Overcoming Healthcare Innovation Barriers: The Role of Open Innovation Approach

Whitepaper: Why and how an Open Innovation approach can help medtech companies to innovate faster and effectively

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Introduction

Examining the causes of research and development failure in the life sciences and healthcare industry, considering the critical role of innovation in success

Research and Development (R&D) undertakings are of paramount importance for numerous sectors, including MedTech firms, manufacturers of medical devices, pharmaceutical companies, and healthcare startups. However, it is rather disconcerting that approximately 90% of these startups fail within their initial ten years. The scenario is even grimmer within the medical device sector, where 75% of startups based in the US and a staggering 98% of digital health startups face failure. The primary reasons behind these high failure rates are the intricate and expensive processes associated with bringing a novel device to market, with regulatory and FDA-related activities accounting for nearly 80% of the total cost[1].

Owing to the complex and detailed procedures involved in launching a new device on the market, the process is inherently costly. For example, the average cost to bring a 510(k) product from conception to the market exceeds $31 million, of which more than 77 percent, approximately $24 million, is spent on regulatory and FDA-related activities. Likewise, the cost of obtaining an FDA premarket approval (PMA) averages at around $94 million, with FDA-related activities costing nearly $75 million, which constitutes approximately 80 percent of the total expenditure.[2]

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⬆ 80%

of the total **costs** arise from regulatory and FDA-related activities.

1 https://www.embroker.com/blog/startup-statistics/
2 https://www.massdevice.com/exploring-fda-approval-pathways-for-medical-devices/

1. Successful scaling of R&D and innovation culture

Author Steven Johnson, in his book "Where Good Ideas Come From" which traces the evolution of innovation, posits that it fundamentally "comes from creating environments where ... ideas can connect." On the other hand, scholars such as Tina Seelig, a professor at Stanford, perceive innovation as a compound mix of various elements. Her concept of the "Innovation Engine" amalgamates six internal and external factors, namely knowledge, imagination, attitude, resources, habitat, and culture.

In periods of growth, companies invest in R&D on a longer time horizon, including hiring to support revenue that may be 3-5 years away, for MedTech or HealthTech industries this investment horizon might be even longer and correspond to 5-7-10 years. However, in a downturn, companies may need to switch to a focus on profits, not revenues, in the short term. But scaling R&D operations is needed to keep up with the increasing competition.

There are several challenges inherent in scaling an effective R&D team, including finding skilled talent, process change, and delayed platform development. Failing to effectively scale R&D teams can lead to lower innovation, reduced efficiency, higher operating expenses, and a less competitive product.

Implications of failure to scale R&D efforts

A successful long-term R&D growth strategy accounts for required investments in people, processes, and technology to increase innovation velocity and quality throughout the company's lifecycle.

Innovation culture, defined as an organisational ethos that nurtures engagement, encourages risk-taking within a secure environment, promotes learning, and stimulates independent thinking, is crucial for the progress of any organisation, including those in healthcare. In the context of healthcare R&D, fostering a culture of innovation can expedite the process of introducing new treatments to the market. It can stimulate collaboration, cultivate creativity, and advocate the use of digital technologies[3]. For MedTech firms, embedding an innovation-centric culture can propel the development of pioneering devices, software, and services, thereby enhancing patient care and bolstering business performance[4].

An innovation culture is crucial for businesses looking to scale R&D and innovation activities. As Peter Drucker once said, "culture eats strategy for breakfast". No matter how well-designed your strategy is, if your employees don't nurture the appropriate culture, your projects will fail. Culture is about how employees act in critical situations, manage pressure, respond to challenges, and treat partners, customers, and each other. By establishing a culture that fosters innovation, businesses can encourage employees to generate and pursue new ideas, leading to increased competitiveness, improved customer satisfaction, and enhanced employee engagement.

Potential steps to create an innovation culture:

Steps	Description
Establish a vision and strategy	Create a clear vision and strategy that outlines the importance of innovation and the organization's goals. Communicate it throughout the organization.
Encourage creativity	Provide opportunities for employees to think outside the box, such as brainstorming sessions, ideation activities, and hackathons.
Empower employees	Give employees ownership of their work and the freedom to experiment and take risks. Create a culture where employees feel valued and supported.
Provide resources	Provide resources such as training, funding, and access to technology to help employees develop and implement new ideas.
Foster collaboration	Create opportunities for employees to work together and share ideas, such as cross-functional teams and partnerships with external organizations.
Recognize and reward innovation	Recognize and reward innovation to encourage employees to continue to pursue new ideas. This can include bonuses, promotions, and other incentives.

