the case study is made up of Formex s.r.l, a small and medium-sized enterprise that aims to become a problem-solving partner by dealing with compliance services in the food contact plastic sector. In fact, FCM legislation is complex, fragmented, and mostly obligatory for the realization of a product on the market. Therefore, a partner who can support the company from the product design phase until the putting on the market is required. These features are the strength of Italversa s.r.l. The experience of I.C.P, center for plastics and plastics in contact with food compliance testing built up by Italversa s.r.l in Mexico, emigrating to Italy would become a sort of accelerator in the FCM compliance Italian market.

11.7.2. Implementation Strategy

A novel Production Execution Information System (PEIS) is needed to digitally transform the food and beverage industry. SMEs in this domain manufacture food and drinks products daily in high volume and in masses; however, they still apply an outdated paper-centric method to handle all their production data documentation and their enterprise business processes to manage the foundational aspects of their business. Because of this, the goal of this research is to develop a new digital PEIS for the F&B industry to: a) radically reduce the time and effort it takes to collect and manage production and quality data; b) ensure full transparency and accurate traceability of production and quality data, using data from the shop floor to fulfil business and industry requirements for document control, data integrity, system validation and information assurance; c) eliminate waste management of physical documents and records; d) fully comply with regulatory data management and record keeping requirements; and e) make it easier for manufacture to generate data analytics reports, improving decision-making to support continuous improvement initiatives.

Afterwards, interviews and subsequent feasibility evaluations were held to capture the specific needs of the business to carry out the implementation strategy for the new PEIS while allowing the organisation to have a central role in shaping the system, the goals of the business for the system, the required functionalities of the system, the data structure design of the system and the methodology for implementation. The new PEIS has a cloud-based architecture design to harness its unique benefits, and benefits of other cloud attributes like reduced infrastructure costs and improved data security.

11.7.3. Outcomes and Benefits

The solution proposed had varied benefits. On the one hand, all the documents kept in the GL to be stored, shared, and consulted electronically, providing quick and easy access to employees and, on the other, benefited the Business Units located in co-located countries. Employees were able to access and share content quickly, avoiding prolonged email conversations that could be a source of errors. Being able to conduct the entire conversation within the same document with someone who shares the same access point made it possible to discover the version that had been the latest modified quickly.

Specific journals and mailboxes, along with alerts, allowed the GL to efficiently control the tasks requested to the Business Units with the right amount of follow-up. The response time from the Business Units was optimized, and it was possible to keep track of the requests made and the answers given. This workflow, applied to new tasks, allowed them to contain the impact on the Business Units' operations. On the other hand,

internal team meetings could validate and solve issues affecting some requests with more than one input or the output of people from various Business Units.

This solution was well accepted by the Business Units. They had practiced and gradually mastered the participation in several documents, normally proceeding to validate the requested adjustments with the GL through a formal email. The solution has evolved over the years, following the internal business evolution roadmaps. The system has managed to keep track of all the documents prepared to date across various GLs in several central models.

11.8. Conclusion

The design of secure production processes in an engineering sector is a prerequisite for successful smart manufacturing processes with a human-centered technology design. This ensures secure and socially acceptable frame conditions for technical developments in the field of Cyber-Physical Systems, especially in the field of Industry 4.0, as well as the deployment of new and reportedly promising technological concepts. The increasing virtualization and networking of production and logistics systems at all levels displaces the formerly geographically delimited hierarchical and regimented structure of production organizations in favor of an open design with regard to functions and number of participants and cyberspace as the central connective element. The transition from traditional manufacturing to cyber-manufacturing is likely to impact the future design of security systems. Furthermore, existing concepts and methods for decision analysis that facilitate concrete, practical choices in relation to threats and opportunities of this transition need to be augmented, adapted, integrated, and extended according to the peculiarities of cyber-manufacturing. Especially in real-time dynamic environments, human actors still represent a major source of threat.

The new design paradigm of intelligent compliance implementation and smart manufacturing systems enhances the security of production assets such that security assurance will never constrain successful operations in the sense of compliance; rather compliance is guaranteed in intelligent ways based on real-time risk and status assessments, and appropriate reconfigurations of the crucial operational elements are initiated if and whenever necessary. We conclude with a very short introduction to the notion of a palladium for security and production. Smart manufacturing systems will develop composite force fields of redundant sources of protection on multiple levels against multiple types of threats and associated consequences.

11.8.1. Future Trends

Based on current developments in smart factory implementation and the digital twins of the shop floor, there are several key proposed future requirements for intelligent compliance processes. These trends include increasing monitoring automation, compliance digital twins, and rising AI support. Other trends are the increasing monitoring speed, support of external solution design, compliance performance visualization and ROI showing, data sharing for mutual trust, increasing standardization support, and altering the compliance landscape, particularly regarding the reversal of the burden of proof for companies from outside the EU. There is a growing need to observe businesses in the region continuously, and Automated Compliance Technology allows this for many signs based on publicly available data.

However, much of that visible data may show an imbalanced view of those businesses, which leads to the proposal for Compliance Digital Twins. These can complement the external view with additional data from various other sources, such as quality assurance and certification bodies, suppliers, customers, and employees. Based on these digital twins, regulations may also define minimal compliance offerings for there to be mutual trust, which could reduce pressure on both sides. The automated monitoring should also comprise the possibility for third parties to propose their own and industry solutions for qualified businesses at a lower cost and backed by sharing data. Additionally, these solutions could be stored in a shared compliance twin and made visible to interested parties. In the future, digital twin decisions also must involve proofs of offering sufficient compliance performance for the emerging generative AI content and likely other future developments, understood as new directions of business activities which could also lead to feedback loops.

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