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A CULTURE OF COLLABORATION INSPIRES INNOVATION AND LIFE-CHANGING THERAPIES

In this article, Justin Westendorf, Product Development Manager at Phillips-Medisize Corporation, describes the company's collaborative approach with a leader in ocular disease treatments to overcome technical and stakeholder challenges.

Pharmaceutical innovation has been in overdrive for decades, aiming to keep pace with demand for safe and effective novel products and therapies that will improve patient outcomes and wellbeing. With that innovation comes increased complexity – particularly in the ocular drug delivery arena – as well as a host of unique and intricate challenges that span ideation and manufacturing to regulation and risk, and everything in between.

Medical solutions are being miniaturised and connected and can provide real-time data on patient health. Meanwhile, technological advances in manufacturing, increased access to data and the need to adhere to ever-more-stringent regulatory standards have made the road longer and increasingly more dynamic for patients and healthcare providers alike. The journey for innovative technologies is filled with potentially intractable challenges that could derail a project, cost time and resources and, most importantly, leave otherwise great ideas with no path forward.

Just as the products have evolved, so have the product development strategies. A collaborative culture, coupled with focused and facilitated ideation sessions with a specialised team throughout the entire product development and manufacturing process, has proven to be an effective way to work through the challenges of next-generation solutions.

Phillips-Medisize's collaborative culture, systematic approach to ideation, discovery and execution allows it to bring ideas to life, no matter how preliminary, from the moment of inspiration to a fully realised product built at the scale you need.

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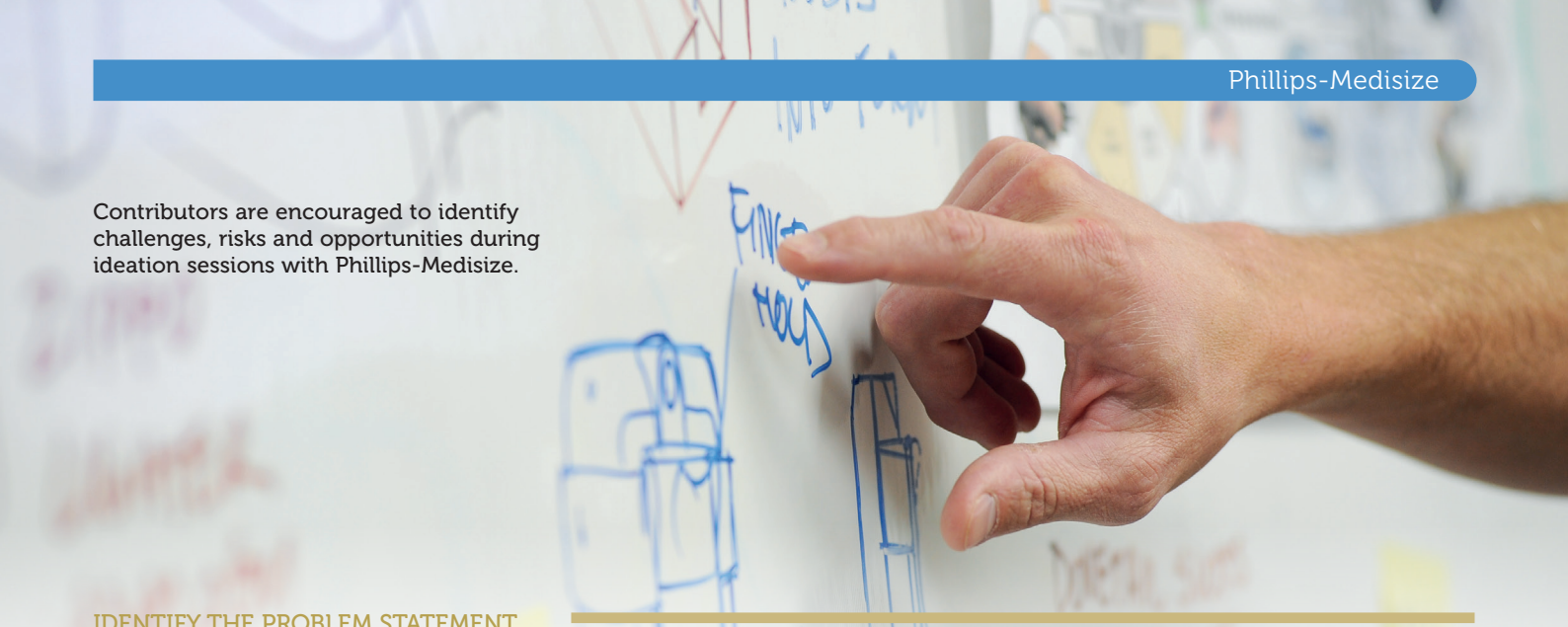

