INDUSTRY STUDY MEDTECH

The big challenges for MedTech companies and the levers to stay ahead of the competition

Study 2022

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Preface

The entire industry is confronted with massively disrupted supply chains, the availability of essential materials is limited, promised delivery dates are postponed or even completely suspended.

The material prices are increasing strongly - this development has now reached absurd levels in especially scarce areas.

Various factors like the pandemic, the Ukraine war and the energy crisis are interacting in a particularly dramatic way.

In addition to the significant increase in procurement costs, this situation is also having a massive impact on the innovation pipeline of many companies.

MedTech companies in particular are hit hard: The effects described are intensified by the new requirements of the EU-MDR. These requirements already lead to a delay in new innovations and, at the same time, lead to an earlier market withdraw of existing and profitable products. Urgently needed sales and profits are lost.

This means: The fuse is burning from 2 sides. An average EBITDA decline of 14% is already apparent - at the same time, it becomes clear that new products are launched on the market on average 12 months later, which means that required sales and earnings are lost.

400 MedTech companies from the DACH region were invited to participate in this study. The results of the survey provide a dramatic picture of the current situation. However, they also show the potential for effectively mitigating these challenges.

Chapter 1 examines the effects of the crisis in more detail, Chapter 2 looks at the potential of companies to counter these challenges, and Chapter 3 provides an outlook on which specific levers are crucial to emerge fast and even stronger from the current crisis.

SPECTARIS
Deutscher Industrieverband für Optik, Photonik, Analysen- und Medizintechnik

1. The crisis

1.1. The golden years are finally over – the MedTech industry is switching to survival mode

Due to the overall economic situation, MedTech companies are under significant pressure. In addition to the immediate effects, there are also those with delayed impact:

In the short and medium term, heavily increased procurement costs and sales loss due to missing parts damage the profitability of companies.

In the long term, delays in the innovation pipeline will result in delay of urgently needed product launches. Within the next 2-3 years their missing sales volume bares high risk of losing competitive advantage on international markets.

1.2. Short-term risks: Availability and cost increases impact sales and margins now and for the coming months

Cost increases and supply bottlenecks
Supply chains in the industry are rated as heavily disrupted by 76% of study participants.

The main challenges are significant price increases for 82% and the lack of availability of raw materials, components and resources for all participants.

In the area of electronic components in particular, 76% have significant supply problems.

Even though 67% say they are coping well with the disruptions, almost all participants have already suffered economic damage, estimated at an average of 14% EBITDA.

Energy market risks
In addition to the previous disruptions and risks, the next few weeks will see the impact of the energy market: 88% are affected by this, 38% even severely. Key areas here are the supply of energy-intensive products such as aluminum, steel, glass, paper, but also internal production steps.

Risk of product discontinuations
An indirect consequence of the supply bottlenecks and cost increases is that current products will have to be discontinued because it is not economically feasible to redevelop them with alternative components. This is expected by 45% of participants. They thus see 23% of the sales volume at risk.

Another cause for possible product discontinuations is the new EU-MDR.76% of the participants see a severe risk of having to withdraw current products from the market because they cannot be re-approved in time or economically in accordance with the EU-MDR. According to the assessment of these companies, additional 18% of sales are thus at risk.

The old truths of Lean & Co no longer apply

A full-scale paradigm shift is taking place right now: The old truths no longer apply - new realities have swept them out of place in order to survive in current conditions.

For many decades, the keys to success in supply chain management was a lean approach to value creation aiming to keep inventories at the lower limit, reducing working capital and, at the same time, intensive use of the global market for cost-optimized procurement of materials and value creation in best-cost countries.

Security of supply instead of inventory and cost optimization

Prior to Covid, core elements of Supply Chain Management strategy for 42% were lean inventory management, and 37% cited minimizing sourcing costs as a core strategic objective.

This has completely reversed: Lean inventory management or optimized procurement costs are now an important target for only 21%.

