Agile AI-Quality Management Concerning LEAN Solutions from a Strategic Perspective

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Abstract

The paper describes the research work about the strategic imperative for agile quality management systems in medical engineering companies in Austrian, Germany, and Switzerland until 2030. The industry operates in a volatile, uncertain, complex, and ambiguous (VUCA) environment, where the advantage of agility is expressed in an Agile Performance Index. Although, current developments of artificial intelligence (AI) need to be factored in. The goal of the research work is to answer a research question about how the strategic imperative can be determined by taking AI into account. Literature review and applying a qualitative research approach with nine expert interviews unveiled four main dimensions: (1) societal impact, (2) operational compatibility, (3) data quality, and (4) model performance. It solicits new approaches for resilient processes. Further, it enables the decision makers to keep the long-term ramifications in mind by leveraging attractive spot business. The result of the research is explained with a SWOT analysis, which contains nine distinct different strategies to tackle the challenges in an VUCA environment for medical engineering companies.

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Introduction

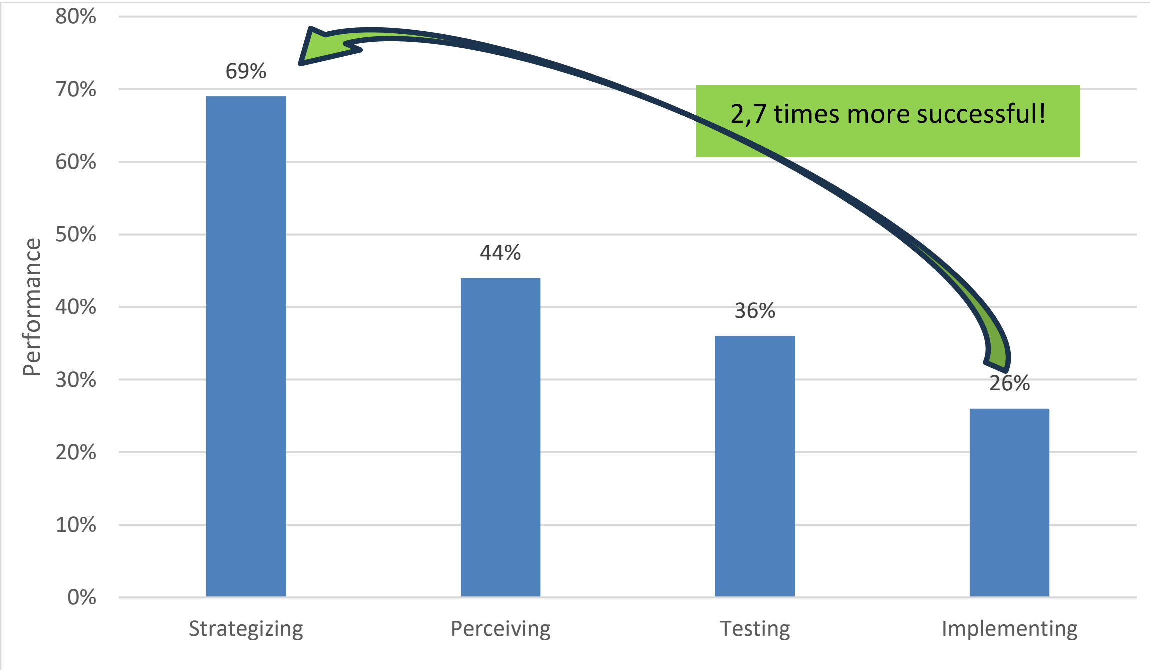
European medical engineering companies are under pressure not only from the recent COVID-19 pandemic, but also from strong global – sometimes unfair – competition. The current generational change, moving the power from generation X to generation Z, and increasing digitalization impose significant challenges on many industries in Europe. A VUCA environment (i.e., volatility, uncertainty, complexity, and ambiguity) brings with it great vulnerability, and requests high-speed of change. These dynamics confront traditional companies with difficult tasks. On the one hand, market growth is almost impossible to predict due to the high volatility of uncertain business developments. And, on the other hand, the time it takes to develop complex – often digital - products must be drastically reduced to attract a global customer base. Due to this shortened market launch phase, new processes aim to produce customized products and make them available to customers even faster by application of artificial intelligence (AI). The challenge is that customized products ought to be produced cost-effectively and be available promptly in perfect condition, namely first-time-right. The competitive pressure is enormous, and to avoid failure, customer requirements must not only be met in the best possible way, but preferably even exceeded! The good news is that in another field, namely software development, there has been a similarly high level of dynamic for quite some time. This might be eligible to learn for the field of medical engineering (Hernández- Santibáñez, 2019; Seow et al., 2019; Irsa, 2018; Purbs, 2022).

