

Digital Company Transformation in the Healthcare, MedTec and PharmaIndustries

Review and development of an approach for regulated environments

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Abstract— Digitalization is transforming our society and with it bringing new opportunities and challenges for organizations operating in today's dynamic markets. Market commentators suggest that companies with highly digitalized supply chains can expect average efficiency gains of 4% annually, while boosting revenue by 3% a year. One hypothesis in this context is that with improved and digitized processes organizations can offer their products and services to customers quicker, pass on savings in the form of price reductions or improve customer experience.

Digital Transformation initiatives help organizations to reach for those goals. This paper discusses existing approaches towards a Digital Transformation based on a comprehensive literature review. Furthermore, the paper concludes with the proposal of an enhanced approach for organizations in the regulated environments of the healthcare, medical technology (MedTec) and pharma industries.

Based on literature review and expert interviews a common fundamental cornerstone can be stated: To improve the value delivered to the end customer, a Digital Transformation needs to focus on the core value creating processes rather than on single (siloeed) departments. It can be also concluded that such an initiative should support the existing corporate strategy and be visualized through the improvement of relevant performance indicators to be effective. In the mentioned industries, special regulatory requirements need to be fulfilled. It is important to consider these during a transformation, such as the need for process requalification, validation, and documentation, as they can influence the velocity of process changes.

Keywords- *Digital Company; Transformation; Approaches; Digitization; Change Management; Healthcare; Regulations*

I. INTRODUCTION

Over the past few years, the idea of Industry 4.0 has increasingly manifested itself in science and in industrial practice. It depicts the trend towards digitization, automation and the wide use of information and communication technology (ICT).[1]Increasingly companies have started utilizing internal digitalization initiatives and programs to push for the implementation of Industry 4.0[2]; to improve their cost model, increase product quality, and reduce time-to-market. This is intended to increase customer value.[3]

Digitalization in this context is understood as the strategically oriented transformation of processes, products, and services up to the transformation of complete business models [4]using information and communication technologies (ICT) with the aim of ensuring sustainable value creation[5].It is used as a synonym to the term of Digital Transformation, which will be used in the context of this article [6]. Measures derived out of such initiatives have the potential of providing a significant contribution to an organization's success and may present a new unique selling point[7].

Improving the performance of an organization has been in the sphere of the practices of lean management, where tools and methods are systematically applied to change processes and in addition to train employees in the mindset of continuous improvement towards those objectives[7]. Technological advancements over recent years offer additional levers to change the performance of organizations[8]. Both measure types (organizational and technological) complement each other and thus a Digital Transformation initiative needs to consider both aspects to be successful [9].

A change of an organization, to whatever extent, is acknowledged successful when defined target conditions are eventually achieved [10]. Thus, on a meta level, Digital Transformation initiatives can only be impactful when improving the organization's key performance indicators.

Actors, especially product and service vendors in the healthcare, medical technology (MedTech) and pharma sector, due to the potential impact on human life, are highly regulated. Those regulations are institutionalized through quality management (QM) systems and additional approval steps [11]. These regulations propose challenges when changing internal processes as often the effort of implementation is greater than in other industries [12]. It must be ensured, that those regulations are properly understood and considered within the context of Digital Transformation initiatives.

There are numerous models proposed on how to initiate, execute, and sustain the Digital Transformation of an organization[13, 14, 15, 16, 17, 18]. Industry related conditions need to be considered, processes to be adapted, people need to

be trained and technology introduced [19], all 'wrapped' within the management of change.

This article discusses existing models for a Digital Transformation, proposed foundational principles and requirements and provides a recommendation for decision makers on relevant success factors for an enhanced approach.

II. HOLISTIC BUSINESS SYSTEMS AS BASIS OF A SUCCESSFUL DIGITAL TRANSFORMATION

Digital Transformation strategy does not operate in its own silo, it is a supporting horizontal to the organization's vision and strategy. It needs alignment with the technology and operations strategy as to the future operating state.

Organizational change initiatives need to fully understand the present state and the value for moving to the future operating state, cf. [20]. Only if the objectives are defined, understood, and communicated to relevant stakeholders, a targeted (Digital) Transformation initiative can be tailored to the business's needs. After understanding and quantifying the need for change in an organization, an appropriate analysis approach can be pursued, and levers (organizational and technical) can be derived to change the organization's standards. Successful change initiatives consider a structured approach of improvement [7].