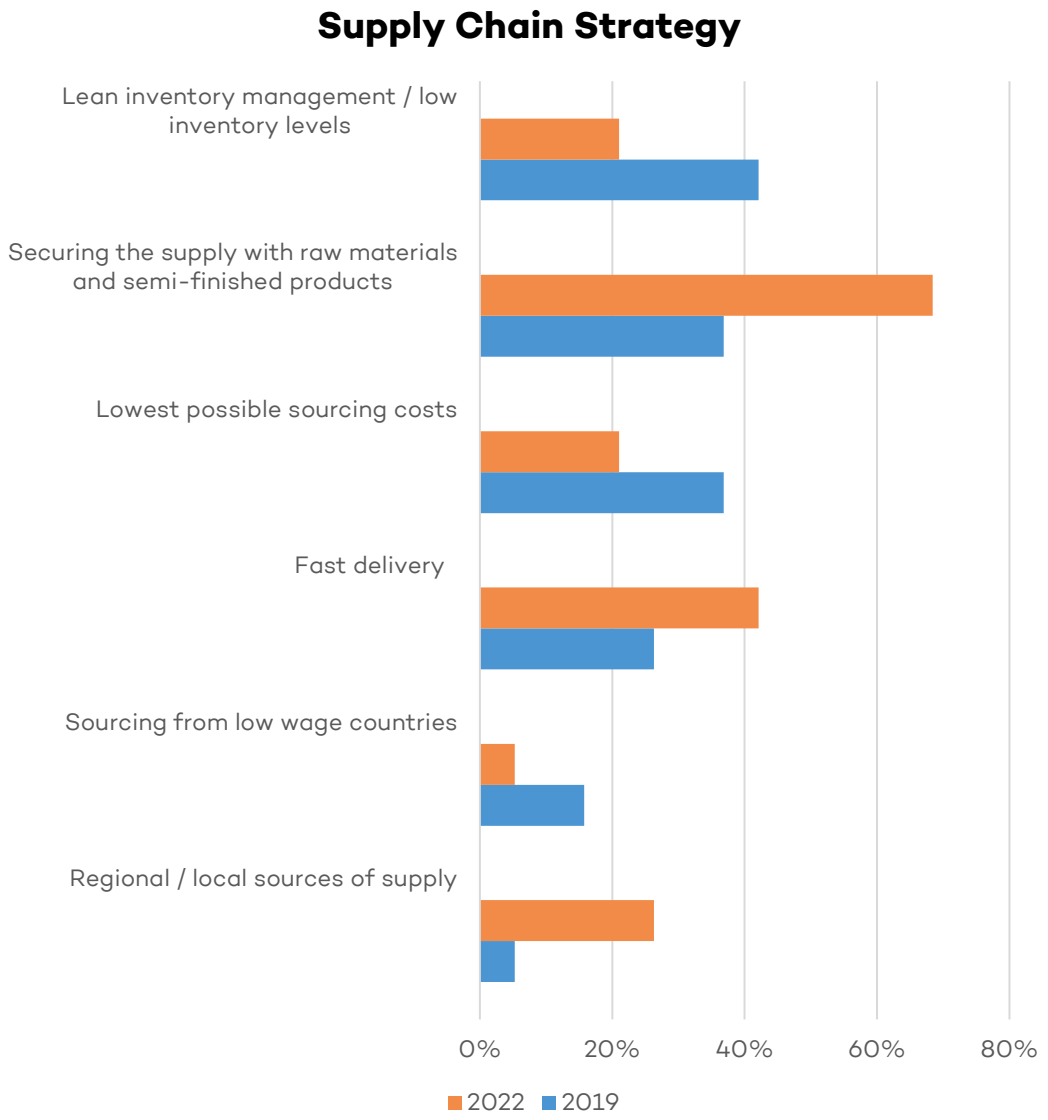
At the same time, 26% are shifting from global supply chains back to local sources of supply (previously 5%) and for 68%, securing supply is particularly important (previously 37%). Keeping procurement costs low is now important for only one in five companies (21%, previously 37%).

This shows that companies are also focusing on the topic of regional decoupling - on the one hand in the supply chain, and on the other in their own footprint.

This change in supply chain strategies is understandable and necessary, but it leads to a significant deterioration in the economic balance sheet.

And even worse: the massive restocking leads to further shortages and inflation in the overall supply market. A vicious circle fueled not only by the MedTech industry, but also by other industries that are often more interesting for suppliers due to volume.

Measures implemented to solve the problems and avert the risks include building up safety stocks for 88% and increasing the speed of material changes to be able to react more flexibly for 47%.



1.3. Long-term risks: Severe delays in new product development will significantly drag out the "recovery" after the crisis

Supply bottlenecks delay innovations
The current supply bottlenecks mean that new products (and thus new sales drivers) will enter the market significantly later. Thus, the supply bottlenecks are also delaying the development of urgently needed product innovations: Engineers are needed to qualify alternative components and suppliers, material for test samples is not available, the still noticeable Covid-related sick leave further reduces the available capacity to develop new products.