Software developers realized that conventional ways of thinking and over-defined processes were not suitable for supporting efficient, fast, and sustainable development work. To meet these requirements, the Manifesto for Agile Software Development was created by a group of 17 authors in 2001. It is based on four values and twelve principles that still characterize software development as of today. One common factor of leading companies in the field of software sales is that they were the first in the market with their solutions, as well as that their software solutions were properly working, fulfilled the functionality and quality desired by the customer. This illustrates the importance of a fast and goal-oriented development phase as well as a rapid market launch in order to win over the competition (Jungnickel, 2020).

In this context, Quality Austria conducted a study in 2020 on the topic how quality will look like in the year 2030. Findings from 21 expert interviews (technical experts and futurologists), six workshops and numerous analyses of trend reports were considered. Among other things, this study sheds light on the relationship between agility and quality, as demanded by VUCA environments. All in all, the outcome was that quality can be understood as the fulfillment of requirements, current and future ones. Further, rapid adaptation to changes is a component of a quality that should not be ignored. Consequently, ISO 9001 contains approaches that require agility from organizations to meet the changing requirements of a product, which can be a service as well. It requires companies to identify external issues (opportunities and risks) as well as internal issues (strengths and weaknesses), which have a significant influence on the achievement of the intended objectives of an enterprise, expressed in her quality management system. Companies are inevitably motivated to deal with the challenges of VUCA and need to take them into account in their strategic orientation by means of suitable measures (Hansen et al., 2020).

The importance of such a debate and the call for more agility can be illustrated by a study conducted by Goetzpartners and NEOMA Business School. Over a period of more than ten years, 285 European managers were surveyed using a questionnaire with a total of 40 questions to assess the maturity level of agility in their companies. The results of the survey were then compared with the financial performance to determine the Agile Performer Index of the companies surveyed. The Agile Performance Index measures 14 indicators (i.e., strategy, identity, purpose, sustainability, structure, information flow, forward-looking approach, innovation, allocation of resources, process of learning, change, leadership, development of skills, remuneration) and correlates them to the financial success of the company. Financial success is defined as Return-on-Assets for producing companies and Return-on-Equity for service companies (Prodoehl et al., 2017).

Figure 1
Agile Performer Index



Source: Authors' Illustration (Olbert et al., 2019)

Figure 1 shows the results of the study graphically. The abscissa is divided into 4 agility quartiles. These represent the maturity level of agility developed in the study: Strategizing, Perceiving, Testing, and Implementing. The first quartile, 'Strategizing', represents the highest maturity level of agility and fourth quartile the least mature. The performance of the Agile Performer Index is shown on the ordinate; 69% performance means that the companies in the cluster 'Strategizing' have performed financially 69% better than the industry median over the last ten years. Companies in the cluster 'Implementing' still performed financially 26% better over the same period compared to the industry median. This relationship between financial success and the degree of agility further indicates that companies in the first quartile were around 2.7 times more successful than the companies in the fourth, which are already significantly better than the industry median. This study makes it clear that agility represents in any case a competitive advantage that can be measured with financial results. In view of this fact, it should be noted that quality management with the focus on agility emerged in less volatile times, when companies had longer product life cycles as well as market launch phases; this means that the impact of agility was not yet as strong as in the VUCA environment nowadays with extensive digitalization capabilities using AI (Olbert et al., 2019).

Based on the problem described in the introduction, this paper aims to answer the following research question: How can the strategic imperative of an agile quality management system - considering normative, regulatory, and legal requirements – be determined in the medical engineering industry for the region of Austria, Germany, and Switzerland until the year 2030?