Effective organizational change initiatives are supported by deep-seated lean business or performance systems [21]. Such a system forms an enterprise-specific, methodical framework of rules for the continuous orientation of all enterprise processes to the customer to achieve the targets set by management. Usually, the application of individual methods and tools in enterprise processes does not necessarily result in an overall optimum. Sustainable success is achieved only through the integration in a (lean)system. It specifies the selection and synchronization of principles, methods, and tools and is understood, accepted, and implemented by all employees of the organization. A selection of lean design principles to improve organizations are [22] customer orientation, waste reduction, and value stream orientation.

In the context of this paper, it is thus recommended to embed Digital Transformation initiatives into lean systems.

III. COMPARISON OF EXISTING APPROACHES FOR DIGITAL TRANSFORMATION

A. Overview

To determine an appropriate approach for a Digital Transformation in the healthcare, MedTec and pharma sectors, existing models are examined with regards to their suitability.

Out of recent studies, a selection of 29 approaches has been examined [23, 21]. Five of those approaches are especially relevant, as they build upon change and lean management principles. A special quality orientation also is shown in those approaches, which enables them on a first glance to be used within the healthcare industry.

A closer look at those models reveals parallels: One of the cornerstones of successful change is the early involvement of key stakeholders with transparent and direct communication [20]. All selected models highlight the importance of a holistic exchange of information throughout the transformation.

B. Model analysis

1) *7-stage implementation process for Industry 4.0*: The first process model under consideration consists of seven stages [13]. The hypothesis behind this transformation approach is, that the transformation of a whole organization is achieved through the transformation of the company's core value-creating processes. This approach aims to digitally transform business processes and workflows step by step. These seven stages can essentially be divided into three main sections: recording and analysis of the processes to be considered, determination of change readiness and implementation planning.

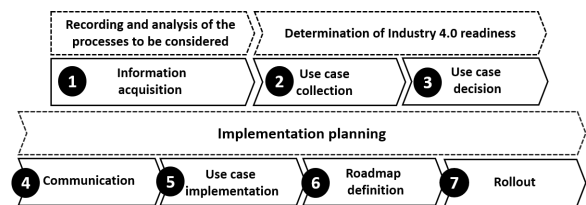


Figure 1. 7-stage implementation process for Industry 4.0 [13]

During the first step, workshops are suggested with managers and employees to determine the department's need for change. In a further step, use cases from various sources are collected systematically, categorized, and evaluated to derive a roadmap to tackle top priorities. After selecting the most suitable use cases, planning for the implementation can begin. In this phase, the communication of the change initiative to all stakeholders involved is in focus. Implementation follows an iterative approach, that means in small steps throughout a repetitive procedure with sprints, which gradually approach the desired target state, minimizing risk. It is suggested to prioritize the use cases and implement improvements according to their business value.

Two characteristics are special in this approach: a) workshops are conducted as a means of change management during the transformation; b) it is a process-related approach with an iterative implementation of changes.

2) *5-step method to transfer knowledge and introduce Industry 4.0 concepts in Small and Medium Enterprises (SMEs)*: This approach aims to implement Industry 4.0 initiatives for the manufacturing industry [15].

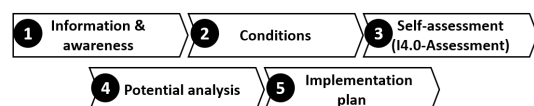


Figure 2. 5-step method to transfer knowledge and introduce Industry 4.0 concepts in SMEs [15]

The first step serves as an orientation, in which information deficits are eliminated and the relevance of the transformation is discussed and explained to employees. Best practices of successful transformations are presented, which are explained in depth during workshops or seminars to support change management. In another step, the requirements are addressed. The categorization of those can be done by design thinking with subsequent transfer into a business model canvas [6].

The next steps are used to gain transparency on internal readiness. Afterwards, the effort required to implement the transformation is estimated based on the difference between the requirements and the actual readiness. In the subsequent and final step actions are defined and put on a roadmap.