As a result, the average delay in launching new products among the study participants is 12.6 months. For 29% of the participants, the delay is even more than 2 years.

The way to the market is cumbersome and long
On average, the complex development of a new product and its approval takes 41 months. 72% of companies launch fewer than 2 new products per year on average. It is therefore all the more important that products, once launched, can also be successfully marketed and retained on the market for a long time.

EU-MDR delays and jeopardizes the development of innovations
The new EU-MDR acts as an additional brake on the innovation pipeline, and thus on the opportunity to recover from the current situation: Companies see that new products will be launched on the market 10.4 months later on average as a result of this regulation. They put the associated additional expense at 19% on average.

Even without EU-MDR and supply crisis: Delays in new products are standard
Planning product innovations is one thing - reality is something else: On average, development takes 32% longer than planned to reach planned product development milestones.

In 11% of the companies, the deviations are even 50% and more.

Developing new products while maintaining old ones slows down innovation

Once the products have been launched on the market, development is far from off the hook: On average, it takes 8.5 months for the production of new products to run stable. At every 5th company, it even takes more than 12 months.

Development is so heavily burdened with these tasks that only 53% of development capacity is available for pre- and series development. 47% goes into regulatory, maintenance of existing products and CAPA measures.

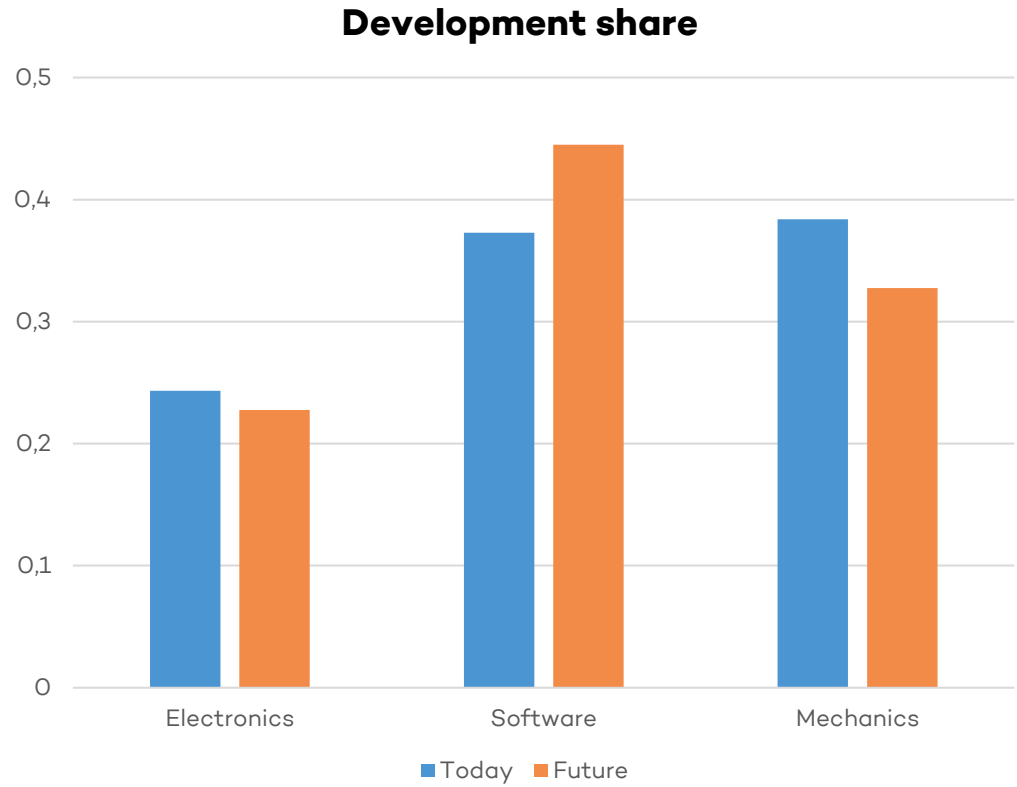
In 71% of the companies, these tasks are performed by the same team that is responsible for new development. It is therefore not surprising that delays regularly occur here.

Product maintenance is THE disruptive factor in product development. Especially in times of missing components, the need for rapid redevelopment increases massively. An in-house team that takes on this work and thus keeps the development team free for new development is considered a good solution by 38% of those surveyed. However, only very few have implemented this so far (10%).