Contributors are encouraged to identify challenges, risks and opportunities during ideation sessions with Phillips-Medisize.

IDENTIFY THE PROBLEM STATEMENT

The ageing population is driving tremendous demand for pharmaceutical innovation. The number of people aged 65 and older is expected to double by 2030, reaching nearly one billion.[1] In this growing population, an important area of focus is wet age-related macular degeneration (AMD) – which is the leading cause of blindness among people aged 60 and older. Currently, nearly 20 million people worldwide suffer from wet AMD and many must undergo monthly eye injections to arrest the growth of abnormal blood vessels in the back of the eye. The hope is that this will preserve their vision – but this process can negatively impact quality of life. The injections into the eye can be uncomfortable and monthly appointments, especially for seniors, can be burdensome and create adherence risks.

This prompted a leader in the field of wet AMD therapies to engage with Phillips-Medisize to develop a better solution; one that is aimed at delivering therapeutic benefit, reducing the frequency of visits and improving quality of life for patients. With a solution in mind, the customer worked with two other service providers before approaching Phillips-Medisize. The customer recognised that they needed to engage with an organisation capable of working collaboratively to solve complex problems, along with having the design and manufacturing capabilities to bring their idea to execution at scale. Therein lies the problem statement – how does Phillips-Medisize manufacture this novel solution?

EXECUTE A SUCCESSFUL AND COLLABORATIVE IDEATION SESSION

The first step in solving the problem statement is the execution of an ideation session. For an ideation session to have a successful outcome, the definition of success needs to be clearly understood by the participants and the facilitator planning the session. "Success" could be described as: "Create a wide range of potential solutions that address the problem statement and select one of the ideas for implementation." More often than not, "success" is not about making a selection, it is about using a collaborative process to:

- Identify potential ideas
- Document the risks and challenges of implementing each idea
- Evaluate ideas according to prioritised metrics and identify the most promising concepts
- Create an investigation or experimentation plan for the selected direction(s).

Execution of these tactics encourages collaboration, knowledge sharing and creative thinking – all beneficial outcomes of an ideation session. The team must also align on where the session should end, and chart the course and tools needed to bring the team members from the problem statement to the definition of success.

TEAMWORK AND POSITIVE FRAMING ENCOURAGES CREATIVITY AND IDEATION

To work through a problem statement, the right team must be assembled for the ideation session to delve into a variety of "what if" questions. Exploring "what if" scenarios in a team setting positively forces idea expansion and the identification and documentation of cross-disciplinary risks for later consideration. These sessions require representation of a broad range of expertise including manufacturing technologies, design and materials, human factors and the customer's pharmaceutical and clinical experts.

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In addition to the right mix of technical knowledge, team members must be willing to adopt a "find a way" mindset that encourages contributions from each representative's area of expertise. It is important that the contributors do not see obstacles but are encouraged to identify challenges, risks and opportunities. Positive framing acknowledges the importance of challenges without stifling creativity so that ideation can flourish.

TEST FOR FEASIBILITY FIRST, THEN VIABILITY

As with many pharmaceutical products pushing the boundaries of innovation, this groundbreaking solution required the assembly of micro, multi-material components at a scale so small that most high-volume commercial manufacturing methods did not have the precision to produce them. The ideation session exposed that structured experiments in manufacturing methods were needed to gain confidence and determine if the solution was feasible. Due to the manufacturing complexity of the solution, rapid prototyping methods would have been a waste of time and resources. These experiments required a significant early investment in advanced manufacturing technology for very specific operations; specially constructed proof-of-principle stations that allowed team

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members to slow down and understand what was going on in an operation and make incremental adjustments to understand changes in the behaviour of the parts they were producing. With an eye towards the longer-term goal of viability, manufacturing methods that could be scaled were chosen and the experiments focused on what would need to be controlled and how to control them.