It is noticeable in this approach, that every stage is accompanied by workshops. In addition, design thinking and the use of business model canvases are proposed.

3) *Digital Transformation roadmap*: Another model is the so called "Digital Transformation roadmap" [16]. The Digital Transformation here refers to the change in existing business models. The approach is divided into five phases, which cannot be strictly applied sequentially, but recursively, meaning leading back to some point in time.

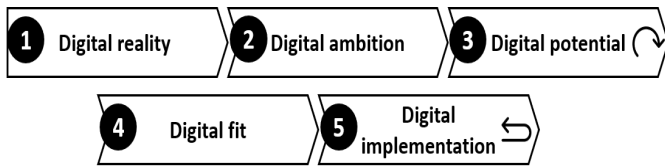


Figure 3. Digital Transformation roadmap [16]

In the beginning, the company's existing business model and the value chain are mapped in detail. Building on this, the "digital ambition" is determined. Here, the goals for the digital transformation are derived and prioritized. In the third step the opportunity is identified by examining industry best practices or benchmarks for their applicability in the organization. In the fourth step, the options of the new business model are evaluated and prioritized based upon pre-defined criteria such as customer value or cost. The fifth step pursues the goal of introducing a new business model. Consideration should be given to the sequence of implementation for the future "North Star" and a close alignment with the IT function is required for any technology or enterprise architecture changes.

As mentioned, the five steps do not have to be sequential. For example, the results of step three can influence the goals of the previous step. Because for instance, goals that were believed to be unachievable may now appear attainable in the face of new technologies.

4) *Industry 4.0 roadmap*: The next model under consideration delivers a roadmap for the structured implementation of so-called smart production and services in companies and consists of three main phases [17].

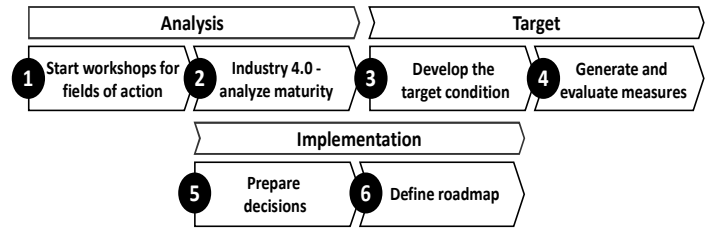


Figure 4. Industry 4.0 roadmap [17]

The roadmap represents a bottom-up approach, in which the organizational functions analyze the current state and define a target state as part of the strategy. The steps of the analysis phase consist of the usage of workshops and maturity level analyses. The workshops include an introduction to Industry 4.0, existing opportunities, risks, and application examples. Furthermore, the use of Value Stream Mapping (VSM) is proposed throughout the model, to generate process related ideas, which are then evaluated with regards to their impact.

The implementation phase aims at a decision on the measures to be executed and the definition of a roadmap. An agile implementation approach is considered, where the delivery of a small solution is scaled-out to achieve a greater benefit, in parallel implementing the next item of the backlog.

One specific of this approach is the use a balance scorecard to measure achievement of the previously defined goals.

5) *Generic Procedure Model for the Introduction of Industry 4.0*: The aim of this approach is to evaluate existing Industry 4.0 technologies and apply them in the further value creation process [18].

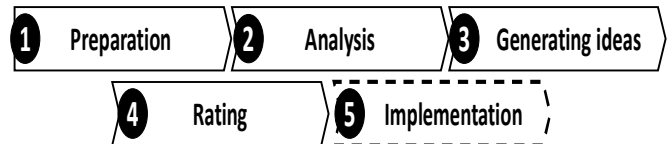


Figure 5. Generic Procedure Model for the Introduction of Industry 4.0 [18]

The preparation phase creates a common understanding of Industry 4.0. It ensures, that all employees are equally informed. Subsequently, the current state of the main value creating process is mapped to identify optimization potential through internal competence and external perception analyses.

The idea generation begins based on the findings. This may involve optimizing sub-processes and further developing the business model influenced by existing technologies and best practices. Initially, the identified potentials of the analysis phase are examined more closely, and a vision of the target state is developed. Based on the authors, this approach provides a systematic way to efficiently drive business ideas towards execution. Afterwards, the rating phase follows, using a framework like the Boston Consulting Group (BCG) matrix. The output is a business plan with capacity and resources, business value and a roadmap.