To make it more geared towards medtech and diagnostic organizations, it's important to involve end-customers, clinicians, and patients in the vision and strategy creation process. This can drive customer-centric solutions that solve real-world problems. Even if it means thinking out of regulatory standards in the beginning, it's important to prioritize innovation that can improve patient outcomes and satisfaction.

3 Innovation in the Pharmaceutical Industry: The Process of Drug Discovery and Development | SpringerLink
4 Winning in the future of medtech (deloitte.com)

2. Sources for innovation

There are generally just two sources of innovation for business: internal and external. Internal relies on the self resources of business: it's employees, technologies, processes and other assets, and investments. While external sources for innovation are not limited at all, they can be associated with some risks and challenges, as it might be difficult for some organization to use and manage the external sources effectively and safely. For healthcare and medtech companies such external source of inovation might be patients and clinicians who use their services and devices in their daily life and professional scenarios.

2.1 Internal or Closed Innovation

ISO processes can help organizations identify sources of innovation by providing a framework to follow. The ISO 5600x standard outlines several key tasks that organizations can undertake to identify opportunities for innovation.

To begin, the organization should consider inputs such as an understanding of their context, innovation intent, scope of the initiative, and past experiences with innovation. The organization can then acquire insights and knowledge about needs and expectations, trends and challenges, and identify and define opportunities. Prioritizing these opportunities is also important.

Evaluation; Once opportunities have been identified, the organization can create concepts by generating new ideas, evaluating potential solutions, selecting preferred ideas, and developing value propositions. This can lead to the development of alternative models for value realization.

The concepts can then be validated by starting with an initial version of the concept and addressing critical uncertainties, hypotheses, or assumptions. The organization can use tests, experiments, pilots, and studies to validate the concept and adjust and improve it based on feedback and new knowledge. Evaluating the feasibility of the concept and addressing remaining uncertainties is also important.

The outputs of these activities can include validated concepts or proof of concepts with acceptable levels of uncertainty for further development, relationships with stakeholders, and new knowledge. By following these ISO processes, organizations can identify sources of innovation and develop concepts that have a higher chance of success.

2.2 External or Open Innovation

Open Innovation is an approach that involves collaborating with external parties to generate new ideas and bring new products or services to the market. This approach can help organizations to access external sources of innovation that they may not have been able to access otherwise. In the following paragraphs, we will discuss how Open Innovation can help with external sources of innovation and also how it can help reduce costs and risks associated with innovation.

Background

The concept of Open Innovation was first introduced by Henry Chesbrough, a professor and faculty director at the University of California, Berkeley. He coined the term in his 2003 book 'Open Innovation: The New Imperative for Creating and Profiting from Technology'.

Benefits

Through Open Innovation, organizations can collaborate with external parties such as customers, suppliers, universities, research institutions, and startups. These external parties can bring in new ideas, technologies, and expertise that can be used to develop innovative products or services. Collaborating with external parties can provide new insights and perspectives that can help organizations to develop more innovative products. For example, a company may collaborate with a university to develop a new technology that can be used to improve their products. Or, they may collaborate with a startup to develop a new product that meets a specific customer need. By collaborating with external parties, organizations can access a wider range of expertise and resources, which can help them to develop more innovative products. Open Innovation can also help organizations to reduce the costs and risks associated with innovation. By collaborating with external parties, organizations can share the costs and risks of innovation. For example, a startup may be willing to work with a larger company to develop a new product, in exchange for access to the larger company's resources and expertise. This can help to reduce the financial burden on the organization and increase the chances of success. Additionally, collaborating with external parties can help organizations to reduce the risks associated with innovation. By collaborating with external parties, organizations can share the risks of innovation, which can help to reduce the overall risk associated with the project. Another benefit of Open Innovation is that it can help organizations to access new markets. By collaborating with external parties, organizations can gain access to new markets that they may not have been able to access otherwise. For example, a company may collaborate with a startup to develop a new product that meets the needs of a specific market. This can help the company to enter a new market and gain a competitive advantage.

Challenges

However, there are also challenges associated with Open Innovation. One challenge is that it can be difficult to manage collaborations with external parties. Organizations need to establish clear goals and expectations for the collaboration and ensure that there is effective communication and collaboration throughout the project. Additionally, organizations need to ensure that they are protecting their intellectual property and that they are not sharing confidential information with external parties.

Benefits

+ Broader set of ideas and technologies
+ Risk sharing
+ Increased competitiveness of ideas
+ Cost efficiency
+ Time to market speed

Challenges

> IP Sharing
> Quality Management
> NDAs & Confidentiality
> Partnering
> Integration of innovatios
> Cultural Resistance

In conclusion, Open Innovation can help organizations to access external sources of innovation and collaborate with external parties to develop new products and services. Additionally, it can help to develop more innovative products, reduce costs and risks, and increase their chances of success in the market.