The required competencies are shifting – and modern development procedures are rather the exception

The participants expect today's distribution of technology to shift massively toward software in the future: Software becomes the most comprehensive discipline.

At the same time, 83% of companies still work in classic development frameworks - more modern methods are not yet very well established. The potential of agile methods is not yet leveraged, yet other industries show how it can be done.



1 Corrective And Preventive Action

1.4. Fire from both sides

The industry is under pressure in both the short and long term.
The main factors that pose a decisive threat to international competitiveness:

Short-term hazards and risks:

- Lower profitability due to higher material and energy costs
- The need for higher inventories and thus more tied-up capital
- The risk of having to discontinue products due to lack of component availability
- The risk of having to withdraw products from the market due to non-timely or non-economic re-registration in accordance with the EU-MDR

Long-term hazards and risks:

- Generally long development times for innovations combined with regular overruns of the planned development duration
- Delays in the development of new products due to additional tasks such as qualification of alternative components and suppliers due to missing prototypes and Covid-related staff absences
- Additional slowdown of the innovation pipeline due to the backlog of EU-MDR approval of new products

2. Status quo: How well are European MedTech companies prepared?

The individual impact of the crisis on the company's earnings and how long it lasts until recovery depend largely on two factors.

Companies that have these 2 factors under control will not only get through current and future crises better but will also recover more quickly.

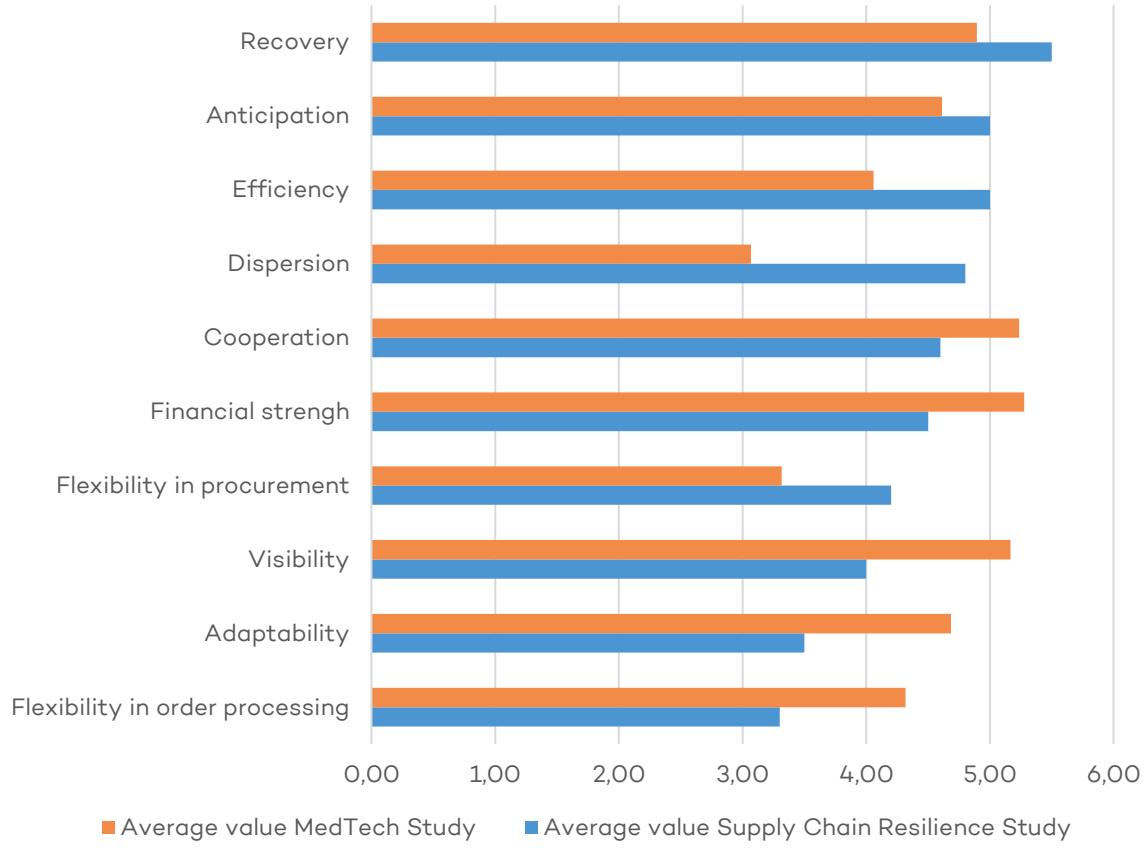
2.1. Supply Chain resilience factors

How MedTech companies can respond appropriately to these supply chain disruptions

The literature[2,3] identifies 10 skills that are critical to handling supply chain disruptions well.

