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AMeLie

Results of the research project New ASE methods for development processes based on product examples from medical technology and life sciences

A framework for application of Systems Engineering in small and medium sized enterprises

Patrik Krause | *editor*

The German part of this research and development project was funded by the German Federal Ministry of Education and Research (BMBF) within the “The Future of Value Creation – Research on Production, Services and Work” Program with the funding numbers 02J19B030 to 02J19B035 and implemented by the Project Management Agency Karlsruhe (PTKA).

The authors are responsible for the content of this publication.

New ASE Methods for Development Processes based on Product Examples from Medical Technology and Life Sciences

Results of the BMBF collaboration project AMeLie

Patrik Krause | editor
3DSE Management Consultants GmbH

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Table of Content

1 Preface

Preface by the Project Management Agency Karlsruhe (PTKA)

In the medical device industry, the development of complex products has recently become very challenging, especially for small and medium sized enterprises, as approval and documentation costs have increased significantly. In the AMeLie project, a short-term implant was analyzed, which is attached to a nerve, in order to avoid mechanical injuries by the surgical procedure. High regulatory demands are placed on these products regarding compatibility, reliability and approval. To meet all requirements, interdisciplinary cooperation supported by suitable methods and software tools is necessary during development and production. Existing Systems Engineering methods and standards are no longer sufficient. In addition, software support is neither universal nor tailored to small and medium sized enterprises.

The aim of the AMeLie project was to develop methods for software-supported Advanced Systems Engineering in the field of medical technology in order to develop and produce competitive products efficiently, quickly and reliably. The focus was on the control and optimization of the overall system, especially for small and medium sized enterprises, with regard to the fulfilment of legal requirements, regulations and functional safety.

The current Systems Engineering knowledge of the partner companies was analyzed. Core topics were the interdisciplinary collaboration of employees, development and production methods used, and the current use of Systems Engineering approaches. Individual approaches to the use of Advanced Systems Engineering methods were identified and evaluated, for example, how the next generation of short-term implants can be developed and produced more efficiently. On this basis, Advanced Systems Engineering methods were developed, piloted and validated using real-world examples to make the solutions available to additional users. To support this, they were integrated into existing software and implemented for the model-based development

of complex technical products with many variants. For sustainable anchoring and use beyond the medical technology sector, a transfer plan was developed for introduction in other sectors, such as aerospace technology.

The international and networked collection and evaluation of product, process and development data by means of software allows people to concentrate much better on cooperative development work and innovation. In AMeLie, research groups and small and medium sized enterprises from Germany and Israel worked together. They contributed their knowledge from Systems Engineering, production, research and medical technology to the method development. The ASE methods were made available across industries in relevant national and international networks (e.g. GfSE, INCOSE and AdWiSE).

The German partners in this joint project with Israeli partners were funded within the “The Future of Value Creation – Research on Production, Services and Work” Program of the German Federal Ministry of Education and Research (BMBF). We would like to take this opportunity to thank all those who contributed to this pioneering research and development work with their knowledge, commitment and experience.

Project Management Agency Karlsruhe (PTKA)
Production, Service and Work
Karlsruhe Institute of Technology (KIT)

Stefan Scherr
February 2024

AMeLie

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PTKA
Project Management Agency Karlsruhe
Karlsruhe Institute of Technology

Preface by Fraunhofer Institute for Mechatronic Systems Design IEM

Dear readers,

We look back on three successful years of research and innovation work on the key question:

How do we design the systems of tomorrow?

The technical systems of the future are true marvels: they are networked, learn independently and act autonomously. And they are an important factor for a sustainable economy and society. But how can companies develop these systems successfully and competitively? And what role do people play in this?

Our answer: Advanced Systems Engineering

The answer to these questions lies in a complex interplay of organizational design, technological know-how and the right methodology. Advanced Systems Engineering (ASE) combines the necessary approaches and provides industrial companies with the tools they need to successfully design innovative products, services and product-service systems. In recent years, nine joint projects have transferred the latest knowledge from research to industry in concrete applications. They are convincing examples of the potential that ASE holds for companies.

Strategy development for Advanced Systems Engineering

The Federal Ministry of Education and Research (BMBF) is funding an accompanying scientific project with the task of providing advanced Systems Engineering with a sound, future-proof framework. To this end, we developed the status quo of engineering in Germany in a performance status survey in 2021. We networked the stakeholders of the joint projects with their various topics, discussed findings and

identified new fields of action. Building on these results, the Advanced Systems Engineering Strategy - A flagship initiative for the future of engineering and innovation in Germany was developed in 2022. It shows where we need to focus in the coming years in order to keep Germany competitive as a location for innovation and production.

Set the course for the future now!

The findings and innovations presented in the final reports are milestones in the relatively new field of advanced Systems Engineering. I would like to thank all those involved, the project partners, researchers and all industrial partners. Together, we have broken new ground - and set an important course for the future.

I hope you enjoy reading this report, gain new insights and experience many aha moments about the engineering of the future.

Prof. Dr.-Ing. Roman Dumitrescu
Fraunhofer Institute for Mechatronic Systems Design IEM,
Paderborn

2 Executive Summary

The implementation and benefits of Systems Engineering, often reserved for large companies, pose challenges for small and medium-sized enterprises due to the need for additional roles and processes. This prompted the initiation of the AMeLie research project in 2020.

This document outlines a framework for implementing and using Systems Engineering in small and medium sized enterprises Advanced Systems Engineering. Instead of devising new methods to fit into the existing landscape, this approach simplifies methods for easy adoption and application by smaller organizations, either independently or with minimal assistance. The framework of Advanced Systems Engineering derived in this project encompasses four areas of engineering and their capabilities within the areas.

Skill Management focuses on human aspects and collaboration, considering both internal staff and collaborative efforts with suppliers and customers. Also, the own organization is part of this area.

Context & Customer Understanding centers on customer-specific requirements, emphasizing the need for a product to be useful and marketable. In today's market, successful products require careful consideration of marketing and public perception from inception.

System Mastery addresses the project development process and frameworks to manage system development complexity, from requirement organization to development, testing, and validation.

Process Efficiency involves internal organizational processes and their management, including process workflows, project management, and documentation organization. It also involves scouting and integrating new technologies.

Finally, the framework enables a quick assessment of an organization's status of usage of Advanced Systems Engineering, allowing for a streamlined approach to understand and continuously evaluate their position post-implementation measures. The usual selection time for improved development methods is reduced from several weeks to just a few days by this approach. At the same time, the integration of the methods into the respective organization can happen more quickly because it builds on a standard set of methods and the adaptation occurs within the company itself. Moreover, an introduction is also possible entirely without external partners.

3 Introduction

Systems Engineering is mostly applied in large companies but should also be implemented in small and medium sized enterprises. To ensure the applicability of Systems Engineering, the research project AMeLie was initiated. In the course of the project, Systems Engineering methods were to be further developed so that they could be applied in the small and medium sized enterprises driven medical technology sector. Even though Germany is known for its strong mid-sized businesses, Systems Engineering hasn't gained much traction here.

The ASE[1] strategy emphasizes that Systems Engineering is an outstanding competence for securing Germany as an innovation hub[2]. Moreover, Germany's innovation is accomplished by small and medium-sized enterprises. To strengthen this innovative power, small and medium sized enterprises must be given tools to better shape their product development in the future.

This user guide is a result of the AMeLie project, which doesn't introduce new Systems Engineering concepts but consolidates proven principles and presents them in such a way that the introduction of Systems Engineering within a small and medium sized enterprise is easily implementable.

Premises for small and medium size companies

In our collaboration with small and medium sized enterprises in the AMeLie research project, we established basic premises that serve as a foundation for the successful development of methods. Even though current research in Systems Engineering covers topics such as digitalization, digital transformation, socio-technical systems, or artificial intelligence, we found that the premises for small and medium sized enterprises focus on entirely different mechanisms, as listed below:

No analysis teams and long analysis time before the introduction of Advanced Systems Engineering

Before introducing Systems Engineering in a company, an analysis typically needs to be conducted to identify the most significant potentials for change. For cost reasons, small and medium sized enterprises may find it financially unfeasible to engage the services of an analysis team. Additionally, it is often impractical in terms of time to have

[1] Fraunhofer IEM: Strategie Advanced Systems Engineering, 2022, [Youtube] https://www.youtube.com/watch?v=qaTDVkuWM00

[2] Albers, A.; Dumitrescu, R.; Gausemeier, J.; Lindow, K.; Riedel, O.; Stark, R. (Hrsg.): Strategie Advanced Systems Engineering –Leitinitiative zur Zukunft des Engineering und Innovationsstandorts Deutschland, München, 2022

an analysis team on-site for several weeks. This is particularly true because the analysis process also ties up internal resources, leading to a reduction in employee productivity. Extended discussions lasting several hours with multiple employees solely for the purpose of analysis are, therefore, not feasible.

- **The introduction of Systems Engineering must be lean and fast**

After the analysis and development of the first solution alternatives, the implementation of Systems Engineering in the company must be as lean and fast as possible. Ideally, little internal personnel should be tied up, and the introduction should not be stretched over several months but should occur in very small, incremental steps with immediate impact. Major changes to products or processes cannot be made as they are often developed or manufactured in daily business. The processes must remain relatively stable, as well as the products, to ensure deliverability.

- **Applying new methods within the organization must be as simple as possible**

When developing the methods in this research project, we ensured that they can be introduced by a company on its own. This is usually possible with the help of templates, guidelines, well-documented instructions, or initially conducted workshops with a group of people to impart knowledge. After that, the knowledge must be independently introduced into the organization, with changes to procedures or restructuring being done by an employee in parallel to the daily business, in their time and with their expertise about the company and product.

- **The day-to-day business within the organization must not be disturbed by new methods**

It's crucial to emphasize that daily business must not suffer from the new methods of Systems Engineering. Small and medium sized enterprises usually operate with a narrow margin on their products and cannot afford downtimes in production or delays in product releases within the development process. It is crucial, therefore, that daily operations continue and employees are pulled out of their work as little as possible. This is a significant difference from large corporations where it's easier to allocate resources solely for the implementation of a Systems Engineering methods project.

Involved consortium in the research project AMeLie

In the research project, 3DSE served as both coordinator and key contributor, overseeing project progress, applying Advanced Systems Engineering methods for small and medium-sized enterprises, ensuring collaboration and integration of methodologies among all partners.

cellasys: This partner provided the "Skin-on-a-Chip in Microwell Plate Format" as a product example for the project. This research object served as a testbed for both the application of ASE methods and further technological development.

Their product example, "Short-Term Implantable Electrodes for Neuromonitoring," was enhanced using ASE methods. Additionally, entire departments at OSYPKA were involved, allowing for a comprehensive examination and refinement of their development processes.

As a technology partner, Notion Systems was responsible for functional printing technology used by both technology partners. This production technology improved the scalability of the systems. Moreover, they developed a CAD/CAM interface specifically for thin-film printing.

As a software partner, Odego developed a demonstrator within their existing software Odego Cquenz®, focusing on the ASE methods developed in the project.

This partner brought an international perspective to the project. Utilizing the project's framework, Sensomedical restructured its organization. The ASE methods have become a daily operational standard within the company.

Fraunhofer IBMT: As a research institute, Fraunhofer IBMT researched functional printing, microfabrication and structured the technology selection process. This partner also contributed a department to test ASE methods, integrating these into their project work.

4 Application of Systems Engineering Framework

Systems Engineering is generally considered a multidisciplinary approach that allows not only engineers to be involved in the development process but also professionals from non-technical departments such as marketing or finance. The focus of development strategies mainly lies on engineering tasks and development activities. The question that arises from this is:

What methods does an organization need to develop a system?

Advanced Systems Engineering is not only about the question of appropriate methodology, but also about organizational structure: What kind of organization is needed to develop a product? What skills are required to develop a system, and which people are necessary to develop this system? Therefore, it is no longer solely about the product, but about the sociotechnical system as a whole. Insights from research must be transferred to the industry because it has long been clear in research that in Systems Engineering, the product is not the only focus. Within the framework of the AMeLie research project, a simple integration of 16 Systems Engineering competencies was carried out, which can be divided into four pillars and answers, for instance, the following questions:

- What do I need for the individual in my organization to perform, and what kind of organization do I need to have in place for that?
- How can I better integrate customers into my product and fulfill their wishes?
- How do I have to adapt my processes?
- What methods do I need in project management?
- Which new technologies can I use?

In order to answer these questions for small and medium sized enterprises, a reference framework was developed as part of the AMeLie research project. This is not based on an innovation in Systems Engineering, but has set itself the task of improving the accessibility of Systems Engineering. Companies are struggling to introduce the mass of Systems Engineering methods and therefore need a simple framework that makes the topic easy to understand and accessible. At the same time, this framework can be used for a quick and easy analysis of the organization. The framework is divided into 16 capabilities, which are summarized in 4 pillars. The description of the individual capabilities is the core of this paper. A brief description of the individual pillars and their characteristics follows on the next page. Later in this document all capabilities will be described together with success factors and, partner testimonials at the end of a chapter.