The model offers an introduction of Industry 4.0 and focuses, in contradiction to the other approaches, on the business model, rather than selected internal processes. Special features of this approach are the tactical tools it contains to digitally optimize products, processes, and business models. In addition, the approach leads to new business models and thus is more innovation-focused than the other approaches.

IV. REQUIREMENTS TOWARDS AN EFFECTIVE ALTERNATIVE APPROACH FOR DIGITAL COMPANY TRANSFORMATION

Based on the screened literature on lean systems, change management and existing process models for Digital Transformation, requirements were consolidated to be able to develop an effective approach especially for organizations in the healthcare industry. They have been derived from the screened literature and of interviews with experts from science as well as MedTec industrial practice.

The requirements for the desired process model consist of six elements. To start with, the model should be based on a process-oriented change approach, which is intended to reduce waste through its focus on lean management. This does not imply to digitally transform department by department or business line by business line, but rather transform value creating process by value creating process with an end-to-end scope. Only in this way it is ensured, that benefits are passed to the customer.

The next point takes regard to the special regulatory considerations in the healthcare industry that must be followed during change initiatives. The healthcare, MedTech, and pharma industries are a very fast-moving and innovation-driven market. There are comprehensive QM-systems, that ensure processes are documented, verified, and validated to comply with regulatory body standards and guidelines. These organizations must also be flexible to react to regulatory changes, thus having access to current, validated and legally compliant information [24]. These regulatory provisions define requirements for QM, which are intended to manage risk and ensure that only safe products are placed on the market. This may contrast with other industries, which orient themselves frequently towards the EN ISO 9000 series of standards. As a result, it may happen, that external entities be involved into the change process. As a means of measurement, the so-called regulatory criticality can be used to assess the severity of possible inhibitions of a transformation (cf. [25]).

Another requirement is that clear goals are to be defined at the beginning. It should aim for business performance indicators like revenue, quality, operation cost, or time related indicators. Only with a clear and measurable objective, can the efforts for such a transformation initiative be weighed against its impact.

It is imperative that a digital strategy is not established in parallel and separate to the existing corporate strategy, as those could conflict with one another and may consume the

same resources. Therefore, a strategy for digital transformation must be pursued that supports and complements the existing business strategy with additional levers.

The last items are a flexible and agile implementation to adapt quickly to changing boundary conditions and the use of best practices out of change management, e.g., bringing across the rationale, working in agile teams and fostering autonomous decision making.

V. RECOMMENDED APPROACH FOR THE REGULATED ENVIRONMENT OF HEALTHCARE, MEDTEC AND PHARMA

Like any organizational change, a Digital Transformation can offer both opportunities and risks. Companies that adapt to new circumstances at an early stage and actively shape the transformation can achieve success [7]. In chapter III, process models were reviewed which offer frameworks to transform organizations.

Based on the examined models and the defined requirements in chapter IV, this chapter describes an enhanced model, cf. Figure 6. The model has been verified by scientific as well as industrial experts.

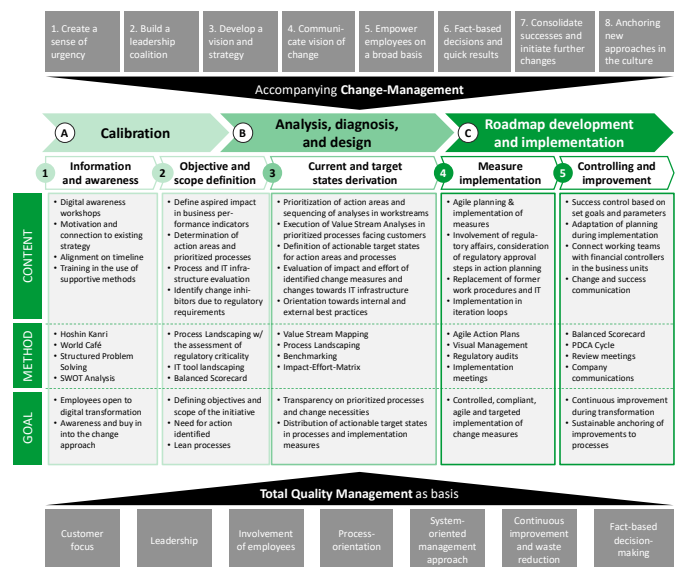


Figure 6. Proposed enhanced process model for the Digital Transformation of organizations in the healthcare, MedTec and pharma industries

