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THE IMPORTANCE OF A GREAT DEVELOPMENT EXPERIENCE TO ACHIEVE A GREAT MEDICAL DEVICE

In this article, William Fortina, Business Development Director at Duoject, considers the importance of the medical device development experience in the healthcare context and discusses the factors that make for a superior development process.

INTRODUCTION

In The Healthcare Context, What Would Be Considered A Great Medical Device?

If I had to describe a great medical device in one sentence, I would say: "A great medical device is one that results in proper ease of use and superior treatment adherence."

Of course, nothing is ever so straightforward. To develop a great medical device, there are multiple stakeholders to consider besides the actual patients. For example, you need to consider members within your organisation, and ask yourself questions such as:

- What are their individual and common objectives?
- What available resources do they have?
- What are their challenges, communication style, priorities, etc?

You should also take into account the type of healthcare system in place and reflect on several topics. For instance:

- What are the challenges related to patient care?
- How are treatments prescribed and administered?
- What qualifications are required for providing the treatment?

Other factors to contemplate may include drug handling, manufacturer's limitations, and how patients' family members may be assisting with the treatment.

There is also a whole ecosystem that influences what a great product should, or could, look like: regulations, supply chain constraints, environmental factors, sustainability, the competitive and patent landscape and more.

"What is a great medical device?" is therefore a complex question to answer. Most importantly, it is project specific. Considering this, the development process becomes crucial to ensure a successful end-

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Figure 1: In-depth interaction between the design company and client is crucial to understanding the project needs.

result. Therefore, we propose to discuss the question "What does a great medical device development process look like?"

DISCUSSION

Should you call on an external organisation to help you develop a new medical device, a few key aspects will ensure an outstanding development experience, resulting in a great product and commercial success. The following issues should be considered as you work with medical device development companies.

Your Medical Device Development Partner Starts By Developing A Thorough Understanding Of Your Project

Before providing any project estimates, the development partner must first gain a solid understanding of your needs. You may be eager to receive ballpark timelines and numbers from them for your own product feasibility assessment. Be wary, however, of any company that would provide numbers without fully understanding your requirements. Such figures would most likely not be close to reality, or may be divorced from your needs entirely.

Your chosen partner should sit with you to discuss the project. Their team members should thoroughly question you and your colleagues, and challenge your requirements and assumptions to ensure their accuracy. Only then will the partner truly understand your needs and be able to provide meaningful estimates for the work to be accomplished. Even if you can promptly supply a comprehensive project brief your partner should still come back to you for clarification nonetheless. If you cannot answer certain questions, remember that your best guess will always be better than theirs (Figure 1).

Once the project has started, your device partner's priority should be to investigate and fully identify the user and patient needs. This is accomplished through early human factors studies (HFS), involving a representative population of end-users. If this activity takes place, take it as a promising sign; while the opposite may also be true. If your partner raises aspects related to the user/patient experience that you had not previously considered, you can be extra confident your project is in good hands.

The Company Demonstrates Superior Communication Skills

Your job will be made easier if your partner shares an initial budget with you in a clear and comprehensible manner. At this stage, there are many unknowns for both companies. However, your experience will be more enjoyable if comprehensive budget and timeline estimates are communicated to you effectively. Your trust will continue to grow if your partner advises what limitations apply to their estimates; they should explicitly state the input and assumptions used to build the proposal. As the project moves forward, the validity of various assumptions will become clearer. Accordingly, a good partner will submit refined versions of those budgets for your review as the project evolves and the mandate becomes clearer.

In addition to providing a budget, your partner should also prepare a high-level project roadmap for you, highlighting the various foreseen project phases. If this roadmap is communicated skilfully, everyone you share it with within your organisation will be able to quickly understand the development path. Once again, a great partner will update, refine and share this roadmap with you on several occasions throughout the various development phases of your project.