SKILL MANAGEMENT

Capabilities in Skill Management encompass all the bells and whistles of the organization and its employees. It is about developing and managing your own organization. Both internal and external expertise must be anchored within the organization and the focus must be on people.

CONTEXT & CUSTOMER UNDERSTANDING

Capabilities in Context & Customer Understanding focus on the customer and their needs. Pure system development based on the organization's own capabilities is no longer up to date, because in order to enable real innovation, the needs of the customer must be addressed.

SYSTEM MASTERY

The skills in System Mastery are about developing the solution. The classic Systems Engineering approach and its methods can be found here. Whether it is system thinking, working on requirements or commissioning the system, everything is covered within these skills.

PROCESS EFFICIENCY

An organization is only as good as its processes and procedures. For this reason, methods are established in the capabilities of Process Efficiency that ensure the improvement of work results. Time, quality and costs play a role here, as does the introduction of new technologies. New technologies must be introduced both in the system itself and for the organization. A structured approach to the introduction of these technologies is essential.

Systems Engineering assessment

The Advanced Systems Engineering assessment contains scientifically founded questions that must be answered by the executors to derive where an organization's potentials for improvement lie.

Only by conducting these assessment methods can be identified that must be applied within the company to improve its abilities. This often involves classical methods such as risk management, project management, or system decomposition. In the context of the AMeLie research project, it has been found that it is more about the simple application of proven methods and structured approaches rather than developing new, state-of-the-art methods with the latest technology. Thus, within the scope of the abilities, the methods of large corporations, as available in the project members' experience, were prepared to be applicable for small and medium sized enterprises as well. It is essential to emphasize that the assessment involves not just individual persons but includes the entire development department and all its employees. This ensures a comprehensive capture of all employees and thus the entire company. Additionally, this assessment helps to identify potential discrepancies between the management level and the organizational level since management often has a different perception of the organization's capabilities than the actual working staff. This assessment reveals both subconscious discrepancies and miscommunication, as well as the actual capabilities in product development.

The assessment is divided into two phases and relies on the 16 capabilities of Systems Engineering as described in the AMeLie Systems Engineering framework above. During the analysis of an enterprise there will be two-staged process to determine the current status of Systems Engineering.

Two-stage process of the assessment

Step 1: Data gathering

> Initially, the attitude towards development within the company is captured from both the management and at least 70% of the employees via an online questionnaire. This is divided into different roles or departments and should therefore be completed by the entire development department. It normally takes no more than 20 minutes per person to complete the survey. This means that it can be integrated into the daily work routine without disrupting it too much. The analysis phase is therefore not disturbing the day-to-day business within the organization.

Step 2: Evaluation and discussion

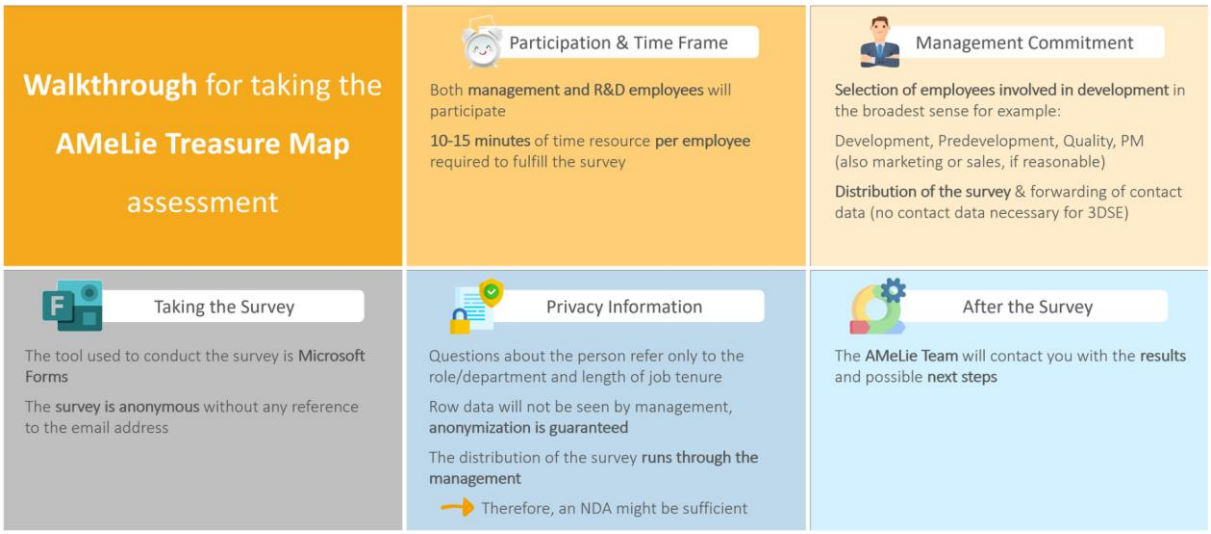
After the data collection, the questionnaire is evaluated using a specific metric, and the results are presented to the management or a selected audience to facilitate discussion. The evaluation also includes initial recommendations on what needs to be adjusted or changed in the company to achieve efficiency improvements. After this phase, the tools developed in the research project can be applied to enhance the respective competencies within the company.

It is essential to highlight that filling out the questionnaire takes a maximum of 20 minutes, ensuring minimal effort for each employee to determine the company's overall status. A lengthy analysis phase by an external service provider is entirely eliminated. With the appropriate participation of all employees, the analysis phase can be completed in less than a week.

Benefits of the assessment

The assessment allows determination of the organization's competencies in the shortest possible time, enabling the initiation of necessary steps and projects to achieve organizational goals and continuous improvements.

Subsequent sections will detail the assessment, its associated competencies, and methods that enhance organizational efficiency and improvements.



5 Skill Management

5.1 ACQUIRE AND DEPLOY SKILLS

The main goal of “Acquire and Deploy Skills” is to ensure each team has broad overarching knowledge including digital abilities alongside their deep specialized skills. Ideally the team is built with T-shaped people in a T-shaped team. A T-shaped individual or team combines deep discipline expertise and is topped with cross-discipline expertise, resulting in a T-shaped diagram. It is crucial for the organization's success to correctly match competences with the right roles.

To understand the difference between skills and competences: Skills are defined as learned abilities which one requires to perform a given job or task successfully, i.e. computer programming or handling accounts. Competence on the other hand is the knowledge and behavior that leads to be successful in a job, i.e. analytical abilities or problem solving. By acquiring and deploying specific skills, employees will develop necessary competences through experience.

The AMeLie project defines competence as followed:

> *"Competence means being able to use skills and abilities appropriately in different contexts to solve problems and to act successfully. Competencies can be learned and are individually influenced by social willingness as well as values and motivation."*

In order to be successful in their job, the team member needs to utilize various competences. These competences are categorized into “social & communicative” or “technical & methodological”. The social and communicative competences include stakeholder management, customer and team orientation, conflict management or adaptability. On the other side, the technical and methodological competences include Systems Engineering, architectural thinking, market understanding or process orientation.

To acquire and deploy skills correctly, a team regularly needs assessments. A competence matrix supports the assessment process within the team and their current level. In the INCOSE competence framework, the different levels of competence are assessed on a total of 5 levels starting with Awareness up to Expert in the last level of competence. These levels are intended to provide an assessment of how good an employee is at a certain competence. It should be noted that the levels include an assessment of both experience and pure knowledge. This will either help to deploy each team member in ist correct Advanced Systems Engineering role or assess which competences or members need further improvement in their field. The core competencies for a successful Systems Engineering implementation are systems

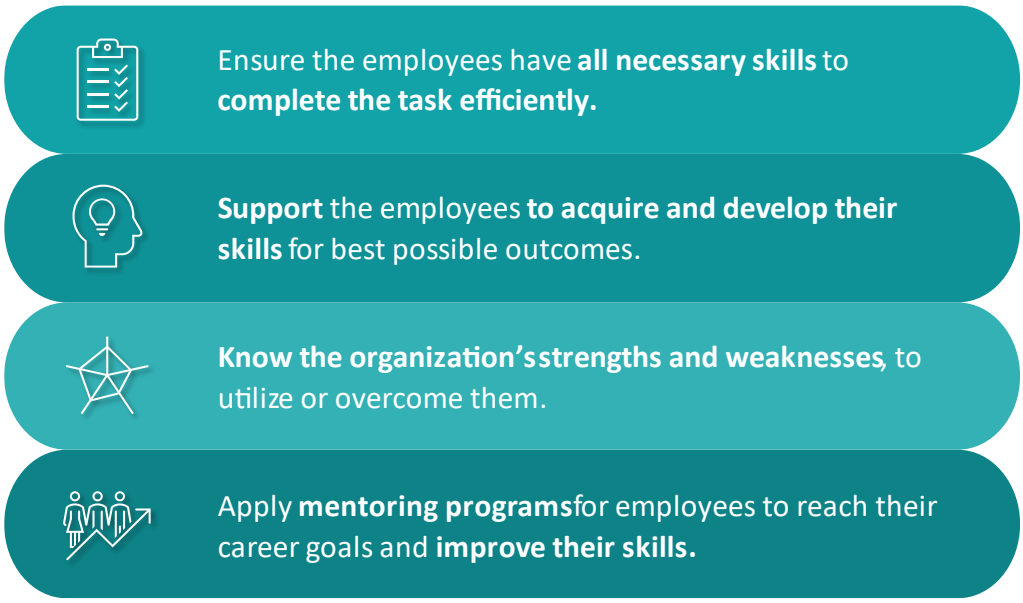
thinking, lifecycles, capability engineering, general engineering, critical thinking as well as systems modelling and analysis. To establish Advanced Systems Engineering successfully, the team needs to contain a set specific role and their responsibilities. The following roles are an excerpt of key Advanced Systems Engineering roles for a lean implementation in small and medium organizations. The Requirements Manager is responsible for the architecture of the (sub)system for the best possible goal achievement. The Verification & Validation Manager is accountable for the virtual as well as physical integration, verification, and validation of the (sub)system. The System Architect is accountable for providing conflict-free and SMART requirements related to the (sub)system. The Technical & Risk Manager is in control for all technical (project) management tasks for the system, tracking and prevention of project risks. The Information Manager oversees defining and maintaining an end-to-end data and information flow. The Release Manager is responsible for the (sub-)system certification and release process to all release/build stages along the product development process. The Configuration Manager provides conflict free and complete configuration baselines to report/review deadlines. Lastly, The System Engineer is responsible for overall technical aspects and decision-making authority for the respective (sub)system.

However, Sheard[3] identified twelve Systems Engineering roles. These roles are

1. Requirements Owner and
2. System Designer.
3. System Analyst,
4. Validation & Verification Engineer,
5. Logistic & Operations Engineer,
6. Glue among Subsystems,
7. Customer Interface,
8. Technical Manager,
9. Information Manager,
10. Process Engineer,
11. Coordinator,
12. other Systems Engineering related tasks,

[3] Sheard, S.A. (1996), “Twelve systems engineering roles”, Paper Presented at Sixth Annual International Symposium, 7.–11. Juli, Marriot Copley Place Hotel, Boston, Massachusetts, USA

But it is important to point out that there is no blueprint for a Systems Engineering organization. This allows the specific needs to define setup and work methods. The distribution of responsibilities and tasks to these roles can be used as a guideline for the Systems Engineering Organization.



5.2 COLLABORATE WITH SPECIALISTS

Following up with acquiring and deploying skills within the own team, collaborating with strong partners and experts is an additional option to draw on knowledge. The goal of these partnerships is to grow prosperity through external assets. Ideally, the partnership is beneficial to both parties involved.

Cooperation versus collaboration

Cooperation is defined by individuals or teams that work on different subtasks of an end result. The individuals or teams work in parallel processes. While individuals or teams work together in parallel on a part of the final result in collaborations various parts are worked on sequentially, i.e. continuously.

Collaboration is further possible to be defined by horizontal, vertical and diagonal collaboration. Horizontal collaboration describes two or more parties, i.e. employees, teams or even companies on the same stage in the value chain working together.

Vertical collaboration is described when two or more parties from different stages of the value chain work together. Lastly, diagonal collaboration describes two parties from different branches and value stages working together.

Finding the right partner as baseline for success

3DSE has defined factors regarding strategy, product, process, organization and company culture that have positive impact on the outcome of partnerships. The factors can be used as guidelines while planning partnerships with external parties.

While planning, one has to consider the co-development strategy. It defines the scope and members of the collaboration, i.e. is the partnership exclusive, multiple or open. Additionally, another element to judge is the product vision and proposition, which is mutually accepted by both parties. Another element is understanding the partners' architecture and interfaces while taking the working model into account. A joint development roadmap helps to synchronize milestones in development of all parties involved and clearly defines the corresponding delivery. Furthermore, funding and controlling is an important element of partnerships. Both partners need to determine

the breakdown and split of development cost, considering internal business cases and potential design tradeoffs.