Method

In order to answer the research question, the research work begins with a literature search that will use a combination of two well-known methods. First, the method of concentric circles, in which one or more sources are used as a starting point and further literature is identified via their bibliographies. The second method used is the strategic search, in which various literature databases, specialist journals or anthologies are inquired for the keywords Artificial Intelligence, Digitalization, LEAN Management, Qualitative Research, and Technological Transformation. This comprehensive literature search and consequently literature review is intended to create a solid basis on which the challenges of artificial intelligence, the requirements of a quality management system, the special features of agile working methods, and VUCA are identified. The theoretical part is concluded with a description of the seven steps according to Sommerhoff, which lead to a sophisticated agile quality management system (Sommerhoff & Wolter, 2019).

Figure 2
Seven steps to sophisticated agile quality

Source: Authors' Illustration (Sommerhoff & Wolter, 2019)

Figure 2 points out the seven steps to a sophisticated quality management system in terms of agility, AI, and LEAN. It starts with a clear customer and business focus and closes with a hands-on approach to LEAN, which is defined to avoid waste in the first place.

The practical part for the research work was carried out using empirical social research and chooses the method of qualitative research. It started with the creation of an interview guide, which is used as a guideline for the subsequent discussions with experts in the medical engineering industry with quality management background. The material obtained from the interviews was systematically analyzed and evaluated using qualitative content analysis according to Grounded Theory. The data obtained was used as input for an analysis to derive strategies that will be included as recommendations for action in the creation of a conceptual guideline for the introduction of an agile quality management system in medical engineering manufacturing, taking into account normative, regulatory and legal requirements, and considering the perspective of AI in a time-horizon up to 2030 (Mey et al., 2019; Strauss & Corbin, 1994)

Figure 3
Research process of conducting experts' interviews

Literature research	Selection of experts	Creation of interview guideline	Preparation of interviews	Performing interviews	Analysis of interviews
Review of literature/ sources Evaluation and processing	Experts' determination Experts' selection Experts' contacting	Apply collecting/ checking/ sorting/ integrating to create guideline	Acquisition of expert knowledge Preparation to interview with expert	Introduction of topic and institute Detail process Record the interviews	Transcript the interviews Analyze the interviews applying Grounded Theory with ATLAS.ti
Phase 1				Phase 2	Phase 3

Source: Authors' Illustration (Friese, 2016)

Figure 3 illustrates the three phases of the research process. The first phase consists of four elements, which are literature research, selection of experts, creation of the interview guideline, and preparation of the interviews. The second phase deals with performing the interviews, and the third phase contains the analysis of the interviews. The interviews served as the primary source for the empiric part of the conducted study, secondary sources were financial statements. Websites were consulted for triangulation and verification of the results.

The following table lists the interview partners. The interview partners were found through serendipity, although certain criteria were applied and are explained below the table. The definition of the size of the companies is according to the Austrian Economic Chamber, where small stand for companies up to 49 employees, mid is for companies from 50 to 249 employees, and large is defined for more than 250 employees (WKO, 2013).

Table 1
Interview partners of the empirical study

Industry	Location	Size	Position interviewee	Job experience
Medical Engineering/devices	Graz	Large	Quality Manager	More than 15 years
Medical Engineering/software	Graz	Small	Project Manager	10 to 15 years
Medical Engineering/devices	Hamburg	Mid	VP LEAN	5 to 10 years
Medical Engineering/devices	Munich	Large	Supply Chain Manager	5 to 10 years
Medical Engineering/implants	Munich	Mid	Managing director	10 to 15 years
Medical Engineering/dental	Stuttgart	Large	SVP Purchasing	More than 15 years
Medical Engineering/surgery	Vienna	Large	Supplier Quality Engineer	10 to 15 years
Medical Engineering/software	Vienna	Small	Chief Operations Officer	More than 15 years
Medical Engineering/implants	Zurich	Large	Quality Manager	5 to 10 years

