APPLYING PROCESS DATA MAPPING METHODOLOGY

for Systematic and Sustainable Transformation Toward Pharma 4.0™

By Emmie Heeren, Frank Krüger, PhD, Venkateshwar Rao Nalluri, PhD, Sebastian Niederhauser, Alexandros Papadopoulos, Dirk Wollaert, and Vinzenz Zauner

Pharma 4.0™ is a reference framework tailored to the pharmaceutical industry, guiding its digital transformation. Although many of today's processes generate sufficient data to enable advanced use cases, structured guidance for transformation is often lacking. To address this, the ISPE Pharma 4.0™ Subcommittee on Process Data Maps and Critical Thinking has introduced an approach to help organizations develop a holistic perspective on transformation.

This article presents a case study that explores the application of this framework, highlighting key aspects that support the adoption of the methodology and accelerate industry-wide transformation.

The case study outlines the steps involved in process mapping, creating process data maps, applying critical thinking, and optimizing data flow. By offering a tangible example, it demonstrates how organizations can shift from a process-oriented to a data-centric perspective. This shift supports multiple Pharma 4.0™ principles, including enhanced data integrity and governance, and lays a stronger foundation for quality by design, risk-based approaches, control strategies, and ultimately, validation.

SYNOPSIS

This article presents a practical case study demonstrating the application of the process data mapping framework for structured transformation. It illustrates the shift from a process-oriented to a data-centric approach to support Pharma 4.0™ principles and enhance data integrity and governance.

BACKGROUND

Pharma 4.0™ is a reference framework designed to guide the pharmaceutical industry through digital transformation. Since its introduction in 2015, Pharma 4.0™ has seen growing adoption, with key industry leaders describing it as an imperative rather than a competitive advantage [1–3]. Digital maturity and data integrity by design are the two key enablers of the Pharma 4.0™ operating model (see Figure 1) [4, 5].

Pharmaceutical industry stakeholders need to digitalize their processes to leverage Pharma 4.0™ benefits such as increased agility, efficiency, flexibility, and quality of their production processes. Although many of today's processes provide sufficient data to enable advanced use cases, structured guidance for transformation is often missing. The current industrial stage traditionally centers around

Figure 1: Pharma 4.0™ operating model [6]

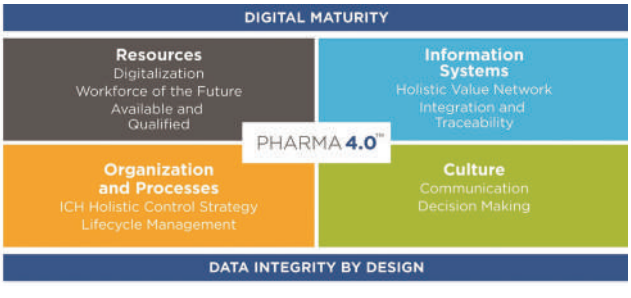
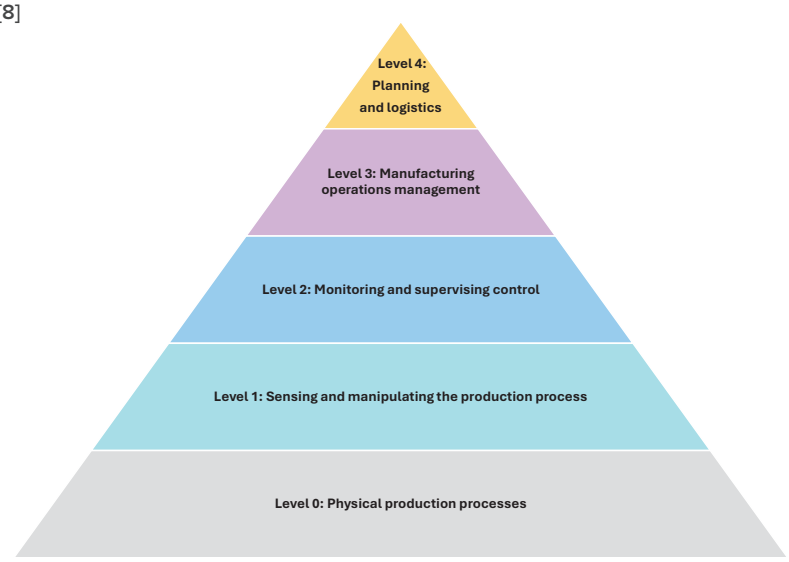


Figure 2: ISA-95 model [8]



the ISA-95 model for digital systems with processes-centricity at its core [7] (see Figure 2).