A great device partner will shed light on market forces at play, which you may not have considered or been aware of. These forces can range from the intellectual property (IP) landscape to potential regulatory hurdles, and from production technologies to competing devices' strengths and shortcomings. This will enable you to better grasp limitations that apply to the project, or even alternate possibilities that exist, which you did not realise were available.

Finally, a good device company communicates regularly through a multitude of channels, as appropriate. For instance, good communication involves scheduling a direct conference call between your legal teams so they can quickly resolve legal

Figure 2: Sketches can be a simple yet effective communication tool.

formalities. Bad communication, however, may be e-mailing you daily and requiring you to forward the messages to your legal team when you should be focusing on the project. Good communication could be a simple acknowledgment your email was read and that an action will be taken, as required, with an indication of when your contact expects to get back to you with the elements you need. Bad communication is leaving you waiting and unsure of what is happening while your partner looks for answers about your various inquiries (Figure 2).

The Medical Device Design Firm Has A Well-Defined And Proven Development Process, Yet Demonstrates Flexibility

Good medical device design firms have a well-defined development process, sometimes showcased on their website. Each phase your partner completes should serve a purpose to ensure the final device they develop functions as intended. Do not hesitate to ask them about their development process, in order to better understand how they will develop your device.

On a side note, their development process should not be limited to designing a great device; it should also integrate design verification and validation activities, manufacturing, assembly and processing considerations. We have witnessed design companies create great designs, which unfortunately were impractical for industrialisation, sterilisation or drug product handling. Some design firms lack this industrial know-how during early development phases, leaving their clients with puzzling fabrication and supply chain challenges later on.

While most medical device design firms have created their proven development "recipes", be mindful that they may lack the agility required to adapt to changing circumstances. As is true for most companies, the bigger they get, the more rigid they become. It is worth noting that working with smaller design firms can offer more flexibility to address your needs and improve overall efficiency for your programme.

Your Selected Partner Can Manage Multiple Peripheral Aspects For You

Medical device design is tightly interconnected with the user and patient experience. Therefore, you will want to work with a company that has experience in designing HFS, and is able to manage them for you. As such, their first-hand findings gathered from HFS will be more readily integrated into your product's development. Your chosen partner should therefore demonstrate a successful track record regarding HFS (Figure 3).

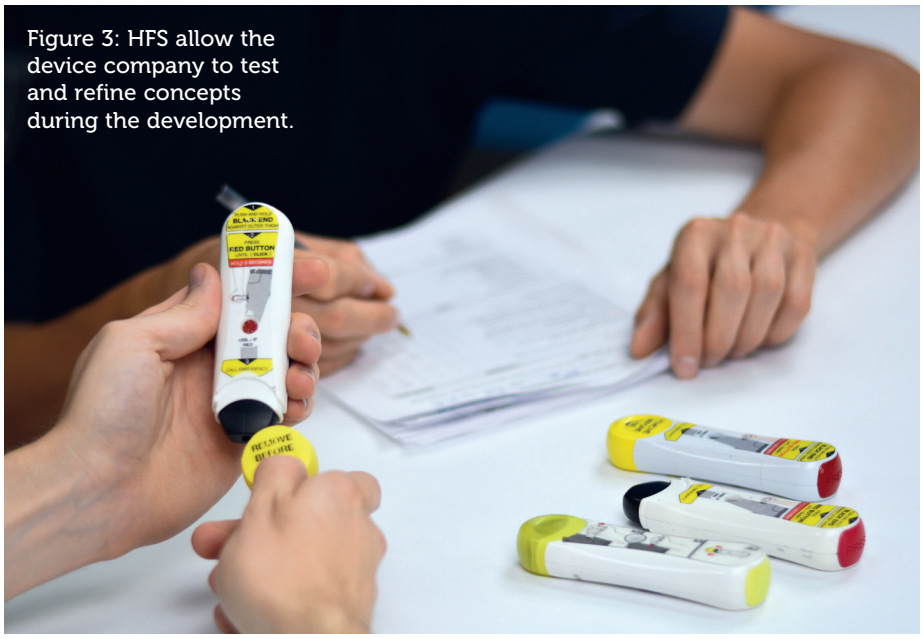

Figure 3: HFS allow the device company to test and refine concepts during the development.