However, organizations need to manage collaborations with external parties effectively and ensure that they are protecting their intellectual property. Overall, Open Innovation can be a powerful tool for organizations looking to innovate and gain a competitive advantage in the market.

For example, medtech companies can openly discuss and align on the roadmap of innovations in the industry and partner for developmen of the new vision of regulations to discuss with governments and regulators worldwide, the same as partnering to develop open industrial standards to reduce cost and time for innovations in digital medical solutions

3. Ideation and prioritization of ideas

Ideation and prioritization of ideas are critical steps in the innovation process. To develop the best ideas and prioritize them effectively, organizations should consider the following best practices:

Best Practices	Description
Establish a clear goal	Establish a clear, SMART goal to focus the ideation process and ensure alignment with objectives.
Encourage diversity	Involve people from different backgrounds, experiences, and perspectives to generate more ideas and ensure creativity.
Use a structured approach	Use a structured approach to ideation, such as brainstorming sessions or idea boards, to ensure all ideas are captured and the process is organized.
Prioritize ideas	Establish criteria for prioritization, such as potential impact, feasibility, and alignment with goals. Use a scoring system to objectively prioritize ideas.
Embrace failure	Embrace failure as an opportunity to learn and improve. Create a culture where employees feel comfortable taking risks and pursuing new ideas.

Any specific methodology for ideation is at the discretion of the management team, however Design Thinking approach works very well for different tasks and industries, especially when there's a need to ideate on topics, where there is a rather vague knowledge at the start.

A proper prioritization might heavily influence the following decisions on which ideas to promote and which of them to decommission.

To prioritize ideas effectively, organizations must define criteria for evaluation and score or rank their ideas accordingly. Criteria can include potential impact, feasibility, alignment with organizational goals, cost, and resources required. There are several approaches to prioritizing ideas, including using a scoring system, matrix, decision matrix, grouping ideas into categories, and considering feedback from stakeholders. Internal and external crash-tests should also be considered when prioritizing ideas.

4. Modelling and prototyping

Modelling and prototyping are essential for testing and validating ideas in the innovation process. Using techniques like 3D printing, CAD, VR, simulation, MVP, Digital Model, Digital Twin and Rapid prototyping can help organizations reduce costs and risks associated with innovation and increase their chances of success in the healthcare market. These techniques can also help organizations communicate and showcase their ideas more effectively to stakeholders. For regulated environments, MVPs can still fulfil regulatory requirements to go to market.

Techniques and Descriptions

Rapid prototyping

Create physical or software models of ideas quickly and cost-effectively to test and make design improvements

MVP

Create a very basic version of a product or service that includes only essential features to test and validate ideas quickly and cost-effectively

Simulation

Model behavior of products and services to test and validate ideas, might

Sandboxing

Test new and innovative ideas in a controlled and safe experimental environment. Sandboxes might be created for hardware, software tasks and for regulatory topics.

3D printing

Rapid prototyping technique to create physical models of ideas quickly and cost-effectively

CAD

Create digital models of ideas to test and make design improvements before physical prototyping

AR/VR/Metaverse

Create virtual prototypes and digital twins to test and validate ideas in a simulated environment

Digital Model

A digital model is described as a digital version of a pre-existing or planned physical object, to correctly define a digital model there is to be no automatic data exchange between the physical model and digital model, might be combined with CAD technique.

Digital Twin

The digital twin is actually a living model of the physical asset or system, which continually adapts to operational changes based on the collected online data and information, and can forecast the future of the corresponding physical counterpart.