With individual, predefined use cases in mind, data flows have been tailored so that generated data is fed through a series of defined connections up to the business solution level. In comparison, Pharma 4.0™ envisions a data-centric architecture of tightly entangled processes and supporting systems where digitalization empowers better decision-making through promoting concepts such as original data, which is used as a single source of truth [9]. To implement Pharma 4.0™ to its full extent, data itself needs to be understood as an asset. Changing to this data-centric viewpoint has not only been linked to substantial improvements in data governance and data integrity, but it also serves as a sustainable basis for next-generation operating models [10, 11].

PURPOSE

ISPE's Pharma 4.0™ Community of Practice (CoP) Process Data Maps and Critical Thinking subcommittee previously published how Reference Architecture Model Industry 4.0 (RAMI 4.0), process maps, data flows, and critical thinking can be leveraged for structured transformation [12]. A four-step approach was presented to let organizations develop a perspective on holistic transformation toward Pharma 4.0™. First, the current process-oriented state is documented. Second, it is transformed into a data-centric view. Third, the data-centric view enables critical thinking, which helps envision a target state. In the fourth and final step, the target state is implemented.

While the general concept of the approach was given in a previous article, this publication focuses on providing a tangible case study. Important aspects during application of the framework are discussed. The aim is to provide relatable guidance to ease adoption of the methodology and therefore accelerate the industry transformation towards Pharma 4.0™.

This case study dives into how companies manage access—think cleanrooms or digital systems—using structured workflows. It's all about mapping out each step clearly, from request to approval, to stay compliant and efficient. These process maps are the first building blocks for smart digital transformation.

MAIN PART: CASE STUDY FOR STRUCTURED TRANSFORMATION

Step 1: Process Maps

In this case study, an access request process is reviewed. This or similar processes have become standard in the industry to manage access permissions to regulated information or environments such as user groups in digital systems, role changes within the company, or key-card access to restricted areas like cleanrooms in production. Process users typically follow a standard workflow, starting with submitting the request for access, adapting the training plan (i.e., training on relevant SOPs), implementing the requested permissions in the target system, verifying permissions

The case study analyzes the process for two key Pharma 4.0™ concepts: single source of truth and data as a strategic asset.

with a second person, and, finally, informing the required personal of the request's outcome (see Figure 3).

For compliant operation in GxP-relevant systems, workflows such as these must be clearly defined in related SOPs. Beyond compliance, efficient operations are driven by such harmonized workflows. The systemic documentation of business processes is foundational to the application of the presented methodology and might already be present within an organization. Only a few companies will have their current process maps on the level of detail that is required for digital transformation.

Companies can start from their individual level and go into detailing selected processes in scope of their digital transformation initiative. Detailed documentation may also result as a byproduct from root cause analysis after findings from internal or external reviewers. It is important to systematically channel information in an overarching process management documentation governance. Detailed literature and insights on process identification, types of notations, and management can be found under the term business process management (BPM).

To begin the systematic Pharma 4.0™ transformation, the process map is complemented by the occurring data sets. Here, a data set is defined as a conceptual view of a data record, independent of its form [9]. Data sets are needed as input for a process step or decision, and as output to record the outcome.

Figure 4 shows the outcome of the data mapping. Four different data sets are identified in the process: change request, training plan, user application access, and screen capture. At each step, the specific data life cycle stage is assessed. The GAMP® structure of the data life cycle is used as a basis, which consists of five different phases: creation, processing, review, reporting and use, retention and retrieval, and destruction [13]. Each identified data set is placed in its appropriate lane of the data life cycle. If a data set is created, it is placed in the creation lane. If a data set is processed in a subsequent step, it is placed in the processing lane, and so on until all process steps have been analyzed.

Specifying processes and mapping data sets according to their data life cycle concludes the first step in the four-step approach. It serves as the foundation for describing the operational details and is potentially already available to some extent.

Step 2: Process Data Maps

The result of the first step yields the existing data sets within one process. If the viewpoint is limited to this one process, one could already start suggesting improvements. However, the identified data sets are likely also used in other processes within the organization. Focusing on the training plan data set, human resources (HR) processes, such as onboarding, offboarding, and periodic reviews, also interact with this data set. After all interacting processes are identified, a holistic overview of the interactions of the training plan is achieved.

To adequately transform a business process of an organization, it is unavoidable to holistically identify each data set and connect it to its process steps in every process. By doing so, an individual process transformation often requires inspecting multiple processes from the data set's point of view. Various software solutions offer building such connected landscapes and inventories. More information on application and data management can be found under the term enterprise architecture management (EAM).