These were examined across industries by our colleagues at the *Procurement Initiative*[4] in the *State of Supply Chain Resilience study*[5].

This shows that MedTech companies are significantly better positioned in certain areas than the participants in the cross-industry study (e.g., "Financial strength", "Collaboration", "Visibility"). However, there are also deficits in the areas of "Dispersion", "Efficiency" and "Flexibility in procurement".
The supply chain resilience factors in which the MedTech companies scored particularly well correlate with their economic stability: The damage caused by the crisis to date was rated significantly lower for companies that scored well here.



2. Pettit, T. J., Croxton, K. L., & Fiksel, J. (2013). Ensuring supply chain resilience: development and implementation of an assessment tool. Journal of Business Logistics, 34(1), 46-76.
3. Pettit, T. J., Fiksel, J., & Croxton, K. L. (2010). Ensuring supply chain resilience: development of a conceptual framework. Journal of Business Logistics, 31(1), 1- 21.
4. www.procurementinitiative.org
5. The Procurement Initiative (2022). State of Supply Chain Resilience Survey

Factor	Capability	Definition	Subfactors
C1	Flexibility in Sourcing	Ability to quickly change inputs ot the mode of receiving inputs	Part commonality, Modular product design, Multiple uses, Supplier contract flexibility, Multiple sources
C2	Flexibility in Order Fulfillment	Ability in quickly change outputs or the mode of delivering outputs	Alternate distribution channels, Risk pooling/sharing, Multisourcing, Delayed commitment/Production postponement, Inventory management, Rerouting of requirements
C3	Efficiency	Capability to produce outputs with minimum resource requirements	Waste elimination, Labor productivity, Asset utilization, Product variability reduction, Failure prevention
C4	Visibility	Knowledge of the status of operating assets and the environment	Business intelligence gathering, Information technology, Product, equipment and people visibility, Information exchange
C5	Adaptability	Ability to modify operations in response to challenges or opportunities	Fast rerouting of requirements, Lead time reduction, Strategic gaming and simulation, Seizing advantage from disruptions, Alternative technology development, Learning from experience
C6	Anticipation	Ability to discern potential future events or situations	Monitoring early warning signals, Forecasting, Deviation and near-miss analysis, Risk management, Business continuity/preparedness planning, Recognition of oppotunities
C7	Recovery	Ability to return to normal operational state repidly	Crisis management, Resource mobilization, Communications strategy, Consequence mitigation
C8	Dispersion	Broad distribution or decentralization of assets	Distributed decision making, Distributed capacity and assets, Decentralization of key resources, Location-specific empowerment, Dispersion of markets
C9	Collaboration	Ability to work effectively with other entities for mutual benefit	Collaborative forecasting, Customer management, Communications, Postponement of orders, Product life. Cycle management, Risk sharing with partners
C10	Financial Strength	Capacity to absorb fluctuations in cash flow	Insurance, Portfolio diversification, Financial reserves and liquidity, Price margin

Capabilities

We used 10 constructs and related subfactors to investigate capabilities. Survey responses were designed in ordinal form using the 7-point Likert scale strongly disagree/strongly agree.

2.2. Development Velocity Factors

The study examined factors and indicators that are crucial for the speed and duration of product development:

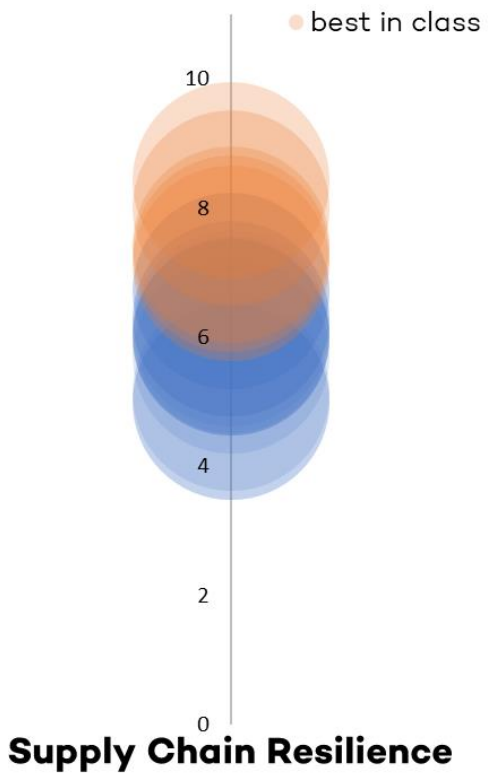
In addition to a sufficient focus on innovations and new product development, the development frameworks used were considered here, as well as the indicators reliability of milestone achievement and stability convergence in the start of series production. The picture is supplemented by the applied frameworks and methods and the consistency in the implementation of the new EU-MDR.