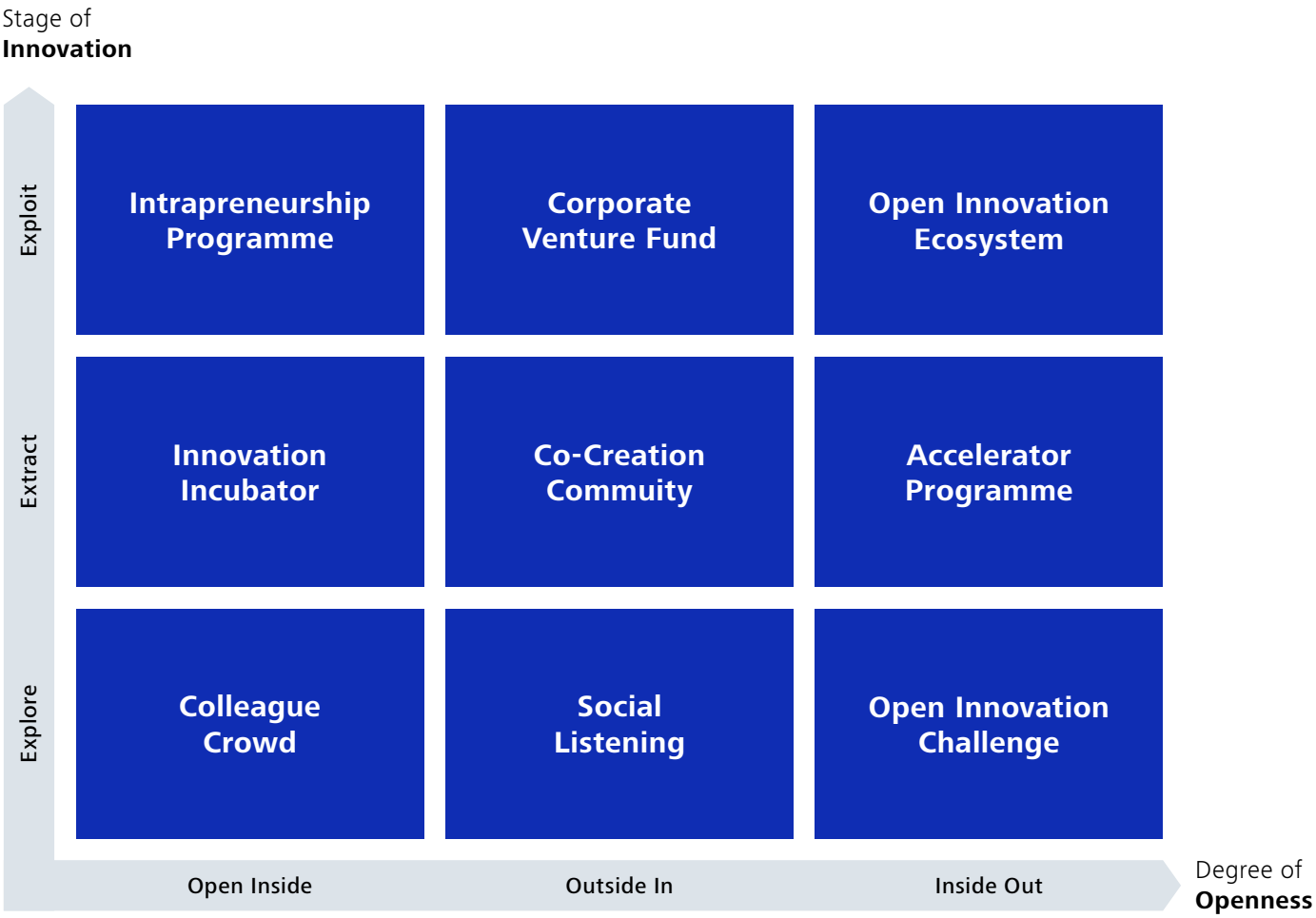
By utilizing these modelling and prototyping techniques, organizations can successfully test and validate their ideas before moving to full-scale production.

5. Scaling R&D through Open Innovation: With applied examples from Medtech manufacturers

We have already touched the approach that can help improve the success rate of R&D projects – Open Innovation. Open Innovation involves collaborating with external partners, such as suppliers, customers, and even competitors, to share knowledge, resources, and expertise.

By doing so, companies can tap into a wider pool of ideas and expertise, reducing the risk of failure and increasing the likelihood of success. This approach can also help companies to reduce the cost and time involved in bringing a new device to market, as external partners can help with regulatory and FDA-related activities. Furthermore, Open Innovation can help companies to stay ahead of the competition by keeping up with the latest trends and technologies in the industry. Overall, Open Innovation can be a valuable tool for companies looking to increase the success rate of their R&D projects.

To practice Open Innovation you need to understand how it works inside and outside of the company, what tools you can use and how to adapt and benefit internally if your organisation is not yet ready for public activities. Some companies like 100% Open have developed their own approaches, which are represented in the Figure below[5]:



Open Innovation Methods Matrix by 100%Open

5 The Open Innovation Methods Matrix – Part 2 | 100%Open (100open.com)

One of the risks of innovation is the disclosure of confidential ideas. Many organizations are hesitant to collaborate with external partners because they fear that their confidential ideas may be stolen or misused. However, the Open Innovation approach can help to mitigate this risk by creating a culture of trust and collaboration.