To eliminate friction from the start, a clear working model and precise roles need to be created and communicated among partners. Especially in research and development cooperations are secure and efficient infrastructures which need to be compatible to the applied working models. A reliable supply chain is elementary for successful partnerships. It is beneficial to implement a common supplier base while considering the resulting business case effects in the architecture of the involved parties.

Lastly, both parties need to agree on a contractual framework including all critical points as well as ensuring a cultural fit through mutual trust and common mindset.

Determine the depth and length of partnership

Different cooperation models can be applied depending on the scope and the degree of a partnership. The degree of partnership determines the degree of trust between the parties required for a successful cooperation. This ranges from supplier with the lowest implementation and trust up to joint ventures. The various cooperation models open different opportunities to business models.

A part or component supplier requires non to very low trust and implementation. The partnership is straight forward without or close to no integration efforts for supplier. Next, an engineering service provider is responsible for system specification and design requiring a higher level of trust and implementation than a part or component supplier. Both business models aim for part costs with one-time expenditure depending on time and material.

The next step in a partnership is the system supplier as subcontractor. The implementation and delivery of systems with medium or high complexity requires integration effort and design share for supplier depending on system properties. This cooperation is monetized the same way as the previous partnerships, while including the opportunity of long-time exclusive distribution rights.

Further, a technology partnership requires a high level of trust and integration due to the cooperation in manufacturing, implementation, specification and design. The business model allows the creation of exclusive usage rights as well as licensing.

The lastly described partnership requires the highest level of trust and implementation, the joint venture. The goal is to collaborate in all areas regarding the product from specifications and design to manufacturing with shared revenue, profit and savings.

Participate proactively in **sharing** know-how and technologies **with other companies**.

Be aware of **specialist knowledge within** own company on **specific topics**.

Apply and use **external knowledge** by integrating freelancer and/or participating on research projects.

5.3 MANAGE KNOWLEDGE

Volatility of knowledge

The volatility of knowledge pertains to the stability and accessibility of information in an organizational or individual context. Knowledge can be categorized into two fundamental types: implicit and explicit knowledge. Implicit knowledge is not recorded but stored in people's memories. It is dynamically created and challenging to teach or capture. In contrast, explicit knowledge is easy to articulate, write down, and share. It is context-independent and straightforward to capture. A crucial aspect of knowledge creation lies in the transformation of implicit knowledge into explicit knowledge. Knowledge volatility depends on the nature of itself. Sensitive, need-based knowledge is highly volatile because it is possessed by individuals, posing a risk of knowledge loss due to fluctuations in the workforce. On the other hand, general knowledge that is openly accessible within an organization has lower volatility and is considered company knowledge. Therefore, it is essential to identify the focus point based on the type of knowledge to effectively manage knowledge volatility.

Knowledge management strategy

It is essential to distinguish between strategic and operational knowledge management when addressing the topic of knowledge management strategy. Strategic Knowledge Management involves a systematic process of evaluating knowledge, gathering feedback, and defining clear knowledge objectives. These objectives serve as a guiding framework for knowledge management initiatives, providing direction to the measures and activities undertaken while determining which knowledge is essential for both present and future needs.

On the other hand, Operative Knowledge Management encompasses a series of interconnected steps, including the identification, acquisition, development, distribution, utilization, and preservation of knowledge. Each of these steps plays a vital role in ensuring that knowledge is effectively leveraged within an organization.

Evaluating knowledge is a fundamental aspect of this continuous effort. Regular assessments are conducted to gauge the ongoing relevance of existing knowledge. These evaluations are crucial for maintaining the quality and applicability of knowledge assets. Moreover, systematic updates are implemented to manage knowledge to prevent obsolescence, ensuring that knowledge remains valuable and aligned with the

evolving needs of the organization. In summary, knowledge management is an ongoing process that requires diligent attention at every stage to optimize its benefits and enhance organizational performance.

Boundary conditions for knowledge management

Correctly identifying knowledge involves ensuring the right type of information is accessible to the appropriate individuals. Recognizing top performers and devising methods to transfer their knowledge to others is key. However, it's imperative to balance this sharing without overwhelming individuals with excessive information, which can lead to an 'information overload' effect.

An appealing design for content is equally important. Recorded knowledge that isn't utilized holds little value, highlighting the need to find the right form of knowledge preservation tailored to the company. Additionally, ensuring the functionality of the software used is adequate and integrating gamification to boost engagement and participation in knowledge-sharing processes is beneficial.

Integrating knowledge management into the corporate culture is essential. Embedding it as a natural part of the workflow and seeking employee input during the development of knowledge management systems can foster higher acceptance from the outset. Rewarding employees for their valuable contributions further incentives active participation.

Motivating contributions is a critical factor in effective knowledge management. Employees should feel encouraged to share knowledge without the fear of being replaceable. However, a balance must be struck as preserving knowledge can inadvertently create rigidity and resistance to new information. Furthermore, there's a risk that preserved knowledge might fall into the wrong hands or be leaked externally, necessitating robust security measures. Striking the right balance between preservation and adaptation is vital for a successful knowledge management strategy.

Utilize **the right tools** to support knowledge management.

Train employees **where to find needed information** and **encourage employees** to share knowledge.

Utilize an **active system** to keep knowledge up to date.

Install a **clear process** to acquire and storage knowledge with **set responsibilities** to manage knowledge.

5.4 DEVELOP YOUR ORGANIZATION

Governance

Governance in an organization refers to the structures, processes, and mechanisms used to exercise authority, make decisions, assign responsibilities, and provide accountability. Governance includes both formal and informal arrangements influenced by laws, norms, power structures, and cultural practices. Governance is not necessarily tied to a system or system development and doesn't always have to be formalized through, for example, specific board meetings or codes of conduct.

In the context of an SME, governance can be described as the framework within which members of an organization (from individual decision-makers to entire departments) communicate their interests, resolve conflicts, reach consensus, and carry out cooperative actions. It also addresses how to deal with regulations or general quality management. Good governance includes characteristics or criteria such as transparency, accountability, efficiency, participation, and adherence to the rule of law. These characteristics are meant to ensure that resource management and direction in an SME are fair and contribute to the firm's objectives.

To introduce good governance in an organization, employees need to be knowledgeable about the organization's individual processes and goals, and there must be accountability to enable stakeholders to make decisions. Governance should be applied across at least a whole department to be effective. To avoid creating a patchwork of different rules within an organization, it's advisable to use working groups or a workshop approach with external moderators to develop and implement later on governance.

Organizational structures

The classical company structure is hierarchical, resembling a tree diagram. Typically, there is a company management, often the board or executive committee. Below them are the company's departments, which can be set up according to specialty (finance, marketing, development, production, etc.). Development projects are staffed with personnel from these individual departments. Both the disciplinary and professional leadership of an employee lies with their immediate supervisor.

The organizational structure outlines, in broad terms, the collaboration model of the employees within an organization. Besides the classic model mentioned, an organization can take many different forms. Transforming an organization requires expertise, and organizations should be reshaped regularly so that employees maintain a certain flexibility and the organization itself can flexibly respond to market changes. When adjusting the organization, the following can be considered:

Matrix Organization: A matrix organization is a hybrid structural model that aims to combine the benefits of functional and project-related structures. In a matrix organization, employees report simultaneously to two managers: a functional manager and a project or product manager. This dual leadership system promotes the efficient use of resources and increased flexibility in responding to changes. This structure, therefore, requires highly developed communication culture and clearly defined decision-making processes. A matrix organization distinguishes between structural organization, outlining the static structure, and process organization, focusing on dynamic aspects such as how work processes are designed and coordinated.

Agile Model: Agile methods aim to increase an organization's adaptability and responsiveness. Agile principles, as articulated in the Agile Manifesto[4], emphasize the value of individuals and interactions, working products, customer collaboration, and the ability to respond to change. Agile methods like Scrum, Kanban, or Lean Development seek to accelerate the development dynamic and enable continuous improvement and adaptation to changing requirements. These approaches alter the traditional structural and process organization by emphasizing flatter hierarchies, multidisciplinary teams, and iterative work cycles.

Spotify Model: The Spotify model is an approach to designing organizational structures that have gained popularity, especially in software development and IT companies. It's based on forming small, cross-functional teams called "Squads," responsible for specific products or services. These squads are embedded in larger units known as "Tribes." This model fosters autonomy and quick decision-making, with a strong emphasis on corporate culture and the principle of "Community of Practice". The goal is to utilize scaling benefits without compromising agility and innovation capability.

[4] Beck, K.; Beedle, M.; van Bennekum, A.; Cockburn, A.; Cunningham, W.; Fowler, M.; Grenning, J.; Highsmith, J.; Hunt, A.; Jeffries, R.; Kern, J.; Marick, B.; Martin, R. C.; Mellor, S.; Schwaber, K.; Sutherland, J. & Thomas, D. (2001), 'Manifesto for Agile Software Development'

There is no one-size-fits-all organizational form. Each option has its pros and cons. To find the best form, an approach should be chosen that involves as many experienced and inexperienced employees as possible. As part of the AMeLie project, an approach was developed for SMEs to be able to sustainably shape the organizational form. A total of 8 workshop days are needed with the goal of developing the organizational form. After completing the workshop series and communicating the decision through management, a transition period from the current to the new organizational form is required.

6 Context & Customer Understanding

6.1 COMMUNICATE THE PRODUCT VALUE

In product development today, relying solely on technical superiority is no longer sufficient. In a saturated market, it's equally important to highlight the value proposition to the customer and pursue a targeted marketing strategy. Successful product sales are therefore composed of two equally weighted parts: 50% development and 50% marketing and sales. An effective marketing strategy must be executed by the appropriate department but should be initiated during the product development phase.

From an early stage in product development, customer-relevant features need to be identified, and all support functions should be aligned to create a tangible value proposition. A marketing strategy focused on these features is intended to make the product's value proposition experiential for the customer. It is crucial to define specific customer profiles and understand the anticipated benefits of the product from the customer's perspective, known as Product-Market Fit, which is particularly challenging for new products.

Once a product has been developed and is communicable, a well-thought-out marketing strategy becomes necessary. Especially in small and medium-sized enterprises, this must be promoted not only by a dedicated department but also by the development team itself. The focus is on telling the story from problem to solution and consistently communicating it. A compelling storyline is indispensable for marketing.

To effectively convey the value of a product, a tailored strategy is required, which can be developed either internally by developers and the marketing department or with the help of external experts. Ultimately, every marketing strategy must be unique and tailored to the specific product and its market.


Know the company's **strengths and weaknesses** during product development process.
Have a **clear plan** about the **kind of products**, the company wants to develop.
Be realistic about the **added value for customers** through company's **innovations and products.**
Coordinate all projects with the company's strategy.

cellasys

Following cellasys' history, product placement initially occurred within the scientific community, where competition primarily revolved around scientific publications. A thorough analysis of the relevant market led to the development of a new product placement strategy. The focus shifted to the growing global market for Organ-on-a-Chip systems, anticipated to reach a value of 440 million euros by 2030. These systems, a fusion of cell culture technology, microsystem technology, and sensor technology, are of interest to both industrial and academic customers for analyzing biological processes, identifying new active substances, and assessing toxicity.
The revised B2B marketing strategy includes several key approaches:

- **Content marketing**
  Utilizing blogs, application notes, and case studies provides deeper insights into the product.
- **Targeted events**
  Workshops with partners and training sessions serve to deepen understanding and provide direct feedback
- **Public presence**
  Participation in fairs and conferences expands the product's reach and strengthens industry presence.
- **Social media platforms**
  Using platforms like LinkedIn and ResearchGate to effectively communicate the message to a broad audience.
- **Search engine optimization (SEO)**
  Targeting relevant keywords to effectively communicate with the desired audience.

cellasys' approach leverages the marketing funnel to increase product awareness and spark interest by emphasizing competitive advantages. Marketing campaigns, such as case studies on ResearchGate, targeted advertising, and interactive workshops, are strategically used to draw attention to the product. This marketing strategy aims to raise awareness of cellasys'

6.2 PUT THE CUSTOMER IN THE CENTER

In the context of this chapter, the customer is going to be the focus of product development. Typically, knowledge-driven, small companies are spearheaded by technical individuals and embodying a high level of technical understanding. However, the demands on the product predominantly come from customers or other stakeholders, necessitating a framework to guide employees on effective stakeholder management.

Stakeholder analysis

Multiple sources of stakeholder input need consideration, both internal and external. Internal sources primarily encompass guidelines on e.g. comfort, manufacturing protocols, or IT applications, while external sources standardly include regulatory compliance such as DIN standards and, of course, customer feedback.

Essentially, each stakeholder must be examined for potential requirements that may arise during product development. These requirements are addressed in the chapter “Manage your requirements”. A step preceding requirement gathering is identifying the stakeholders, and through systematic identification, it's possible to incorporate diverse aspects into product development. The identification of stakeholders is intertwined with the creation of personas during the course of development. This ensures that the target individuals or groups are accurately analyzed. Personas thereby provide a solid foundation for deriving requirements for product development. There are particularly significant touchpoints and methods stemming from marketing on how stakeholders can be identified.