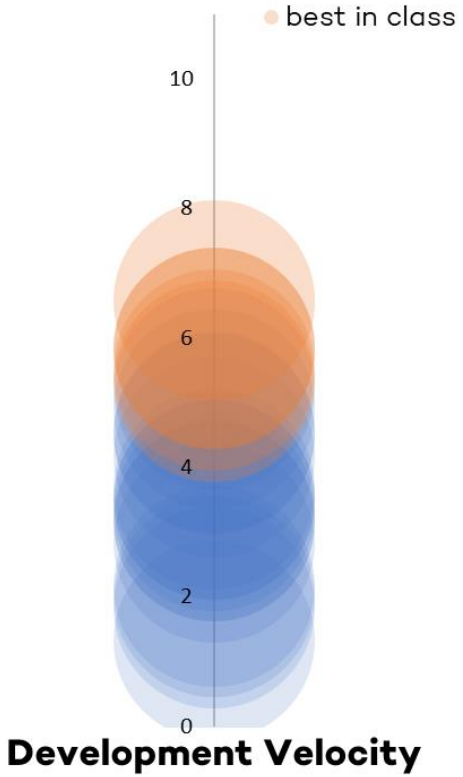
2.3. Temperature Check of the MedTech Industry

Supply Chain Resilience: shows how resilient the company is in order to respond as flexibly and quickly as possible to disruptions in the supply chain and to minimize short-term damage.

Development Velocity: shows how to ensure that as many resources as possible are focused efficiently on future revenue generators (and innovations) and that the development cycle is optimized in terms of time.

There is a clear spread of scores among the study participants. In the area of Supply Chain Resilience, the overall score is higher. In comparison with the *State of Supply Chain Resilience study*[6] , the participating MedTech companies are almost on a par (average MedTech: 6.37 / cross-industry: 6.34).





6. The Procurement Initiative (2022). State of Supply Chain Resilience Survey

3. Outlook and perspective

3.1. Ways out of the supply chain crisis

The study shows that most companies face significant supply challenges and are in a constant firefighting mode to ensure continuity of supply.

However, consistently implementing the four key competencies of the top performers from our survey, will increase stability. Understanding the current state of resilience and creating a concrete action plan are good first steps. Moving to the next level requires rethinking the current way supply chains are organized and managed.

Key topics here are demand planning and S&OP, which often requires a significant adjustment of planning parameters and the overall approach as well as an increase in planning quality as suppliers are less able to cover as they did in the past. This can only be achieved through a more systematic synchronization of Sales, Procurement and Manufacturing.

Other levers in the Resilience Framework are supplier and contract risk management,
as well as adjustments in the PLM process, which often does not sufficiently consider component risks, especially when facing long product development cycles.

In the end, fostering more sustainable approach along critical factors is particularly important here. This leads to long-term resilience and robustness of supply chain networks.