Figure 5 shows the completed mapping for the data set training plan. The connection between the processes through the data set is shown, including the respective data life cycle stages. For the upcoming transformation, it is required to identify where, and in which format, the data set is stored. This is done with reference to the related computerized system or other types of storage.

Next, the process steps are rearranged from a process-oriented to data-oriented view along the data life cycle. This visualizes where data is created, processed, reviewed, reported, used, retained, retrieved, and destroyed. Figure 6 shows this view on the data set training plan.

This holistic data-oriented view along the data life cycle phases concludes the second step in the four-step approach. With this step, the data set is put in the focus and reveals its usage across multiple processes. This perspective is often novel to an organization. The sorting across the data live cycle provides the foundation to identify optimization potentials.

Step 3: Critical Thinking

The *ISPE GAMP® Guide: Records and Data Integrity* defines critical thinking as "a systematic, rational, and disciplined process of evaluating information from a variety of perspectives to yield a balanced and well-reasoned answer" [13].

During critical review of the process, multiple questions arise naturally, such as, why is the training plan created twice within the onboarding, once in paper form training plan form and once in digital form in the learning management system? And when following the life cycle phases, how do the paper-based training plan forms get destroyed when no destruction process is defined? During the critical thinking step, each phase is analyzed to determine if the activity occurs in the appropriate process step, the right storage is used, and there is no redundancy.

A more in-depth insight into critical thinking is given in *ISPE GAMP® 5 Guide: A Risk-Based Approach to Compliant GxP Computerized Systems (Second Edition)* [14]. It should be noted that the business

process review (BPR) should not be limited to the current way of working. Instead of incremental optimizations, the process data map should provide a basis from which a strategic objective could be derived and how the process might look in the near or distant future. Depending on the level of complexity, it can prove useful to include internal and external subject matter experts and to analyze related processes in different industries.

During the critical thinking step, it is imperative to not limit creativity. It is important to stress that the details of this long-term objective do not need to be clear yet. In fact, omitting details facilitates the process. Potential solutions might be discovered outside the scope of currently considered technical solutions. As one example, today's artificial intelligence (AI)-powered virtual assistants seemed far-fetched in 2009.

In the case study, the focus is set on analyzing the process for two key concepts of Pharma 4.0™: single source of truth and data as an asset. Application of the first concept concludes in removing redundancies and avoiding the training data being created in both a paper-based format and an electronic format. To achieve the usage of data as an asset itself, the current process's data sets are mapped on the RAMI architecture (see Figure 7).

The RAMI model was developed as a general design tool for Industry 4.0 processes. The four-step approach applies it as an analysis tool to assess the level of integration of data sets [12]. In this representation, a classification on the asset layer means that the availability of the data is limited to the asset itself where it was generated with no automatic integrations to other systems. An entry on the integration layer on the other hand signifies that a digital representation of the data is available. By such integration, physical assets are made available to the other layers in the form of an administrative shell.

The communication layer represents the method of communication at the underlying use cases, services or any other function or data models. Communication methods can include physical systems like wired connections, data links (wireless connections), networks (like internet protocols), or applications. Including the communication layer onto every data set exceeds practicality. A detailed description of each layer in context of the four-step approach is provided in , "Methodology to Define a Pharma 4.0™ Roadmap" by Heeren et al. (*Pharmaceutical Engineering*, May/June 2023) [12]. Critical thinking and holistic identification of transformation potentials with the support of RAMI concludes the third step in the four-step approach. This step is the core for digital transformation of the processes in perspective of the data life cycle.

Step 4: Optimized Data Flow

In the final step of the four-step approach, the identified solutions are implemented to enhance data flow. This transformation project requires following clear regulatory documentation requirements, especially if GxP-relevant processes are impacted. ISPE guidelines are available for further information on effective project management [15]. To optimize the training plan data set, the outdated training plan form storage is eliminated and directly integrated into the learning management system for creating, reviewing, and approving training plans, as well as for recording the training outcome. This not only enhances the integrity of the data set and thus improves regulatory compliance, but also simplifies the process for the user by not having to deal with more than one record.

> Pharma 4.0™ isn't a sprint—it's smart, steady, data-driven evolution.