Stakeholder identification

Throughout the course of this research project AMeLie, it has been established that the PESTEL method is the simplest yet most effective approach. This method can be applied in the early phases of product development as well as when the development is well underway, to retrospectively ascertain whether all stakeholders have been considered. Once identified, it's crucial to assess the frequency at which each

stakeholder’s input is evaluated, and how later on, the requirements from each stakeholder are integrated into product development.

Conclusion

This capability closely interlinks with other disciplines in the company such as marketing and sales, who also need to recognize the value of Systems Engineering and thus contribute to the documents essential for technical development. Hence, gathering requirements from the market is not solely the engineer’s task but extends to other departments that may not have a technical contribution to the product. Furthermore, it's intriguing how different stakeholders engage with the product. For instance, it's advisable for companies to participate in committees that enact laws to facilitate bringing their product to the market later on.

6.3 KNOW YOUR CONTEXT

To know the context is crucial for any product development process. It involves developing a deep understanding of the market, users, and the product itself to minimize risks and ensure a successful launch. This chapter covers four aspects: Market Understanding, User Understanding, Product Understanding, and Risk Management. By focusing on these four aspects, product developers can ensure that their product meets the needs of the market and the users, while minimizing risks and maximizing success.

Market understanding

To explore the market, analyzing competitors and evaluating the market are two essential tools. Analyzing competitors helps in understanding both the business and its competitors. It is key to learning, growing, and staying ahead, especially in a volatile industry that needs to evolve and innovate with disruptive technologies. By analyzing competitors, customer pain points get uncovered to refine product value and directly address those needs. Market assessment helps to understand the direction that an entire industry is moving. It can help to avoid making the same mistakes as the competitors. By using these two tools, it is possible to better understand the market and staying ahead of the competition.

User understanding

Target groups and personas are essential tools for understanding potential users better. A target group consists of individuals with similar characteristics who have similar interests in a particular product or service. Identifying the target group enables more effective customization of marketing efforts. On the other hand, a persona is a fictitious representation of a person who embodies key characteristics of a specific target audience. This aids in grasping the needs, challenges, and concerns of the ideal customers. Creating a persona ensures that the entire team tailors the product to address the target audience's requirements, increasing the success. The utilization of these two tools leads to a more comprehensive understanding of users, facilitating the development of a product that truly caters to their needs.

Product understanding

Activity charts and the value proposition canvas serve as critical tools for product exploration. Activity charts offer insights into customer actions while using the product, identifying potential areas for product improvement. Conversely, the value proposition canvas helps understand the product's value and effective communication strategies. It's vital for grasping genuine customer needs and the value of products and services. Using these tools yields a deeper understanding of the product, aligning it better with customer needs.

Risk management

Risk management is a crucial aspect of any business, and it involves three main areas: risk identification, risk assessment, and risk mitigation. Effective risk management requires continuous monitoring and improvement of the process to ensure that the business can respond to changes in the risk landscape.

To effectively manage risks, companies need to have a comprehensive understanding of their risk landscape within the organization and the development project at the same time. One way to identify risks is by using a stakeholder diagram, which helps identify all stakeholders involved in a project or process. By understanding the stakeholders and relationships between each other, companies can identify potential risks that could impact the project's success.

Another way to identify risks is by using a project plan. A project plan outlines the scope, timeline, and resources required for a project. By reviewing the project plan, companies can identify potential risks that could impact the project's success. Additionally, reviewing the project plan can help to identify dependencies and potential bottlenecks that could impact the project's timeline.

Architectural diagrams are another tool that can be used to identify risks. An architectural diagram provides a visual representation of a system or process. By reviewing the architectural diagram, companies can identify potential risks that could impact the system's or process' functionality.

Once risks have been identified, the next step is to evaluate them. A risk evaluation matrix is a tool that can be used to evaluate risks. The matrix helps quantify the likelihood and impact of each risk. By using a risk evaluation matrix, companies can prioritize risks and determine which risks require immediate attention.

Finally, to manage risks, companies can use a risk measures table. A risk measures table outlines the measures that will be taken to mitigate each risk. The table includes the risk, the likelihood of occurrence, the impact, and the measures that will be taken to mitigate the risk. By using a risk measures table, companies can ensure that they have a plan in place to mitigate each risk.

The methods previously discussed should be effectively integrated into an organization's operational structure to ensure their beneficial application. For smaller SMEs (small and medium-sized enterprises), the individual application of these methods tends to be simpler. However, as soon as multiple development projects are simultaneously advanced within the organization, it's recommended to implement a consistent and overarching risk management process. The goal is to harmonize the approaches presented and firmly establish them within the company.

cellasys

The story of cellasys, a spin-off company from the Technical University of Munich, illustrates the crucial role of customer orientation in product development and also in marketing. Initially, the company was enthralled by the technological aspects of its products, which was reflected in a strong technical focus during market launch and the years after. However, it became apparent that the expected commercial success was not materializing. A thorough stakeholder analysis as introduced during the AMeLie project led to a significant insight: Potential customers were more interested in the improvement of their problem-solving capabilities than in the pure technical features of the product.

Based on this realization, cellasys fundamentally revised its marketing strategy. Through a detailed analysis of customers and the market, the company developed first time a differentiated strategies for various customer segments. The targeted approach to addressing the individual interests and needs of customers, based on thorough analysis, made it possible to shape the communication strategy more effectively. Particularly useful was the examination of different customer personas to better understand the specific requirements and desires of different customer groups.

cellasys' realigned communication strategy aimed to engage customers on a more personal level by focusing on the potential problem solutions and benefits that the product could offer. This approach generated stronger resonance and interaction from the customer side, thereby increasing the company's relevance and attractiveness to various customer groups. Focusing on customer needs and specifically addressing their problems proved to be key in more effectively marketing the product and increasing revenue potential.

The case of cellasys underscores the importance of a deep understanding of customer desires and needs for a product's success. By adjusting their strategy to the customer perspective, cellasys was not only able to achieve broader market recognition but also improve its positioning and success in the long term.

Fraunhofer IBMT

The importance of proper risk management in R&D projects is often underestimated. Certainly, the identification of possible risks and the definition of appropriate mitigation measures is part of the preparation phase of a new research project. But in this early phase before the start of a project, the focus is normally on the technical concept, on the planning of project tasks with deliverables and milestones to be reached and on the calculation of the necessary project budget. The aspect of risk management is often considered with minor priority and not implemented thoroughly into the overall planning of the project and even less during the project execution. As a result, R&D projects repeatedly suffer from many iterative development phases with avoidable dead ends and high development effort.

The Advanced Systems Engineering approach developed within the AMeLie project addresses helps to effectively integrate risk management throughout the project lifecycle. The ASE method is structured around three main steps: risk identification, evaluation, and management. This process is applied across three critical perspectives: stakeholders, project plan, and product.

- **Stakeholder perspective:** By analyzing the relationships among project partners, potential conflicts can be identified early. Proactive measures for conflict mitigation or avoidance are then integrated into the initial stages of the project.
- **Project plan perspective:** Emphasizing the organization of the work plan becomes crucial. Detailing each step to achieve specific objectives (milestones, deliverables) allows for a more strategic approach in planning and reduces organizational risks.
- **Product perspective:** Defining and describing the system architecture in detail, including all systems, subsystems, components, and their interfaces, is key to pinpointing technical risks associated with the product development.

This approach, with its straightforward structure, manageable workflow, and clear visualization, enhances the implementation of risk management in both the preparation and execution phases of our R&D projects. This structured approach not only mitigates risks but also streamlines the project management process, ensuring a more robust and efficient pathway to project completion.

6.4 INNOVATE TO EVOLVE OR DISRUPT

Innovation is a critical factor for success in today's rapidly evolving business landscape. A company's ability to generate technological innovation and effectively navigate new markets through structured processes is essential.

Technological innovation

Technological innovation is at the forefront in this environment. The extent and market impact of innovations vary, and effective communication among market stakeholders is essential. Innovations can be categorized into different types:

- **Sustaining innovation**
  This occurs when a product undergoes significant improvements to maintain its position in an existing market, despite not being technologically new.
- **Incremental innovation**
  Characterized by gradual enhancements to existing products or services, these innovations have low technological newness and market impact.
- **Disruptive innovation**
  Marked by high technological newness and significant market impact, disruptive innovations can be new technologies or business models that upend existing markets.
- **Radical innovation**
  These are technological breakthroughs that drastically transform industries and often create new markets, characterized by high technological newness but low initial market impact.

The diffusion of innovations typically follows a curve, starting with "Innovators," who are eager and willing to take risks, followed by "Early Adopters," who are influential within their social circles. Next are the "Early Majority," who are more cautious but open to new ideas, and finally the "Late Majority," who are typically sceptical and influenced by peer pressure.

The right innovation strategy

Innovation within a company should not be left to chance. Too often, innovative ideas get lost in the day-to-day operations. Each new idea with potential for innovation needs to be developed to a certain degree to create momentum for implementation. This momentum can be achieved through a structured approach that maximizes market potential or explores new markets. This approach can be summarized in three key areas:

- **Understanding the customer problem:** Focusing on problem identification, ideation, and use case development.
- **Understanding the technology:** Involving development, feature exploration, work assessment, and considerations of time and team.
- **Understanding the market:** Entailing market scoping, preparation for market entry, and market penetration strategies.

In the AMeLie project, one of the consortium partners developed an innovative strategy for new technology, addressing key aspects of the venture. This strategy critically evaluates current technology challenges in the targeted domain, positioning the new technology as a strategic solution. It provides a detailed market analysis, highlighting significant statistics and trends to emphasize the market's potential and growth prospects.

The business case analysis includes a break-even point analysis to determine the economic feasibility. The partner company's market positioning is strategically articulated through a comparative analysis, showcasing its strengths and unique value propositions against competitors. The strategy also highlights strategic partnerships, creating a collaborative ecosystem and potential synergies.To attract future investors, the strategy presents compelling reasons for investment, focusing on the company's growth potential.

Set company **apart from competition** through innovation.

Include **planning, managing and controlling** of innovative technologies and ideas as part of **product development**.

Engage in an **innovative company culture** that enables taking risks and **work creatively.**

Set clear, smart **innovation targets** that are **supported** by top management.

7 System Mastery

7.1 THINK IN SYSTEMS

Systems thinking

The ability to “think in systems” refers to the process of breaking down a complex system into smaller units that are manageable for the developer. One of the fundamental principles of Systems Engineering is "Divide et Impera". A system, regardless of its size and complexity, can be broken down into smaller parts by drawing system boundaries within the system itself. It's important to define the interfaces between different system boundaries to understand how the systems interact. Interfaces can primarily include mechanical components, but also aspects such as fluid dynamics, electronics, or electrical systems.

To gain an overview of one's system and to think systematically, an operational concept is first created. This provides insight into how the system is supposed to function. This can involve flow or sequence diagrams, or other models, to make the system's operation more comprehensible. An operational concept and its alternatives form the foundation for sophisticated systems. Only by considering concept alternatives on a lower level the overall system concept and also the operational concepts can be different. Real alternatives are created. Here, new technologies, different algorithms, or the development of new capabilities play a role. The operational concept thus represents the functioning of the system.

Requirements and architecture

Starting from this concept, the requirements, which are covered in the chapter "Manage your Requirements", must be documented first. Along with the operational concept and the functioning of one's system, the system architecture also plays a role. For an overarching concept it is needed to design one's system and enable the functions. Functions describe a change in the system's state or a state change brought about by the system. For instance, in the automotive sector, classic functions such as driving or braking are encountered. The realization of these functions occurs within the system via different subsystems and components, referring both to software and hardware.

Architecture is an overarching element that unites all artifacts within system development. Typically, breakdown structures are highlighted, with which a system can be described, as well as the work organization required to build this system. Notable representatives include the "Product breakdown structure" or "Functional breakdown

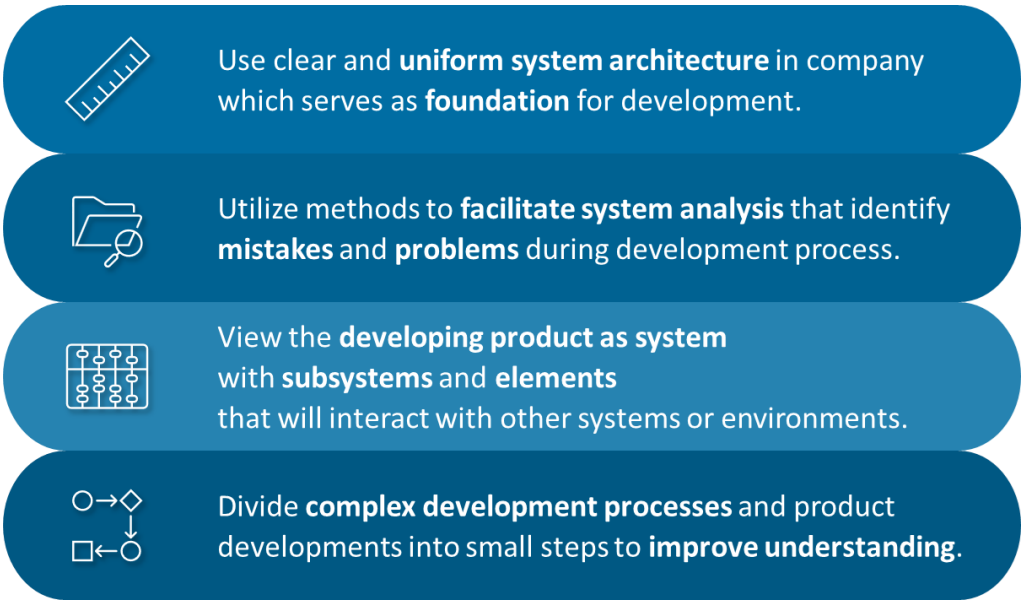
structure" describing the "what", and the "Organization breakdown structure", "Work breakdown structure" and "Cost breakdown structure" explaining the "how." The further the system's development has progressed, the more one can rely on software to depict the different structural elements. Especially when involving thousands of employees and numerous other development artifacts, it's essential to create a structure early in the development project where artifacts can be developed. This aspect of systems thinking covers the entire repertoire of Systems Engineering, from stakeholder management to validation.