The proposed model is based on the eight-step change management process [26] and in addition framed by basic pillars of Total Quality Management (TQM). It is important, that a change initiative such as a Digital Transformation meets the required quality regulations of the industry. Due to the high-quality standards within the MedTech industry, it is recommended to use TQM as the supporting foundation of the transformation [27]. The holistic focus on quality assurance and the need for thorough documentation and standardization ensures that the transformation leads to actual changes of work procedures and behaviors.

In the following sections the proposed model is discussed in detail, subdivided into the three overarching phases (A, B and C, shown in Figure 6), with a focus on its adaptations towards the application in regulated environments.

A. Calibration

The goal of the calibration phase is to align the organization on a new direction, to create a sense of urgency and to provide the necessary skillset for the upcoming change initiative.

In a first step, the employees of the organization are prepared for the initiative. The preparation includes workshop modules that evaluate the need for action and show the relevance of the Digital Transformation for the organization.

An awareness program for all employees should commence to gain knowledge of relevant digital trends and technologies. As far as possible, trainings should also cover improvement and project management methods like Structured Problem Solving, Agile Mindset, Value Stream Mapping (VSM) and Visual Management. The application of these methods will support the transformation by gaining more employee participation, buy-in and a higher confidence about the initiative.

For senior management, it is advisable to review the strategic plan of the organization and embed the vision of the transformation within it. Perhaps supporting SWOTs [28] or World Cafés [14] can be used to shape the direction of the necessary change.

In a further step, the objectives for the desired change to the organisation's performance indicators are defined and communicated. This drives the initiative in the intended direction and sets expectations. Based on the identified gaps in performance the data should be reviewed, process landscapes are created, IT tools are assessed, and action areas identified.

To ensure the organization is focusing on the right processes, i.e., those that create real business impact, there should be an in-depth analysis of core processes that show true opportunity for improvement. This may be started through adapted Process Landscaping (cf. [29, 30, 31]), which shows where to focus with improvements that would create benefit for the organization. Combining this with a benchmark analysis, the method can highlight where a new process needs to be implemented (process blind spots). Figure 7 shows an example process landscape for an organization including a prioritization based on process performance indicators.

As a guiding principle, processes with a high customer proximity, high frequency, high manual processing effort, low digitalization rate, and a high number of media should be addressed firstly with further analyses.

Another cornerstone, that may influence the pace of improvements and the Digital Transformation itself, is the regulatory criticality (cf. [25]) of a process change. This factor can be also assessed easily in this process landscape by a quality expert, e.g., on a scale from low to high where low being the mere adaption of process documentation and

high perhaps requiring an external auditor / entity for process approval (e.g. Food and Drug Administration). It is important to mind regulatory requirements, such as the need for process requalification, validation, and documentation as this can influence the timeline of a change.

No.	Process name	Process owner	Process frequency [min,h,d,w,m,y]	Lead time [min,h,d,w,m,...]	End customer proximity [low,medium,high]	Involvement workforce [F/TE]	Manual processing effort [low,medium,high]	Degree of automation [25%,50%,75%,100%]	Regulatory criticality [low,medium,high]	Amount of media [F]	Degree of digitalization [25%,50%,75%,100%]	...	Improvement priority [1,2,3,4]	Analysis method
1	Order entry process	Mrs. Smith	min	h	high	4	high	0%	low	6	0%		1	VSM
2	Production planning	Ms. Goldberg	...											
3	Demand forecasting	Mr. Meyer												
4	Material ordering	Mr. Heinz	h	d	low	8	high	0%	medium	8	25%		3	VSM
5	New product introduction	Mrs. Reyes	...											
6	Product change process	Mr. Sato	y	m	medium	11	high	0%	high	16	25%		4	VSM
7	Long term capacity planning	Mrs. Smith												
8	Customer order notification	Ms. Goldberg	h	min	high	2	medium	25%	low	6	0%		2	VSM
9	Delivery process	Mr. Meyer	...											
10	Non-conformity process	Mr. Heinz												
11	Performance management	Mr. Meyer												
12												

Figure 7. Example rated process landscape of an organization, including the rating of the regulatory criticality of a potential process change

B. Analysis, diagnosis, and design

The objectives of this phase are to generate transparency on cross-organizational processes and actionable target states. It ends with the definition of implementation measures, that are usually of an organizational and technical change management nature.