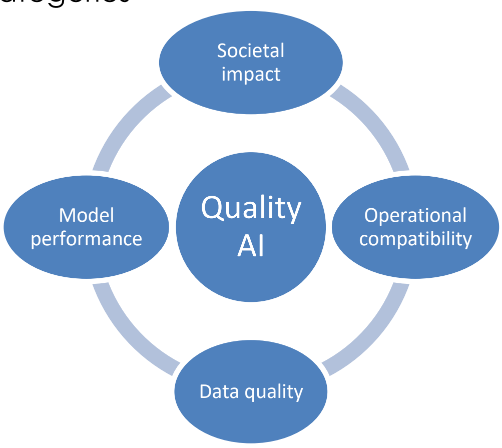
Source: Own research

Table 1 lists nine experts in the medical industry with longstanding, substantial experience, expressed in the fifth column. The number of interview partners is considered as sufficient as qualitative saturation has been reached with the eighth interview, no more additional new inputs were observed. Reaching qualitative saturation is an important validation criterion in the qualitative research genre.

Results

This section provides the results of the conducted and analyzed interviews. The four main categories are displayed in the following figure.

Figure 4
Interrelation of the main categories



Source: Authors' Illustration

Figure 4 shows the interrelationship around quality from an AI perspective. The research unveiled four main dimensions: (1) the societal impact, (2) the operational compatibility, (3) the data quality, and (4) the model performance. Consequently, a SWOT analysis is performed.

SWOT Analysis – Practical implications

In strategic planning, the SWOT analysis, which originally comes from business administration, is an important tool in many different disciplines, contexts, and industries. A SWOT analysis makes important internal and external aspects visible. The input data for the four aspects were condensed from the four main dimensions of the previous figure concerning agile quality management from an AI perspective (Bazjek et a., 2021).

Table 2
Transition from agile to LEAN-agile

		External Conditions	
		Opportunities O1: volatile market conditions O2: modularity O3: AI literacy	**Threats** T1: losing best-practice T2: length of implementation T3: losing track
Internal Conditions	**Strengths** S1: LEAN experience S2: subsidiarity S3: step-by-step approach	**SO-Strategies** S1/O1: Excell in Responsivity S2/O3: Competence development S3/O2: *Linking the requirements*	**ST-Strategies** S1/T2: Pre-audit S3/T3: Objective
	Weaknesses W1: low process-orientation W2: mediocre control W3: incomplete documentation	**WO-Strategies** W2/O2: Project controlling W3/O3: Stabilize procedures	**WT-Strategies** W1/T1: Restrict degree of freedom W3/T3: Process inputs/outputs

Source: Own research

The results show in Table 1 that the Grounded Theory method delivered high-aggregated findings for external and internal conditions. Opportunities and Threats, respectively Strength and Weaknesses, three for each of them, in total twelve. The combination of them is displayed in the four light quadrants, expressed as strategies (i.e., SO, ST, WT, and WO). Again, all findings of the four distinct strategies evolved from the nine interviews with the subject matter experts.

Discussion

In this section the ramifications of the results are discussed. First, the underlying principles are stated, then – secondly – the SO, ST, WT, and WO strategies are defined. The theoretical contribution encompasses the awareness, that the SWOT analysis is still a suitable tool in high-digitalized industries including AI.

Principles and strategy definition

The following principles are applied for practical implications – certainly for the topic at hand but perhaps for other industries as well: (1) maximizing strengths and opportunities, (2) transforming weaknesses, and (3) minimizing risks. By taking these principles into account, the following strategies were derived and defined.

SO-Strategies

These combine which strengths go hand in hand with which opportunities. The strengths of the internal aspects are merged with the opportunities of the external aspects. The following strategies were created.

S1/O1 Excell in responsivity

While introducing an agile quality management system, processes and interfaces should be optimized and documentation streamlined. This point goes hand in hand with the frequently changing requirements of a VUCA environment, as this allows a rigid and agile system to react quickly. It should therefore be possible to adapt the system quickly to requirements.

S2/O3 Competence development

To promote the subsidiarity required in agile quality management and to link this to the constantly changing requirements of a VUCA environment, it is necessary to build up or expand the skills of employees in AI. In this way, the necessary knowledge can be imparted, and the required skills taught through a well-founded training program that is constantly adapted to the technological changes.