By thinking systematically and viewing one's product not just as a single aspect, it's possible to work at different levels of detail during development. Thus, at the start of a development process, it's not necessary to understand the depth of every technical component since the focus lies on the bigger picture. In the role of the system architect, the task is first to break down the individual parts of the system to be realized and later, during the implementation phase (see chapter "Integrate, Verify and Validate"), to bring them back together.

Necessity of documentation

Working with documents or models is particularly important in this context. In Systems Engineering, different types of documents can support system development. However, it's crucial to emphasize that using every template isn't mandatory. Therefore, both the processes and the deliverables of these processes must be tailored to the specific needs of system development (see process efficiency). A fundamental understanding of the different systems, levels, and separations within the system should be present among employees. However, not every employee needs to delve deeply into this skill.

As evident with all skills in skill management, a good distribution of skills within the organization and the designated roles is essential. The basics of systemic thinking can be conveyed rather quickly. A few days of training or workshops with the respective employees might suffice to provide an understanding of what Systems Engineering and systems thinking could look like. However, the comprehensive implementation in a company is complex and represents one of today's significant challenges.


Use clear and **uniform system architecture** in company which serves as **foundation** for development.
Utilize methods to **facilitate system analysis** that identify **mistakes** and **problems** during development process.
View the **developing product as system** with **subsystems** and **elements** that will interact with other systems or environments.
Divide **complex development processes** and product developments into small steps to **improve understanding**.

Unlike other management methods, Advanced Systems Engineering recognizes people as a central element in the system analysis. Despite the convenience provided by software tools in our daily lives, a project cannot succeed without skilled and motivated employees. Therefore, OSYPKA conducted a three-day workshop, led by the project partner 3DSE. The workshop aimed to critically examine development processes, identify inefficiencies, discover or devise new methods, and prepare for their implementation. Attended by the (technical) project leaders of the development departments, the workshop effectively disseminated its content across various specialized departments. The group activities, collaborative problem-solving, expertise of the internal senior project managers, and excellent workshop leadership helped alleviate employee concerns and sparked interest in new methods and processes. The key outcomes not only by the workshop but also from continued work included:

- **Creation of product architectures:** By using product architectures and linking requirements to other information elements we have a better understanding of our product and save on coordination efforts. Additionally, project leaders have a basis for communication with customers, eliminating the need for complex presentations. This saves time and reduces frustration among employees.
- **Enhanced integration of existing software:** Advanced Systems Engineering methods enable seamless integration of existing software applications into our central PLM system. These fosters improved collaboration between departments and teams, enhancing information exchange and increasing efficiency within the company.
- **Utilization of digital twins:** The introduction of digital twins within the company allows for more efficient planning and simulation of products and projects, leading to improved product design and optimized resource use.

Implementing those methods will not only boost our productivity but also enhance the quality of our work and the overall competitiveness of our company. This represents a significant step towards a more efficient and digitally interconnected future for OSYPKA.

7.2 MANAGE YOUR REQUIREMENTS

The precise description of a problem can be effectively achieved by gathering requirements.

First, the question must be clarified which stakeholders need to be considered when gathering requirements for a product. This is explained in more detail in the chapter "Put the Customer in the Center."

Requirement gathering

Requirements are gathered at every level of a system and must be linked to ensure seamless traceability. Starting from each stakeholder requirement, at least one system requirement that meets SMART criteria (specific, measurable, accepted, realistic, traceable) is generated. Requirements at the highest level should describe the overall system without being considered in isolation. These requirements are often still so general that they need to be more precisely formulated at further system levels.

It is essential to ensure that requirements are created following a fixed sentence template, leading to a uniform formulation. The goal is a clear description of a problem, not the creation of prose text. In developing the system and subdividing it into different subsystems, components, and equipment, the interplay between problem description based on the requirements and system development based on functions, logical and physical structures, must go hand in hand.

When developing a system, the breakdown is done into subsystems, components, and equipment. In this process, the problem description, based on the requirements, must align with system development, which is based on functions, logical, and physical structures. This work can be done very well with software support. Most tools are too complicated to use and are therefore not used by small companies. For this reason, the AMeLie project developed a solution that can quickly and easily display the architecture of the systems and the breakdown of the requirements, see figure A1. The recording of requirements is better designed and immediately grouped.

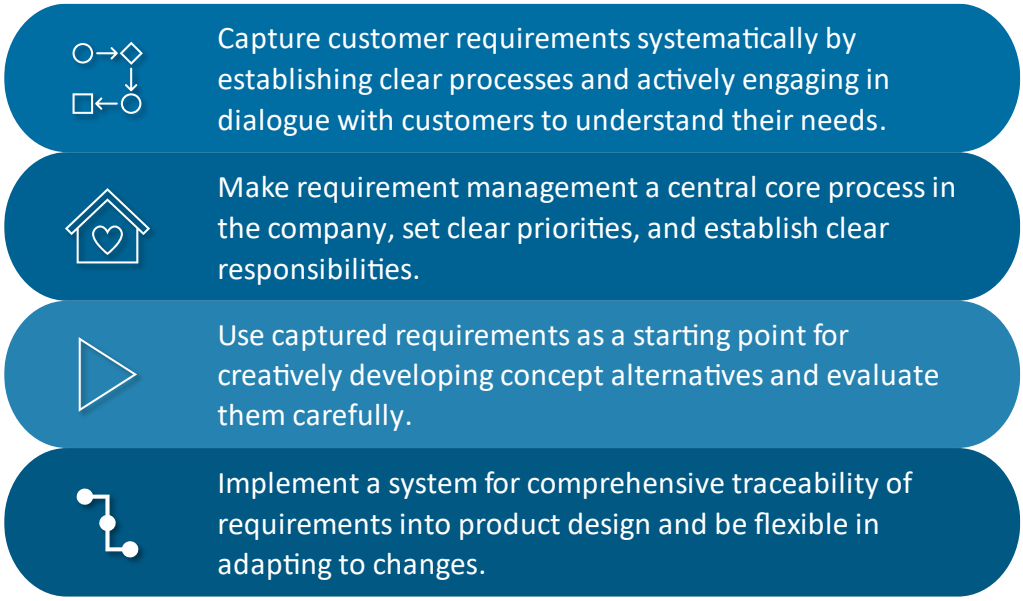
Requirement management

Effective requirements management is always accompanied by change management. The requirements set at the beginning of a development project and, for example,

agreed upon with the customer, do not remain constant throughout the project. Requirements change as the technical conditions are better understood, but they can also be adjusted due to changed framework conditions of the stakeholders or the relevance to the finished product. During a project, requirements can thus be deleted, changed, or entirely new requirements added. With a change management approach, it is possible to make all these changes to the system transparent and to design them in such a way that the complex system remains manageable. Change management allows a product to be developed over several months and years of development time in a way that satisfies all stakeholders.

At various times during product development, requirements must be able to be handed over to a subsystem. This requires defined baselines. These include a set of requirements or other documents, which have reached a level of maturity at a certain point in time that can be passed on to a supplier, for example. The supplier works based on this baseline and carries out its development based on it until a new baseline is published, which in turn contains changes.

The proper handling of requirements is thus an essential component of good system development and should be considered even for the smallest products that initially appear to be of little complexity. Only with such proper requirements management is it possible to ensure traceability throughout system development and later also to master the system's verification and validation. The tool mentioned above can also be used to manage requirements during the development phase. There is a web version of the software as well as the option to export to Excel and thus integrate it into existing working methods in system development.



7.3 INTEGRATE, VERIFY, AND VALIDATE ☑

Once a system has been fully developed and it's time to check whether the development goals have been correctly implemented, the phases of integration, verification, and validation must be carried out.

Integration, in particular, focuses on correctly assembling the development results, whether it's hardware or software. The verification phase involves tests that are conducted to ensure that the system has been developed according to the specified requirements. Validation involves tests to ensure that the developed system meets the needs and expectations of the users.

For a smooth execution of the integration, verification, and validation phases, early planning of the activities is essential. Right from the beginning of the development or during it, the focus should be on assembly and testing. To clearly structure the planning across various development projects and enhance quality, maturity management is an effective tool.

Maturity management

Maturity management is a process that involves assessing the level of maturity of an organization or project and identifying areas and tasks to be fulfilled. It is used to synchronize the maturing of respective system components to create a consistent total system.

The maturity of a system can be measured in terms of maturity degrees, which represent the level of maturity of the system at a given point in time. Maturity objects are the individual components of a system that are assessed for maturity, such as software modules or hardware components. Maturity management involves the synchronized planning of maturity for each system element, so that the resulting system is consistent and meets the needs of its users. By using maturity management, organizations and project teams can ensure that their systems are developed in a synchronized manner and meet the needs and quality standards of their users. Software support can help linking the maturity of requirements, verification items and design elements to the overall product architecture. Within AMeLie, an approach was developed, see figure A2.

IVV strategy and plan

Integration, Verification, and Validation (IVV) strategy and plan involves the planning and execution of tests to ensure that the system meets the specified requirements and is free of defects. Establishing the IVV strategy should be initiated during the early stages of development, while the subsequent planning of verification activities is typically undertaken during the system design phases. The commencement of the IVV strategy execution is delineated within the strategy itself. It typically includes several key components.

The first component is the planning phase, which involves the definition of the test strategy. This includes identifying the key issues that need to be covered by V&V (Verification and Validation), determining which prototypes will be used for verification, and specifying when the verification will take place. The prioritization of the objects under test is also important, as it involves determining which objects are most critical and should be tested first. Finally, the definition of tests is critical, as it involves specifying the integration level at which the tests will be performed and the method that is suitable for the tests.

The second component is the specification phase, which involves the determination of test resources. This includes identifying the personnel, equipment, and facilities that will be needed to perform the tests and specifying the prerequisites that need to be fulfilled. The definition of test cases is also critical, as it involves specifying the test cases that are necessary for coverage of requirements. Finally, the definition of measures of effectiveness is important, as it involves specifying the criteria that will be used to evaluate the success of the tests.

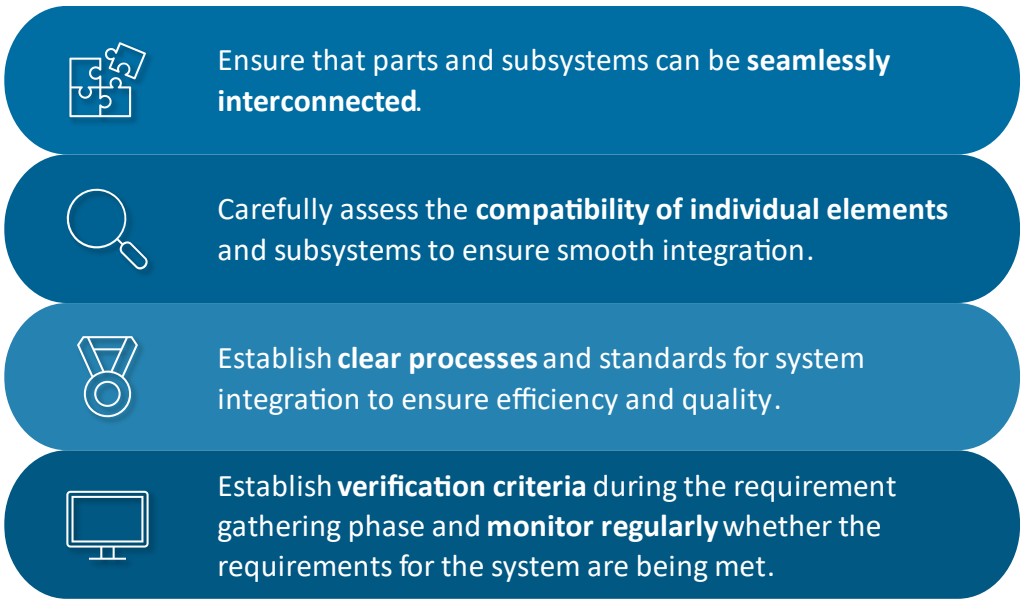
System reviews and releases

System reviews and releases are integral components of the V&V process in software development. The review planning and preparation processes are important for ensuring that all relevant aspects are covered, and evaluation criteria should be used to make go/no-go decisions and achieve project goals. By using effective review and release processes, organizations can ensure that their software systems are of high quality and meet the needs of their users.