Once the team determined microassembly was feasible, it began considering if it was viable. Viability looks at the reproducibility and scalability of a given technical solution. In addition to assessing each step of the process to determine whether it could be done in a manufacturing environment, the team had to determine whether it could be done at scale. Manufacturing advanced medical devices requires specialised manufacturing capabilities, including increased precision and controls. There were numerous challenges to evaluate, from dispensing adhesive in nanolitres in a band no more than a few hundred microns wide, to using features so small they could not be measured using available measurement equipment. In determining the viability of this solution, not only did there need to be precise and reproducible manufacturing methods – but equally precise and reproducible measurement and inspection methods.

CONSIDER ALL STAKEHOLDERS

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As with many new treatments for ocular diseases, this solution was part of a larger system with many stakeholders, including the customer, the clinician who opens the product package, the surgeon performing the procedure, regulatory bodies and payers.

Understanding who all the stakeholders are, as well as their motivation to change, is central to designing a holistic product and preventing wasted effort on creating a solution in which a key stakeholder is not interested. This is especially important when bringing a novel product to market. To ensure adoption by all stakeholders, the product or procedure must account for their risks so those stakeholders are comfortable adopting the solution.

Healthcare is nuanced and complex. Improving the patient experience alone may not be enough to convince stakeholders to make a change. Phillips-Medisize believes that, for a product to be successful in the marketplace, it must be useful, usable, desirable and manufacturable – criteria that must be applied to all the stakeholders who touch the product.

Physicians need to be confident in the device; that they can hold the instrument securely in all orientations; that they can properly target the right location of the eye; and that there are mitigations for procedural anomalies. Solving this stakeholder challenge required deploying additional product solutions, each of which needed to be designed and developed as a complementary piece of the holistic solution.

A holistic solution also means extending the stakeholder landscape into the manufacturing supply base. Due to the sensitivity of the eye to contamination, suppliers and sub-suppliers involved in the entire manufacturing process – from materials and components of the product all the way through to the gloves operators wear during manufacturing – needed to be taken into consideration in the design and manufacturing development process. Doing this effectively required a clear translation between quality, manufacturing, operations and supply chain to make sure cleanliness requirements were well understood and executed at every level.

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Identifying who the various stakeholders are and what they need from the solution is as important as identifying and collaboratively solving technical and manufacturing challenges. Phillips-Medisize's collaborative culture and systematic approach to ideation, discovery and execution allows it to work through the ambiguity that often comes with the development of novel pharmaceutical products. It's a tried-and-true approach that its customers trust to "Bring Possibilities to Life".

ABOUT THE COMPANY

Phillips-Medisize, a Molex company, brings decades of innovation to leading healthcare and life science companies to develop groundbreaking solutions that help people live healthier, more productive lives. On average, the company commercialises 50 new products a year for customers, including the first-to-market US FDA-registered drug-delivery device using a connected health system. Molex brings decades of experience in advanced electronics, connectivity and sensor technologies to help transform medical and pharmaceutical solutions.

REFERENCE

1. *"How Ageing Population and Rising Longevity Drive Megatrends." Research, Euromonitor International, Jan 2020.*

ABOUT THE AUTHOR

Justin Westendorf is a Product Development Manager, playing a lead role in Phillips-Medisize's product design and development efforts to solve complex problems serving millions of people worldwide with medical devices and combination products. With over 20 years of experience, he has a strong project management background and leads a multidisciplinary design and engineering team that values the user experience and the role of manufacturing development in bringing products to market in a highly automated and regulated environment. Mr Westendorf has a BSc degree in Engineering from Winona State University (MN, US).

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Design, development and manufacturing on a global scale with lower risk.

Bringing Possibilities to Life

Phillips-Medisize, a Molex company, helps you get from concept to creation quickly while reducing the inherent risks of any new product journey. We act as a singular resource for your company, offering robust end-to-end capabilities, including drug delivery device platforms. For over 60 years, pharma, diagnostic, and med tech companies have trusted us to deliver quality products that help people live healthier lives.

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