Transferring the creation and approval of training plans from the access request process to an HR-specific process further streamlines operations. This simplifies maintenance and designates a single function for this critical aspect. The strategic redesign results in a more consistent data life cycle for the training plan. It is now elevated to the information layer, serving as a single source of truth without relying on system-specific interfaces (Figure 8). The integration of this data set and the resulting data availability allow for further improvements of the overall access management process. Further data sets and transformation can be addressed by the next iteration of the four-step approach. The data-centric optimization concludes the fourth and final step in the four-step approach.

CONCLUSION

As the pharmaceutical industry continues to evolve, adopting Pharma 4.0™ principles will not only enhance data governance and integrity but also position companies for success. Optimizing processes toward Pharma 4.0™ is an iterative and continuous endeavor. The journey toward optimized data flows requires commitment, adaptability, innovation, and holistic contemplation. As organizations embrace change, they position themselves for sustained success in an environment where data is a strategic asset, and its seamless integration is key to achieving business goals.

Transformation necessitates a reevaluation of both process and data flows. Here, using the RAMI model as an analysis tool ensures alignment with industry standards, fostering a seamless flow of data across different layers. It facilitates a bottom-up approach to transformation, moving from the asset layer toward the business layer. The RAMI representation aims to create an administrative shell that facilitates seamless communication with integrated systems, databases, and applications. Once all processes align with the "single source of truth" principle, the business layer is examined from a bidirectional view. This defines how layers integrate to achieve overarching business objectives.

In the presented case study, the applied four-step approach revealed inefficiencies and redundant data storage and facilitated

critical thinking. This case study provides a systematic framework to map, analyze, and optimize processes and serves as the bridge between current practices and long-term objectives, steering organizations toward a future-ready state.

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About the author

Emmie Heeren is a Senior Manager with Kite Pharma, a company connecting business goals with advanced technology, and she has been involved in international digitalization processes for most of her career. For many years she chaired the Pharma 4.0™ CoP Data Integrity by Design subcommittee. Recently she was involved as co-founder of the local Dutch ISPE Pharma 4.0™ CoP. She joined ISPE in 2020.

Frank Krüger, PhD, is Senior Digital Business Process Specialist in the CMC development of the Healthcare Business of Merck KGaA, Darmstadt, Germany. He holds a PhD in information science from the University Saarbrücken and has more than 25 years of experience in computerized system validation and data integrity at both pharmaceutical manufacturers and suppliers. He is a founding member of the ISPE Pharma 4.0™ CoP Process Data Mapping and Critical Thinking subcommittee. He joined ISPE in 2009.

Venkateshwar Rao Nalluri, PhD, is Senior Scientist at Janssen Cilag AG in Schaffhausen, Switzerland. He has 14 years of experience in the pharmaceutical industry in biologics manufacturing. He received his BPharm from BITS-Pilani, India, and his PhD from University of Basel, Switzerland. He is an active contributor to the Pharma 4.0™ CoP Process Data Mapping and Critical Thinking subcommittee. He has been an ISPE member since 2017.

Sebastian Niederhauser is the Branch Manager and Authorized Officer at cts GmbH in Vienna. He has more than 20 years of experience in the pharmaceutical industry. His main focus is in process automation, ranging from field instrumentation up to DCS, batch, and historian systems. He holds a degree in electrical engineering. He joined the ISPE Pharma 4.0™ CoP Process Data Mapping and Critical Thinking subcommittee in 2018.

Alexandros Papadopoulos is the Operational Technology Manager at Viralgen in San Sebastián, Spain. He is focused on optimizing operations through a holistic, systems-driven approach. He joined the Pharma 4.0™ CoP Process Data Mapping and Critical Thinking subcommittee in 2022 to further contribute to the field. He holds a master's degree in biochemical engineering from the Karlsruhe Institute of Technology in Germany. He has been an active member of ISPE since 2017.

Dirk Wollaert is a member of the Siemens competent center for pharma and life sciences. He is a board member for the ISPE Belgium Affiliate, co-authored the ISPE Baseline® Guide: Pharma 4.0™, and is an active contributor to the Pharma 4.0™ CoP Process Data Mapping and Critical Thinking subcommittee. He has a master's degree in computer science and a graduate degree in business management. He joined ISPE in 2021.

Vinzenz Zauner is a Consultant focused on systematic digital transformation with business process management and enterprise architecture management. He has served as the Emerging Leaders Chair of the ISPE Pharma 4.0™ CoP Steering Committee since 2022 and as an Emerging Leader Representative for conferences and hackathons. He is a member of the editorial board for Pharmaceutical Engineering. He holds an MSc in biotechnology and an MSc in innovation management, entrepreneurship, and sustainability. He joined ISPE in 2019.

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