The review planning process for the overall project involves planning for all reviews within the system life cycle and ensuring that they are aligned with the project master plan. The review preparation process is also critical, as it involves preparing the content

for the review and aligning the participants. Experts and representatives from different domains should be involved in the review process in order to incorporate various perspectives.

Evaluation criteria are also important in the review and release process. These criteria include relevant factors for the project like for example technical feasibility and profitability. Go/no-go decisions should be made based on these criteria, and measures should be put in place to achieve the project goals.



7.4 KEEP COSTS UNDER CONTROL

Platform architecture

The developed model for modular platform architecture for small and medium sized enterprises addresses several key areas aimed at optimizing financial performance while ensuring flexibility and adaptability. It is segmented into six areas:

- Within the **portfolio and platform strategy**, strategic intentions and market demands are outlined. This includes defining the portfolio, product plan, positioning, and target systems. Market intelligence and competitive benchmarking are also critical aspects in this context.
- The **financial model and business case** focus on developing a reference baseline and a business case framework. This involves modeling the business case, conducting sensitivity analyses, and providing economic justifications.
- The **design phase of modular architecture** emphasizes a comprehensive documentation framework, defining the architecture and system, and outlining modules and sub-systems. Determining the functional structure and development and derivation logic play pivotal roles here.
- The **operating model** encompasses designing the process landscape, organizational structures, governance mechanisms, including KPIs. Managing variants and complexity are further significant aspects within this realm.
- **The integration of Product Lifecycle Management** and the product data model involves managing the product lifecycle, defining the product data structure, and implementing suitable IT tool landscapes and infrastructure.
- During the **introduction and transition of the model**, the focus lies on planning and managing the transition, including change initiatives, communications, training, and seamless transfer to ensure sustainability.

Modularization

Designing a modular product architecture aims to increase standardization levels and facilitate easy interchangeability of modules while reducing development timelines through defined architectural principles and clear guidelines. Modularization offers numerous advantages directly impacting company success, including increased revenue, cost savings, and risk mitigation. Reusing modules across different products significantly reduces unique parts, enabling adaptation to individual customer needs through easily interchangeable modules.

Realizing the benefits of modularization requires a structured approach. This involves creating a detailed project plan and developing a modularization process tailored to the company's needs and structure. Defining roles, establishing governance, effective communication, and introducing the process through specific application examples are pivotal components.

To quantify the monetary savings, conducting a financial analysis across all affected areas within the company is essential. Beyond financial savings, highlighting additional benefits such as streamlining production processes is crucial.

Certain aspects need consideration during the implementation of modularization to ensure sustainable success:

1. The process should be adaptable across various product families to maximize its impact.
2. Clear definition of project scope and goals is essential for alignment and coordination.
3. Establishing roles and responsibilities is crucial for smooth process operation.
4. Initial team training in the early project phases deepens understanding and sets the foundation for successful implementation.
5. Incorporating all relevant requirements ensures that modularization delivers the desired outcomes.
6. Effective communication within the team, with management, and customers is vital for understanding, support, and overcoming obstacles.

Lastly, developing a plan for extending the process across the entire organization is paramount. This facilitates leveraging further synergies, using defined modules across various applications, and centrally managing their specifications.

Value stream analysis

The Value Stream Analysis serves as a data-driven methodology, laying the foundation for process and organizational enhancements. It acts as a methodology for optimizing organizations and processes within an R&D domain. It assesses the allocation of efforts into individual value streams, offering a transparent depiction of the current operational model. This analysis facilitates systematically derived activities to enhance effectiveness and efficiency, even within sizable organizations, grounded in data and systematic insights. The steps involved in its execution include:

- **Defining value streams**
  Identifying and defining robust value streams based on the organizational context, detailing them at varying levels of granularity as per project requirements.
- **Capturing target data**
  Gathering qualitative and quantitative data in standardized sessions, capturing roles involved in value streams and the necessary efforts involved.
- **Interpreting results**
  Processing data into dashboards, analyzing and interpreting them. Observations are discussed and validated by the organizations management team, leading to actionable insights and formulated optimization measures to act on in a next step.

The benefits derived from this method include a transparent overview of effort distribution across value creation, data-driven identification of optimization potential across different organizational levels, and a quantitative baseline for evaluating optimization measures.

Maintain clear and realistic cost targets for development and define a strategy to manage these costs.

Regularly **analyze each project's financial status** to ensure cost objectives are met.

Routinely **evaluate projects** for their contribution to the company.

Leverage platforms to advance product development.

8 Process Efficiency

8.1 TAILOR YOUR PROCESSES

Understanding the essence of a process is highly relevant. In addition to the process analysis using the SIPOC (Supplier, Input, Process, Output, Customer) method, process optimization was further enhanced through the application of the Synchroplan approach.

By implementing established processes, companies can scale their workflows while integrating quality standards. It's essential that processes follow a defined pattern and are comparable in their execution. The focus of each process step is on achieving one or more work outcomes, with various roles from different departments of the company involved. Synchronizing the process workflows and outcomes is crucial to handle multiple development projects simultaneously. Employees are flexibly deployed across different projects to develop systems. Precise synchronization of processes allows for accelerated development, minimizes bottlenecks in employee allocation, and reduces delays in system development.

Definition of a process

The definition of a process, as described in the standards DIN EN ISO 8402 and EN ISO 9000:2015, implies that a process is an ordered sequence of activities and resources that serves to transform inputs into outputs. This definition emphasizes the interactions and interdependence of the individual elements within a process. Essentially, a process is a structured approach in which different steps and resources are coordinated to achieve a specific objective.

Process analysis

The SIPOC (Supplier, Input, Process, Output, Customer) method is a process analysis method that is used in various fields, including Systems Engineering. The method is used to depict processes and workflows quickly and clearly by dividing the process into five to seven steps. For each step, inputs and outputs as well as suppliers and customers are identified. The method enables the identification and resolution of problems, inconsistencies, and gaps in processes. The results of the SIPOC analysis

are a shared understanding of the process being analyzed, fact-based discussions, and clear, prioritized, and actionable decisions on the next steps.

The SIPOC analysis provides several benefits, including a clear depiction of the process on a single page. The analysis also makes visible the interfaces to predecessor and successor processes, creating accountability for the responsibility model and the essential results. It describes the essential inputs and outputs of the process, providing a clear understanding of the purpose and goals. Additionally, the analysis identifies useful methods and tools for improving the process and provides metrics for measuring process progress and quality.

Process optimization

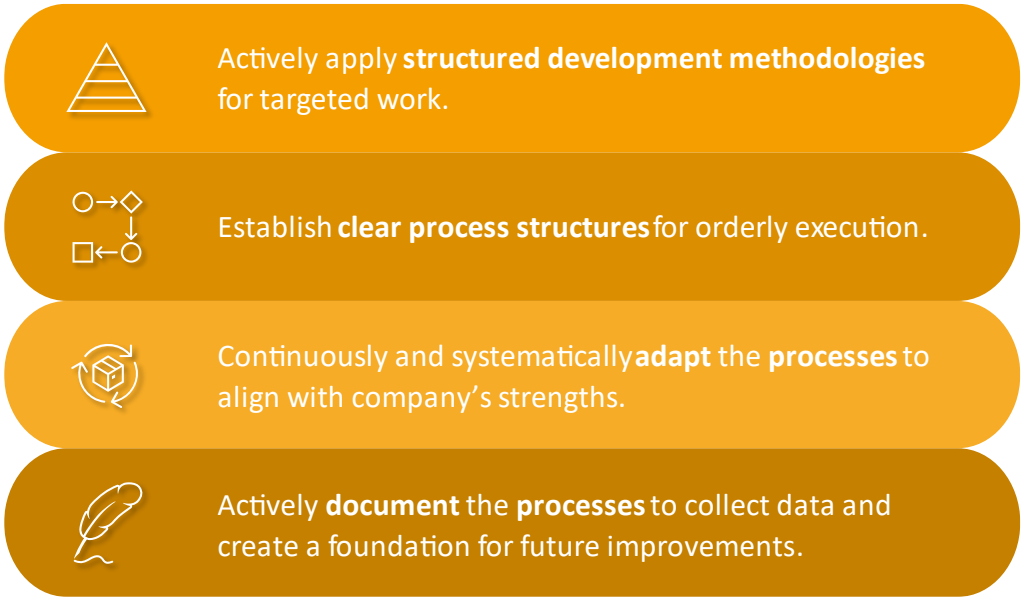
The Synchroplan method is an approach to coordinate activities in various industries. Its primary goal is to align activities of different teams or departments in a project to ensure they work towards a common objective. This is achieved through the creation of a comprehensive plan that outlines the activities, timelines, and interdependencies of each participating team or department in the project.

The plan serves as a coordinating mechanism, ensuring that teams or departments work together in a synchronized manner. The Synchroplan method provides a result-oriented, visually clear representation of processes in the project context. It offers transparency regarding critical outcomes, milestones, deadlines, and dependencies across various process areas or organizational units. This is particularly valuable in complex projects with multiple stakeholders and contributes to keeping all stakeholders focused on the same end goal, making on-time and within-budget project completion more achievable. By incorporating the Synchroplan method into processes, organizations can enhance efficiency and effectiveness and achieve better results.

Implications for small and medium-sized companies

Small and medium-sized enterprises often face the challenge of optimizing their business processes to remain competitive. However, in this context, simple and efficient methods are of importance, as small organizations typically have limited resources in terms of time, budget, and specialized personnel. In this regard, the SIPOC analysis, which aims to identify and improve processes, is tendentially too complex for those enterprises but it is a valuable method for process optimization.

However, it often requires comprehensive data collection and analysis to identify and rectify process weaknesses. Therefore, many enterprises seek simpler and more accessible methods for process optimization that better align with their limited resources. A SIPOC must therefore be carried out on a slimmed-down basis. This can certainly be done because small and medium-sized enterprises usually do not have too complex processes and the existing ones can therefore be analyzed and improved very well. The application of such a customized analysis should be done by third parties who take an unfiltered look at the organization.



Just a decade or two ago, project management tasks could be effectively organized through face-to-face meetings, email communication, and direct task assignments. However, in recent years, the exponentially increased need for documentation of complex systems and growing cost pressures have particularly overwhelmed small and medium-sized enterprises. Additional efforts are required in all areas, from project planning and system development to the completion of development projects.
In the "Advanced Technologies" department of OSYPKA, the development processes in the AMeLie project were redefined. Identified deficits were discussed in the consortium, and the agile solution approach found was recorded in a quality management agreement. This solution allows for a creative development process without sacrificing sufficient documentation and control.

The fact that the initiated restructuring is to be continued and expanded over the next two years underscores its relevance for OSYPKA. As mentioned, such profound changes in the system process are not without effort, but with a pay-off in approximately 3-4 years.

The implementation of Advanced Systems Engineering promises OSYPKA a transformative improvement in work processes across nearly all areas of the company. This increase in efficiency is achieved through the following aspects:

- **Error prevention:** The automation of processes and reduction of manual interventions help to minimize errors and to improving the accuracy and quality of our processes and results.
- **Optimized project processing:** The use of Advanced Systems Engineering makes project workflows more efficient and seamless. This leads to shorter project durations and increased productivity in the execution.
- **More effective controlling:** The central PLM system allows for more accurate monitoring and control of project workflows which leads to improved management and optimization of our processes.

The introduction of Advanced Systems Engineering methods in this area will not only increase our productivity but also improve the quality of our work and the overall competitiveness of our company. This is a significant step toward a more efficient and digitally interconnected future for OSYPKA.

8.2 PLAN AND EXECUTE

The core of the capability comprises classical project management (PM), agile project management, and selected elements of Systems Engineering. In order to address these topics, a lean project management process tailored to SMEs was developed, and a project management workshop was established to provide an introduction to the mentioned subjects.

Tailored project management process

Within the AMeLie research project, it was established that it is crucial for SMEs to work in a structured and coordinated manner. It is relevant to adapt project management methods to the company's specific needs. In addition to the existing PM framework, it is essential to embed these practices within the individuals rather than implementing a massive process within the organization. This approach is driven by the fact that PM processes are often oversized for small and medium-sized enterprises. It is often important to develop a customized package of elements from both classical and agile project management methods, making it manageable and value-adding for SMEs.

Furthermore, it is essential to define a Project Management Vision as the foundation for the PM implementation. This should include long-term objectives. The concrete operationalization of PM is facilitated by a cadence of bi-annual, monthly, and weekly meetings. This approach allows for addressing long-term strategic matters in annual and bi-annual meetings while emphasizing short-term project management in weekly and monthly meetings.