3.2. Ways to shorten development times

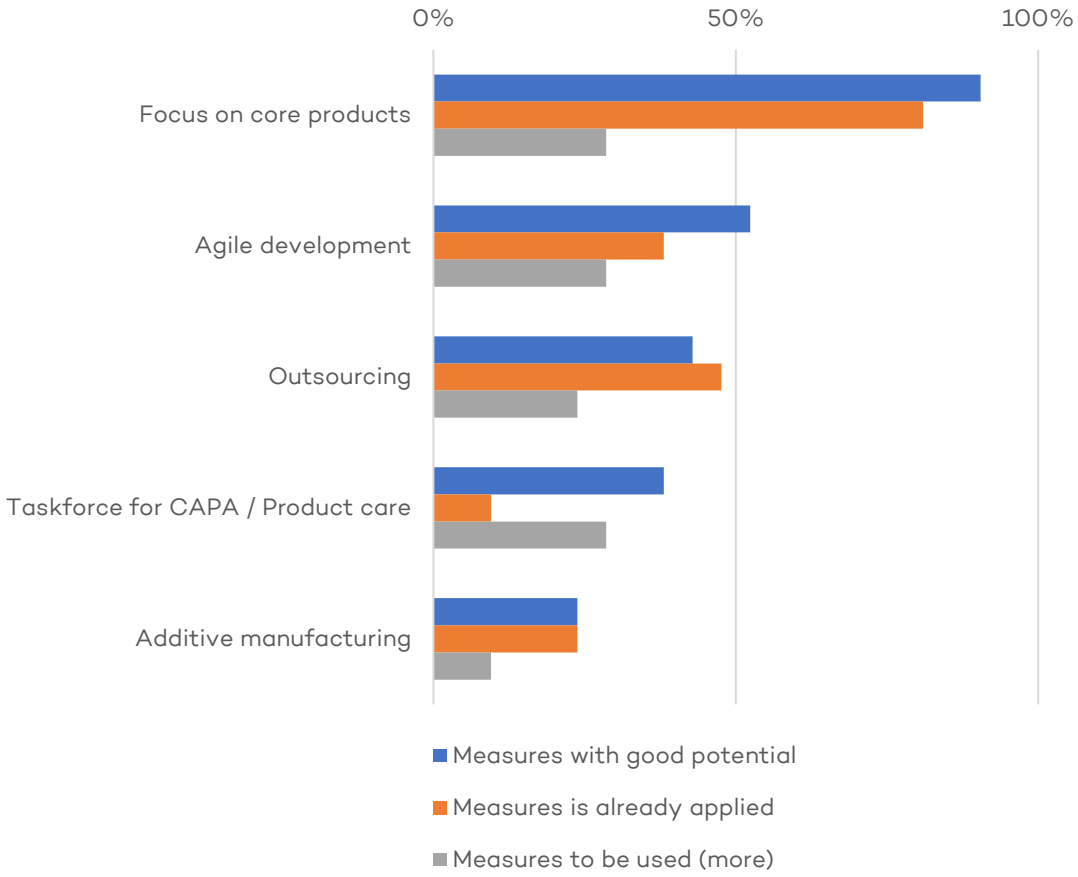
Important approaches to shortening the duration of product developments lie in a more stringent focus on core products, use of agile development methods and more extensive outsourcing of clearly defined work packages. These levers are already being used to some extent today.

The focus of the development area can be significantly strengthened if the topics of product maintenance and implementation of CAPA measures are outsourced and performed separately. These are clearly disruptive factors - especially in times of uncertain supply chains. It is more crucial than ever not to slow down the innovation pipeline.

There is also great potential in the use of modern development frameworks – already a standard in many industries today, agile methods and procedures allow focused development that is strictly aligned with market needs and lay the foundation for true quality frontloading, which reduces late and expensive correction loops.

With the growing importance of data, the decoupling of hardware and software is also becoming increasingly important. The hardware must be marketable for as long as possible, while the software must be flexible and frequently enhanced to ensure market differentiation. It must therefore be developed much more agile and in faster cycles. Ultimately, the two must fit together technically, but not necessarily be developed together.

Measures to increase development velocity



About the authors

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... stands for consulting with head, heart, and hand. Together with our clients, we develop and implement individual concepts and solutions worldwide. H&Z is one of the leading business consultancies for excellence and transformation, focusing on the areas of Strategy & Performance and Procurement. International corporations and renowned mid-sized companies are among H&Z's clients for more than 25 years.

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SPECTARIS Fachverband Medizintechnik
represents around 130 German companies in the capital goods and auxiliary equipment sector, which primarily manufacture high-tech products and are strongly export-oriented. The members cover an extensive field of research and application, which in a broader sense can be classified as "life sciences". The trade association offers its members targeted services, a platform for networking and represents the interests of its members vis-à-vis politicians and the public, so that the framework conditions for innovation and growth continue to improve. In particular dealing with the complex regulatory requirements in the healthcare sector is the subject of numerous working groups of the trade association.
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This study was conducted in the period October and November 2022. Around 400 executives from medical technology companies in the DACH region were invited. With nearly 50 participations from C-Levels, BU-Leads and other Executives, supplemented by further expert interviews, a sound picture of current challenges and trends emerges.

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