S3/O2 Linking the requirements

The incremental-iterative working method possible in agile quality management is combined with the requirements of a VUCA environment. To make this connection feasible, an attempt must be made to use Scrum instead of a linear/sequential approach in product development. This combination allows to incorporate continuously the wishes of customers into product development.

ST-Strategies

These strategies clarify which strengths from the internal aspects of agile quality management go hand in hand with the risks from the external aspects. The aim of these strategies is to reduce the usage of well-selected strengths for the sake of risk prevention in context to contemporary risk management according to ISO31000. The following strategies were developed for this purpose.

S1/T3 Pre-audit

To avoid the high pressure of a VUCA environment during the long implementation period of AI products, it is advised to carry out a pre-audit to narrow down to relevant solutions before implementation. Such an approach allows quick implementation into existing processes using AI.

S3/T3 Objective

Even though the incremental-iterative working method in agile quality management is stronger in terms of customer orientation, there is a great danger that both parties (customers and suppliers) will get lost in details and thus stray from the original goal. To reduce this risk, it is necessary to build fixed anchors, expressed as objectives, into the processes to maintain the balance between agility and stability.

WO-Strategies

These are intended to help the organization minimize its weaknesses by transforming them into strengths. In a figurative sense, weaknesses should be weakened, and strengths created as a result. The following strategies were derived for this purpose.

W2/O2 Project controlling

The fact that self-managing teams must be controlled and monitored is a weak point from the perspective of self-sufficiency. Assuming that the chosen method is Scrum, it is necessary for the Product Owner as a project manager and the Scrum Master as a quality manager to perform their roles with particular care. For example, the Product Owner could be assigned to the task of controlling project objectives. This could take the form of writing down the initially defined goal and documenting and presenting any deviations and extensions so that the change in the goal is made visible to the customer, employees, and stakeholders.

W3/O3 Stabilize procedures

As already described in weaknesses, there is the risk that an agile design of the quality management system will result in exuberant process documentation. The opportunity offered to the organization to inspire employees to tackle a VUCA environment and react accordingly can compensate for this weakness. However, the competencies of the employees play a major role, and this strategy derivation also makes it clear how important it is that knowledge and competence are promoted in the organization.

WT Strategies:

These types of strategies are designed to help companies reduce their identified weaknesses to avoid risks. To this end, the following strategies were derived from the SWOT analysis.

W1/T1 Restrict degree of freedom

Because the introduction of an agile quality management system encourages the organization to reduce standardized processes, there is also a risk that very well-functioning established processes will be completely revised so that years of experience are lost. When introducing agile processes, organizations should evaluate which process is to be made agile, which is to be optimized with a hybrid variant or remaining completely non-agile.

W3/T3 Process inputs/output

In a rigid quality management system, process inputs and outputs are documented and displayed. As an attempt is made to streamline the management system during the introduction of agile quality management and to reduce over-documentation, there is a risk that process objectives are no longer clearly defined. In order not to lose the defined outputs of the processes due to the additional possible plan changes, it is advisable that they are always visualized and visible to everyone. If the objective changes fundamentally, the documentation or specifications must also be changed.

Conclusion

Through the intensive familiarization with the topics of agile methods, digitalization, quality management and the research results from the empirical study, the research question can be answered as follows: The SWOT analysis unveils in total nine distinct different strategies to deal with the challenges of a VUCA environment. AI plays an important role until 2030, although no miracles are expected. The rational, sound human judgment of business decisions will prevail. The use of agile methods in the companies of the surveyed experts still has room for improvement and the requirements of an agile quality management system are a moving target. Still, every expert had only positive reactions about the significance of the subject matter and spoke about the need that the currently still rigid systems in medical engineering need to become more agile. There was no doubt that this could be changed. With the necessary support from management and the whole company, as well as the appropriate choice of skills development in AI, a medical device manufacturer's quality management system can be made agile through change management projects, expressed in nine distinct different strategy choices found through a SWOT analysis.

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