Project management implementation within small companies

The workshop consists of theoretical content intertwined with a case study that participants work on during the on-site event. This ensures a balanced mix of theory and hands-on practice. The goal is for participants to independently integrate the content into their professional lives after completing the workshop, eliminating the need for ongoing external support. A follow-up was conducted to inquire about the integration of the content into participants' professional routines. In addition to project management methods, elements from the AMeLie capabilities have been incorporated, such as requirements management.

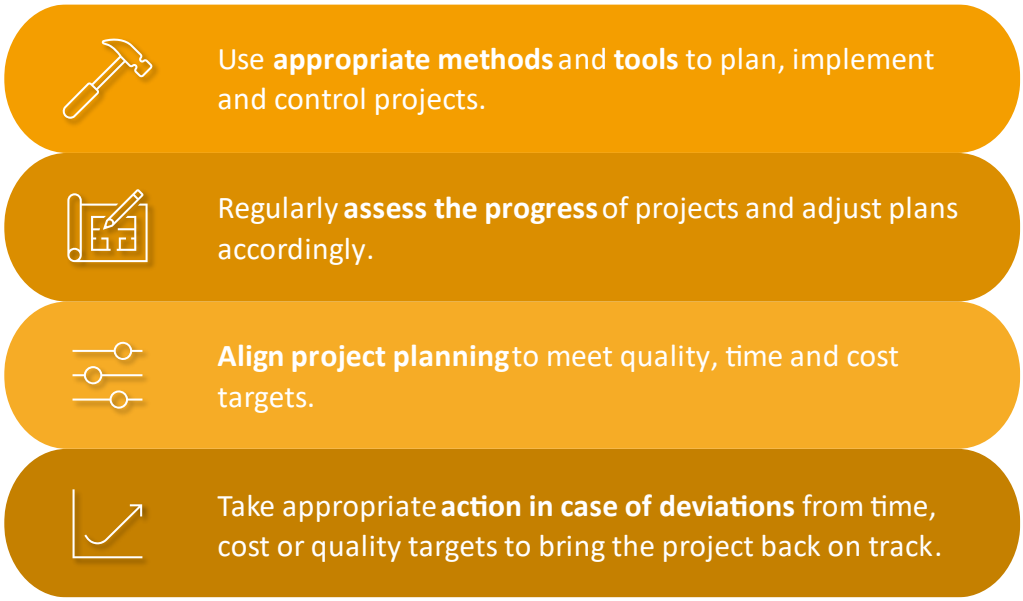
The following seven areas are covered:

1. **Introduction to project management:** This section covers the basics of project management, including an introduction to project management itself and the project management process. It also discusses the significance of agile approaches and Scrum in project management.
2. **Requirements and structure:** This section focuses on capturing requirements and creating a clear project structure. It includes the RFLP method (Requirements, Functional, Logical, Physical), requirement elicitation, and the definition of SMART requirements. Additionally, it addresses system decisions, trade studies to define the project's structure and the creation of structures like the “Product Breakdown Structure”, “Work Breakdown Structure”, and “Organizational Breakdown Structure”.
3. **Risk management and decision-making:** This section deals with risk management in the project, including conducting risk assessment workshops. Tools like the Eisenhower Matrix and the RACI model are introduced to support decision-making in the project.
4. **Knowledge management and competence development:** Effective project execution relies on knowledge management. This section covers the organization, storage, and exchange of knowledge within the project. It also addresses the development of team members' competencies to achieve project goals.
5. **Development process:** This section examines the development process within the context of the V-Model. This model ensures that development occurs in structured phases with gate decisions based on maturity levels. Creating a project master plan that defines the project phases and milestones is a crucial part of this section.
6. **Project phases and plans:** This section delves into various project phases and plans, including controlling and managing the project lifecycle, defining gate criteria, and maturing the project.
7. **Personal productivity management:** In SMEs, individuals often play multiple roles, which requires that the activities in each role be streamlined to ensure they can be completed in the required time and quality. Therefore, enhancing personal productivity is often more relevant in SMEs before delving deeper into project management. For this purpose, a toolkit was developed based on the three main sections “time management”, “priority management”, and “boosting memory”.

Follow-up a couple of months after the workshop

A survey of both partner companies where the workshop was conducted revealed that only few of the project management tools were implemented. It was also noted that the implementation of project management topics would be feasible with continuous support. In contrast, methods for personal productivity were implemented, integrated into daily work, and yielded positive results.

In conclusion, project management is relevant for SMEs, but a one-time training mode is insufficient for integration into daily operations. Consistent support throughout the implementation period is necessary. In contrast, methods for increasing personal productivity are well-received, can be anchored without continuous support, and lead to positive results.



Fraunhofer IBMT

Within our institution, R&D projects vary significantly in scale and complexity, ranging from small, internal endeavors involving just a couple of employees over a few months, to large, multi-year international collaborations with over 20 partners. This diversity necessitates versatile project management skills among our project leaders. The acquisition and application of project management knowledge and experience by these leaders are diverse, with some relying on internal and external training programs, but most learning predominantly through hands-on experience in their daily work.
The project management workshop with 3DSE, developed in the AMeLie project was a learning experience for both seasoned and new project leaders within they learned the first time the basics or refreshed them, gained knowledge about project management tools and methods, and also learned a lot about “dos and don’ts”. A key feature of this workshop was the effective alternation between theoretical lessons and practical, interactive group exercises focused on a case study. This approach facilitated a deeper comprehension of various project management methods and highlighted the crucial phases of project management in the context of actual project implementation.

The case study was particularly beneficial, as it allowed participants to draw parallels with ongoing research projects, discuss specific challenges, and apply the learned concepts to real-world example. This exercise emerged as a vital tool in identifying and understanding aspects of project management that will be instrumental in future research projects.

Looking ahead, our focus will shift to integrating risk management and knowledge management more prominently into our project management practices. These areas are especially crucial in interdisciplinary R&D work. Additionally, tools and methods for personal work and time optimization were identified as valuable assets by the project managers. These tools are seen as essential in enhancing daily work routines, thereby contributing to more efficient and effective project management overall.

This holistic approach of the workshop combining theoretical knowledge with practical application and a focus on key areas like project management, risk management and knowledge management, is essential for the successful implementation and completion of diverse R&D projects in our institution.

8.3 DOCUMENT CONTINUOUSLY

Building on this capability, it is essential to adopt a structured approach when documenting processes, procedures, technical manuals, user guides, and training materials. Furthermore, it is imperative to emphasize the creation of documentation and prioritize its continuous improvement and accessibility.

Documentation concept development

One core element is the creation of a documentation concept. This concept serves as a roadmap for documentation efforts and defines why documents are created, what goals they are intended to achieve, and who will use the document. In this context, it is relevant to keep the following three questions in mind:

Why are documents created? Clearly define the purpose of documentations. Is it for instance for compliance, knowledge sharing, or process optimization?

What goals should be achieved? Set specific objectives for documentation efforts. These objectives should be measurable and aligned with the overall organization strategy.

Who will be using the documentation? Identify the target audience for the documentation. Understanding the audience's needs is crucial for creating user-friendly and effective documents.

Subsequently, it is crucial to define what needs to be documented. The scope of documentation can vary, but common elements to consider include standard operating procedures, technical manuals, user guides, process documentations and training materials.

Preconditions

To ensure the effectiveness and sustainability of documentation, several key considerations must be addressed. Firstly, clearly defined access and editing rights are crucial to control who can edit, review, and approve documents, thereby preventing unauthorized changes and maintaining document integrity. Additionally, establishing a strong traceability between documents and the products, processes, or systems they pertain to is vital for quality control and accountability, as it enables easy identification of document relevance and context. Furthermore, for enhanced user-friendliness and

accessibility, it is essential to use clear and easily understood language that avoids unnecessary jargon and technical terms that might confuse or alienate users. Lastly, fostering a culture of continuous documentation within the organization is paramount. Encouraging employees to actively contribute to the documentation process ensures that information remains up-to-date and relevant, while also promoting a sense of ownership and responsibility for maintaining accurate records.

How to document?

Consistency in document structure and format is essential for clarity and ease of use. This entails establishing a standardized structure and format that remains consistent across all types of documentation. By adhering to this uniform approach, comprehension is enhanced, and navigation is simplified, making it easier for users to find the information they seek. Equally crucial is the choice of medium for documentation. It's important to consider the most suitable options, whether it be printed documents, online portals, PDFs, or a combination of these, while tailoring these choices to align with user preferences and accessibility requirements. Additionally, implementing a robust classification and versioning system is of importance. Such a system tracks document revisions and ensures that users consistently access the latest and most up-to-date information. Also by doing this the company ensures compliance with potential regulations.

Continuous improvement

An integral part of for a successful documentation concept is a commitment to continuous process improvement. Therefore, it is useful to establish a structured process for collecting user feedback and adapting documentation to changing requirements. Regular review and update documents to ensure they remain accurate and relevant.

Concept integration in tool requirements

Once the documentation concept is in place, the next step is to integrate it into the tools and technologies.

Preserving the integrity of documentation is important. This involves establishing routine backup procedures to mitigate the risk of data loss and developing a robust data restoration plan for unforeseen contingencies to ensure ongoing security and accessibility.

Implementing regular backups is essential to prevent data loss and maintain the security and accessibility of documentations. Additionally, monitoring and tracking the usage of documentation is of importance.

Anticipating future needs and scalability is a significant consideration. It's important for the organization to verify that the chosen tools have the capacity for adaptability and scalability, accommodating evolving requirements and growing documentation demands.

Establishing clear guidelines for document lifecycle management is necessary. This covers facets from the inception and approval of documents to their archiving and eventual disposal. A well-defined process enforces accountability throughout the document's lifecycle.

In conclusion, the "Document Continuously" capability plays a central role in effective knowledge management and quality control within organizations. Diligent adherence to a structured approach, the clear definition of objectives, careful consideration of fundamental elements, and the seamless integration of the concept into suitable tools and processes equip organizations to realize required documentation standards.

The situation at OSYPKA reflects the working conditions of many small and medium-sized enterprises. The limitations of manual project management became particularly apparent in document management, such as the management of specifications and requirements documents. These documents are highly relevant for project processing and are continuously adjusted and updated over the course of a long-term project due to customer change requests, project results, or regulatory changes. The growing size of project teams, the diverse ways of transmitting information, the large number of applicable documents requiring updates, and the use of multiple storage locations make the correct management of such documents challenging.
The implementation of a Product Lifecycle Management software can be seen as the backbone of the improvement. Although the introduction of the software has only just begun at the end of the AMeLie project, initial improvements were already noticeable. The process started with the implementation of a project management system that enables joint project planning. This also includes time and resource planning and allocation, making project management processes more transparent and predictable. In the future, the entire document management is also to be controlled via the software, which will improve the flow of information itself, simplify the management of documents, allow cross-linking, and enable easy task allocation. The structured implementation of such a software comes with a few benefits, which will pay off in the long term:

- **Elimination of manual data transfer:** The seamless integration of Advanced Systems Engineering into our existing system allows us to dispense with manual data entries and transfers. This simplification not only saves time but also reduces the risk of human error.
- **Improved information flow:** The introduction of Advanced Systems Engineering optimizes the information flow within the company. This leads to relevant data and information is available more quickly, which accelerates decisions and increases responsiveness.

The implementation of Advanced Systems Engineering methods in this area will not only increase our productivity but also improve the quality of our work and the overall competitiveness of our company. This is a significant step towards a more efficient and digitally interconnected future for OSYPKA.

8.4 UTILIZE TECHNOLOGY

In today's fast-paced world, technologies and tools are constantly evolving. This evolution offers organizations and development departments the opportunity to integrate new capabilities through technological innovations. On one hand, new technologies can help to enhance products, make them more cost-effective, or improve their quality. On the other hand, they facilitate more efficient ways of working within an organization. However, implementing technology isn't automatic. Regardless whether a new technology is identified to develop a product or improve the organization, effective change management is required.

Technology selection

When selecting a technology for a product, there's significant overlap with the company's innovation capability as well as the correct specification of requirements and product architecture. Only through careful consideration and analysis the right technology for a product can be chosen. This chapter aims to untangle the complex dynamics resulting from the interaction between technological change, organizational integration, and effective change management. It introduces a framework that supports companies in making informed decisions about implementing new technologies on both product-related and organizational levels. Through thorough analysis and strategic planning, companies can maximize their innovation capability and continuously improve both their products and their internal processes.

In the research project AMeLie, it was found that SMEs have little trouble developing and testing new technologies. Even if the documentation of the application of a new technology in the product is a shortcoming, the process is largely present and understood within the SME itself.

However, the situation changes when it comes to the introduction of new IT technologies. Many SMEs still rely exclusively on tools such as Microsoft products for information processing. Also, options like SaaS or XaaS in general are hardly used by these companies. Introducing new technology can, in most cases, result in the company experiencing a significant productivity boost among its employees. Frequently used tools include those for:

1. Project Management
2. Knowledge Management
3. Product Life Cycle Management

4. System Architectures
5. Enterprise Resource Management
6. Customer Relationship Management

It is evident that any possible IT infrastructure to be introduced should be considered. The productivity increase can occur not only in development but also, and maybe even more, in administrative tasks that affect every work of each employee.