In Open Innovation, organizations collaborate with external partners to generate new ideas and bring new products or services to the market. These partnerships are based on mutual trust and respect, and information is shared openly to ensure that all parties are aligned on goals and objectives. This approach helps to create a culture of innovation where ideas are shared openly, and the focus is on developing solutions quickly and effectively.

The pace of innovation and time-to-market are more crucial to competitive business success than holding onto internal ideas that have not become products or solutions yet, or even the ones that have been even validated with the market. In today's fast-paced business environment, organizations need to innovate quickly to stay ahead of the competition. Holding onto internal secrets can slow down the innovation process and delay time-to-market, which can be detrimental to business success. The interesting example comes from the pharma market that those substances that were designed in the Open Innovation approach got approved significantly more, than the substances that were developed using traditional closed innovation methods. This is because the Open Innovation approach allows for more collaboration and sharing of knowledge and resources, which can lead to faster and more effective development of products. Additionally, by sharing information and collaborating with external partners, companies can gain a better understanding of market needs and trends, leading to more successful and targeted product launches.

There are various cases from MedTech, HealthTech and Pharmaceutical markets of applying Open Innovation, below three examples:

Pfizer

Pfizer has implemented Open Innovation through its Centers for Therapeutic Innovation (CTI) program. The program involves collaborating with academic institutions and biotech companies to develop new therapies for diseases such as cancer, Alzheimer's, and diabetes. The CTI program has led to the development of several successful drug candidates.[6]

Philips

Philips has implemented Open Innovation through its Innovation Campus program, which involves collaborating with external partners to develop new healthcare technologies. The program includes partnerships with academic institutions, startups, and other companies. Through the program, Philips has developed several successful healthcare products, including imaging equipment and patient monitoring systems.[7]

GE Healthcare

GE Healthcare has embraced Open Innovation through its Healthymagination program, which involves collaborating with external partners to develop new healthcare technologies. The program includes partnerships with academic institutions, startups, and other companies. Through the program, GE Healthcare has developed several successful healthcare products, including imaging equipment and patient monitoring systems.[8]

6 Pfizer: "Pfizer Launches Centers for Therapeutic Innovation (CTI) in San Francisco and New York City" (Press Release), Pfizer, September 27, 2010
7 Philips: "Philips innovation campus partners with academic institutions to drive healthcare innovation" (Press Release), Philips, April 7, 2016.
8 GE Healthcare: "Healthymagination" (website), GE Healthcare, accessed August 9, 2021.

6. Open Innovation at ZEISS

ZEISS employs an Open Innovation approach aimed at fostering the entrepreneurial spirit among its employees and promoting early-stage business development. This approach takes form in initiatives like ZEISS Digital Innovation's participation in the German government sponosored Open Innovation program, Cluster4Future – Secure Medical Microsystem and Cojmmunications (SEMECO).

ZEISS Digital Innovation

ZEISS Digital Innovation provides consultancy and helps customers to scale their R&D and innovation via connecting experts from research institutions and from its ZEISS network to prototype ideas with professional teams experienced in healthcare and diagnostics domain as well as in progressive digital and software technologies. One prominent example of that is the SEMECO Cluster4Future initiative, where ZEISS Digital Innovation Health Solutions plays a key contributing role.

- SEMECO is a research project that aims to accelerate the development and approval of medical devices and implants to promote progress in the field of medical technology.

- The project involves research institutions and companies that work together to increase the innovation pace in medical technology and break the innovation bottleneck in the industry. The project utilizes artificial intelligence to improve the efficiency of the regulatory process for the certification of medical devices and implants. Also hardware and software platforms are developed to offer healthcare solution providers secure and trustworthy components. The project was awarded as one of the winners of the Cluster4Future competition of the Federal Ministry of Education and Research. The ZEISS Digital Innovation Health Solutions team brings its expertise in the collection of requirements and practical implementation of cloud-based connectivity solutions for complex medical devices.

- By combining the knowledge of ZEISS Digital Innovation Health Solutions experts with the complementary expertise of other companies and institutions like Telekom MMS and secunet Security Networks, innovative ideas for the design and improvement of cloud-based solutions are created. After implementation, reusable components are available, which solution providers can utilize to build their innovative healthcare solutions.

- Together, they work on various tasks in the area of IT security, data protection and cloud integration, to lay the foundation for revolutionary, fast, and secure functionalities such as online update capabilities and a true "cloud nativity" of products in the field of medical technology to ultimately improve the health and well-being of people worldwide.

Click **here** to find out more about the SEMECO initiative and our contributions.

Reach out to us to gain further insights and to innovate together healthcare! Discover more about our longstanding firsthand ZEISS experiences and comprehensive and specialized services in medtech and diagnostics software development and quality assurance.

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