On a tactical level, it is proposed to carry out a series of VSMs [32] for those cross-organizational processes to understand, where potential for improvement lies – and where also digitalization measures would make a difference. After improvement potential is identified out of the analyses, target states can be derived for each of the prioritized processes. In this stage it is advisable to involve technology experts for digitalization and process automation. They can provide expert knowledge and good practices, where a technological improvement measure may be brought to the process to make it better.

Out of these process analyses and target state designs, the organizational and technical change measures result. To be assured of the intended improvement to the process, attention must already be paid to the measurability of the change actions when defining them [33]. It is important to ensure, that the key indicators set by management can be influenced by the team and at the same time have an influence on the success of the business performance [33].

The organizational measures usually can be addressed through the change in standard operating procedures and implemented through regular management routines or specially designed employee trainings. The implementation of technological measures like a process digitalization or automation should be supported through IT projects.

C. Roadmap development and implementation

After the cross-organizational core processes have been analyzed and measures have been defined, changes to the processes need to be made. On management level, the use of a

visual roadmap is beneficial to depict interdependencies for all process improvements (especially extensive changes in the IT system architecture), while each of the process improvement teams plan their activities using action plans, such as Kanban boards. Through regular implementation review meetings using the simple visuals, the status on the organizational and process level can be tracked and the direction changed if needed.

In this phase, the measurement of business performance indicators parallel to the actual implementation is required where possible, but it is more likely that the impact of the change shows over time. Depending on the objective of the Digital Transformation initiative, usually cost, lead time, flexibility or quality goals must be taken into consideration and represented, e.g., through a balanced scorecard [28].

If a process requires regulatory compliance and validation, the necessary (re-)qualification steps need to be planned accordingly in the team action plans. Additionally, regulatory audits can be performed with internal or external experts, even before a change is implemented. Usually, regulatory measures lead to an extension of the change implementation timeline and need to be planned as early as possible.

Like all organizational change management initiatives, ensuring employee buy-in and involvement is essential. Training and exposure to the new processes and technology, to which they have ownership is a key element of the new system design.

VI. CONCLUSION AND OUTLOOK

A Digital Transformation is a company-wide change, that needs to be thoroughly incorporated into the existing organization's strategy. To become effective and impactful, it needs a clear objective, which can be visualized and communicated through an improvement in business performance indicators. When executing such a transformation initiative, processes and technologies need to be considered.

It has been shown in this paper, that definitions in the context of Digital Transformation vary strongly across the screened literature. They alternate between the poles of distinct process improvement to innovating in new business models. For this paper and the proposed approach, improving, and setting up internal processes has been defined as being core. The improvement should reduce costs, improve quality and flexibility, decrease internal lead times to eventually increase customer satisfaction. Those improvements need to be driven, beginning with the interfaces to the end customer to be most effective. Silo thinking can be reduced by taking an holistic view of the organization, rather than on single departments.

The effects of changes in processes using digital technologies are often unknown and can vary greatly. Thus, a measurement of impact and a consistent end-to-end scope is emphasized. Pilots and delivery in iterations is advised and where possible to scale-out solutions before embarking on the next scale-up version, this is where maximum return can be

gained. The proposed approach was developed to address specific needs of the healthcare, MedTec and pharma industries with consideration of the requirement for regulatory compliance. An agile implementation process is recommended in spite of the regulatory requirements of these industries.

The proposed concept combines lean management with change management paradigms to make the transformation a success. Eventually, for the transformation to succeed, organizational and technical changes must be considered, driven by teams, management, and IT experts, jointly collaborating. Furthermore, it could be noted, that the developed approach might be applicable to other regulated industries as well.

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