Tool selection for project management

One of the most significant levers for tools identified in the project was the introduction of a project management tool. There are currently several tools available for introduction. In choosing a tool, the selection should not be made blindly, but a structured approach should be used. Common mistakes can thus be avoided. Because even SMEs already have processes and procedures that may not be compatible with a tool. For this reason, the requirements for a tool to be introduced, whether for project management or otherwise, must be carefully recorded.

Regardless of the type of new software, it requires integration into a company-wide information model as a foundation. This ensures that no double data maintenance can arise. Building such an information model requires a workshop approach involving all disciplines and capturing all business objects across the entire company. The smaller the SME, the easier it is to model this information model with all its different levels. The approach should be moderated by external persons to close potential gaps and thus obtain a completeness of all objects.

The tool selection is based on use cases that need to be recorded in the individual departments. These use cases can be bundled and prioritized based on various criteria. Tool test runs can then be carried out, where suitable programs for the company can be found. Depending on the IT strategy, it makes sense to either introduce an on-premise solution or use a cloud version.

Integrating a tool for project management

When introducing new tools, care must be taken to design them as user-friendly as possible to achieve broad acceptance within the workforce. A tool that nobody wants to use is a useless tool. Even if tools are already designed by designers to be used by

a broad user base, integration into existing processes must occur. The tool should follow the processes, not the other way around.

For a tool to be used effectively within a company, it needs to be integrated into the respective departments. It's important to note that no tool can cover all the necessary functions a company needs. Hence, integrating different tools for different task areas is very feasible, and integrating tools for collaboration in all relevant departments is necessary. Two approaches are needed to perform this integration successfully.

Tools must be accepted and used by employees. With the help of multipliers, it can be ensured that tools are used and valued by the entire workforce. Multipliers act both as advocates for the newly introduced technology in the company and as support for questions among colleagues. These multipliers are usually also power users and can familiarize themselves with a tool very quickly and help other colleagues.

On the other hand, management must also support the introduction of new IT tools and not reject them. If management or parts of it speak negatively about the introduction of a tool, this can lead to unrest or confusion in the workforce as to whether to use the new tool. Introducing new and company-wide IT is thus always a management issue and a management decision.

Fraunhofer IBMT

In the AMeLie project, Fraunhofer IBMT, as a research institution, played a crucial role in providing technological support to small and medium sized enterprise partners. The project involved developing electrodes for two distinct applications in the biomedical and biotechnological fields. The process of selecting the appropriate production technology was a meticulous one, requiring careful consideration of various user requirements and the constraints posed by the intended applications.
The technology selection process began with a detailed definition of user requirements. This phase focused on three primary aspects: design, materials, and the manufacturing processes available at Fraunhofer IBMT. To facilitate this process, various Systems Engineering methods and tools were employed. One such tool was the use of a simple sentence pattern for requirement formulation, featuring clearly defined building blocks. This structured approach aided in identifying and deciding on the most suitable manufacturing approach for the electrodes.

An important factor in the technology selection phase was the consideration of potential technical risks associated with the fabrication process. By identifying these risks early on, it was possible to mitigate them effectively during the development and manufacturing stages.

The actual production of the electrodes was accomplished through an iterative development process. This process was characterized by constant communication between the partners (as users) and Fraunhofer IBMT (as the technology enabler). During this phase, adjustments to the process parameters and sequences were made as needed to align with the evolving requirements and challenges.

Looking forward, Fraunhofer IBMT plans to continue leveraging this structured approach, employing Systems Engineering methods and tools in future projects. This methodology has proven effective in achieving development goals more efficiently, and its continued application is expected to yield similarly positive results in upcoming ventures. This structured approach ensures that user requirements are met accurately, risks are managed effectively, and the overall development process remains adaptive and responsive to the needs of the involved stakeholders.

9 Additional outcomes of the research project

During the research project, in addition to the solutions already mentioned, other innovative approaches emerged that contributed to the improvement of products from cellasys, OSYPKA, and Sensomedical. These solutions include:

- **Software solution from Odego**
  Odego Cquenz® enables initial system modeling without the need for knowledge in Model-Based Systems Engineering languages like SysML. With a simple web interface and drag-and-drop functions, users can visualize their architecture which can be based on the components of the RFLP approach (Requirement, Function, Logic, Physic). In addition, other domains such as risks, opportunities, costs, or schedules can be integrated and later, verification items are attached to artifacts, leading to an early increase of system knowledge and a reduction in development time in the early phase.

- **CAD/CAM interface by Notion Systems**
  This interface enables the direct printing of a PCB design from a CAD tool without the need for additional software. The defined interface speeds up the printing process. The print parameters are created based on the CAD file and transferred directly to the printer. This reduces the time from development to printing to almost zero and facilitates rapid prototyping, as design changes can be implemented almost immediately.

- **Cross-Functional method development**
  Additionally, a method called Product Development Sprint was developed, to be able to develop a prototype in a few days from a blank idea, while simultaneously considering documentation. This method combines elements from various capabilities and fields from requirements to documentation. This methodology leads to the successful development of a prototype within maximum a week of focused work instead of months of cluttered in-between work sessions.

- **Systems Engineering awareness training**
  To establish an initial understanding of the concept of Systems Engineering, a simulation was developed based on the diverse competencies outlined in the previously described reference model. This simulation incorporates a variety of roles and tasks typical for Systems Engineering and focuses on the development of a prototype. The target audience for this simulation includes both emerging developers and experts from adjacent disciplines and sectors, such as marketing or production. By participating in this simulation, which can be completed in just a few hours, not only is awareness of the importance of

Systems Engineering within one's own organization heightened, but it also enables the identification of critical areas where urgent action is needed.

The application of these methods led to the improvement of the products and also to technological insights. The technologies are treated as prototypes by the partners[5] and are intended to be further developed into finished products afterwards. Implementation of Advanced Systems Engineering is not completed yet, therefore more time is needed to enhance the capabilities in sector of small and medium sized companies in the upcoming years.

[5] Joachim Wiest, Systems engineering of microphysiometry, Organs-on-a-Chip, Volume 4, 2022, ISSN 2666-1020, https://doi.org/10.1016/j.ooc.2022.100016.

10 Appendix

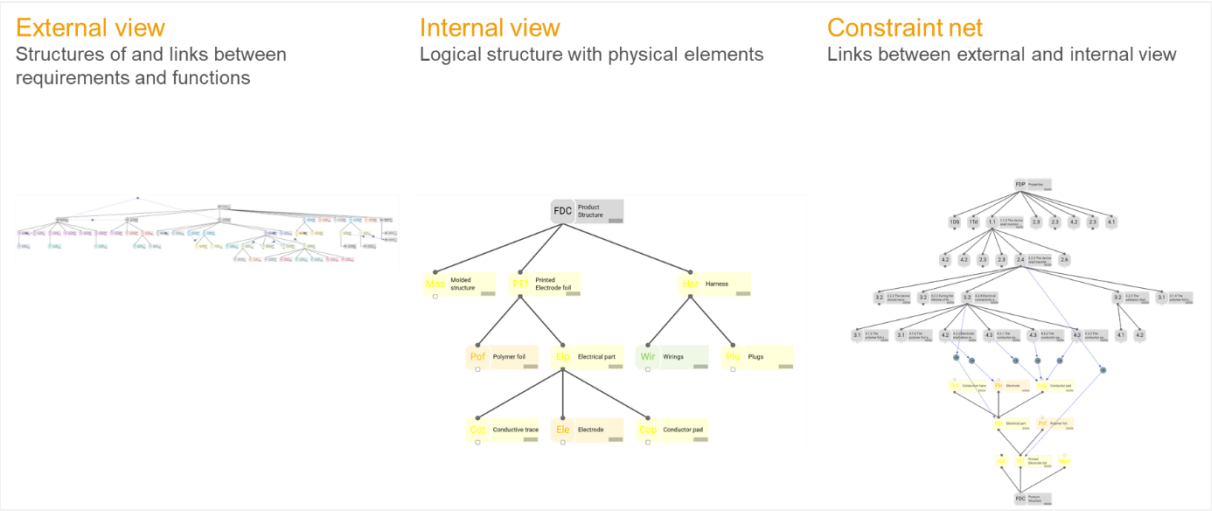
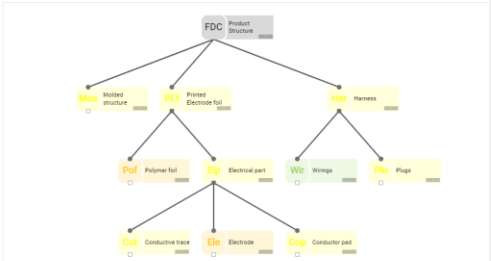


Figure A1: Software support solution

Product Structure

Choose a component:
Printed Electrode foil



Component	CompLevel	CompStatus	Requirement	Verification method	Status	Verification level	Acceptance criteria	User requiremer
Printed Electrode foil	1	50,57%	2.2.6 All components shall resist strain to a specific force	tension tests	1	Phase 3b	20N	
			2.1.7 The edges of components in touch with the patient shall not damage the human body	Haptic analysis	3	Phase 3b	min. radius of 0,5 mm	
			2.3.3 The device should record electrical signals	Functional test	2	Phase 3b	Validity check	
			2.2.4 The device shall transfer electrical signals	Functional test	1	Phase 1/3b	Validity check	
			2.1.9 The overall device shall be compliant to DIN EN ISO 10993-5 Biologische Beurteilung von Medizinprodukten -	Verifications of norm compiliance	1	Phase 3a/3b	DIN EN ISO 10993-5	
			2.2.1 The biocompatibility of the device shall be approved to not harm the patient for up to 24h	Corrosive tests	1	Phase 3b	3 Days in saline solution	
			2.2.3 The printed electrode foil shall adopt to the 3D structure of the molded structure	Design verification	3	Phase 1/3b	n.a.	
Polymer foil	2	44,44%	3.1.5 The polymer foil shall act as a plain strain constrain	Design verification	2	Phase 3b	n.a.	
			3.1.6 The polymer foil shall be able to be used as a strain relief	Design verification	2	Phase 3b	n.a.	
			3.1.3 The polymer foil shall not break the adhesion due to a strain of 2 N	Adhesion tests	1	Phase 1/3b	2N	
			3.1.2 The polymer foil shall be compatible with the ink	Bending tests	1	Phase 1/3b	r= 5 mm, n=10000	
			3.1.1 The printed electrode foil shall have a shore hardiness A between 30 and 70	Hardness test (Shore A)	1	Phase 1/3a	between 30 and 70	
			3.1.4 The polymer foil shall withstand strain up to 2 N to not break the ink	Tension tests	1	Phase 3b	2N	
Electrical part	2	50,00%	3.2.5 The adhesion shall withstand a specific strain of -8%	Adhesion tests	1	Phase 3b	-0,08	
			3.2.4 Electrical connectivity shall not get interrupted during use	tension tests	1	Phase 1/3b	n.a.	
			3.2.3 During the lifetime of the device, the foil shall provide adhesion between conductor path and substrate	Aging tests	1	Phase 3b	3 Days in saline solution	
			3.2.2 The device should record electrical signals	Functional test	3	Phase 3b	Validity check	
			2.3.2 The component electrical resistance shall be below 75 Ohm (each conductor line)	Resistance measurement	3	Phase 1/3b	75 Ohm	
Conductor pad	3	55,56%	4.3.2 The conductor pad shall have a port between conductor pad and wiring	Design verification	2	Phase 1/3b	n.a.	
			4.3.3 The conductor pad shall be able to be used as a strain relief	Functional test	1	Phase 3b	n.a.	
			4.3.1 The conductor pad shall have a port between conductor pad and printed foil to ensure electrical connectivity	Design verification	2	Phase 1/3b	n.a.	
Electrode	3	38,89%	4.2.2 Electrode shall allow measurement of voltage amplitude	Functional test	1	Phase 1/3b	Validity check	
			4.1.2 The leads shall be generated by Jet stream printing	Design verification	2	Phase 1/3b	n.a.	
			4.2.6 The electrode shall allow for measurement of the voltage potential of the nerve	Functional test	1	Phase 3b	Validity check	
			4.2.5 The electrode shall be made out of biocompatible material	Verifications of norm compiliance	1	Phase 3b	DIN EN ISO 10993-5	
			4.2.4 Under a strain of -8%, the electrode shall not form cracks	Bending tests	1	Phase 3b	-0,08	
			4.2.3 The electrode shall indicate a critical distance	Functional test	1	Phase 1/3b	Distance of 2 cm	
Conductive trace	3	50,00%	4.1.1 The conductive trace shall not crack under a strain of -8%	Bending tests	1	Phase 3b	-0,08	
			4.1.2 The leads shall be generated by Jet stream printing	Design verification	2	Phase 1/3b	n.a.	

Figure A2: Requirements tracking and traceability over all domains and structure levels

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