> "Your partner should be able to work with you to identify the optimal regulatory path for your specific project and execute everything related to the device and drug-device combination."

Also, your partner should make your job easier by identifying and qualifying the most suitable Contract Development and Manufacturer Organisations (CDMOs), as required, for your programme (i.e. contract fillers, manufacturers, sterilisers, etc).

Finally, one of the most crucial aspects of your project – a great design firm will support you through regulatory filing. Your partner should be able to work with you to identify the optimal regulatory path for your specific project and execute everything related to the device and drug-device combination. They should generate the required product documentation and be by your side to answer questions before, during and after filing to regulatory

Figure 4: Rapid prototyping is a powerful tool to bring credibility and certainty to the project.

agencies, if required. The ideal partner should also demonstrate a track record of successful product filings, at least in the market you are aiming for, or have a clear strategy for applications in new markets. A design firm lacking this experience may not be the right partner for your medical device development.

A Partner Who Goes The Extra Mile

The last item on your checklist to a great development experience is an indication that your device design partner will go the extra mile for you. This should not be confused with simply working overtime to meet a tight deadline. Going the extra mile means a lot more than that. It is about offering better quality services:

- Have they ever invited you to attend a user testing session, offering insights into how people will use your device?
- Have they ever shared videos of such tests if you were not able to attend?
- Are they trying to help you solve your own internal challenges, for example, getting management buy-in, solving legal delays, IP hurdles, etc?
- Do they share extra deliverables to make the project more tangible within your organisation? It could be something as simple as including your logo on concept renderings, mailing you a mock-up prototype during the early development stages or sharing a product animation (Figure 4).
- Do they ask for your opinion and feedback to build upon and improve the quality of their services?

There are many ways to go the extra mile, and you will notice them when you catch yourself being positively surprised in some way by your partner.

If you want your device development experience to be just as this article described, we suggest seeking out three important traits when selecting your device development partner:

- A true **"Partner Mindset"** in order to understand your needs, make your job easier and demonstrate empathetic flexibility
- **Leadership** skills to guide your understanding of possibilities and limitations, provide guidance and manage all aspects of the project besides pure design
- **Creativity** to develop novel solutions and find innovative ways to increase your product value.

CONCLUSION

You want your products to be better than good, you want them to be great, and to impact patients' lives positively. A great medical device development experience will help you achieve this goal. The Duoject team strives to pursue all efforts to make the complete process a great experience for you. We accomplish this by constantly questioning ourselves and challenging our assumptions, by fostering honest and open communication with our clients and by going the extra mile whenever and however we can. If you have an unmet need for a medical device, let us work together on developing a great product for you and your patients.

ABOUT THE COMPANY

Duoject designs and develops advanced medical devices for the pharmaceutical industry. The company collaborates with its clients to create custom solutions aligned with their unique needs and goals. Duoject's technologies improve upon industry standards in safety, precision and ease of use, to optimise patients' adherence to treatments.

In addition to being a design and engineering partner for medical devices, Duoject provides a 360-degree service to support its client's missions at every step of the development process; including through regulatory affairs, manufacturing and project management support. Every project the company works on creates a strong IP background to ensure clients' commercial success for many years to come.

ABOUT THE AUTHOR

William Fortina is Business Development Director at Duoject Medical Systems, where he leads sales and marketing activities as well as strategic initiatives. He graduated from the University of New South Wales, Sydney, Australia, with a Master of Commerce before taking on sales roles in China, France, the US and Canada. Prior to joining Duoject in 2019, Mr Fortina worked for a leading drug delivery device manufacturer on projects involving ophthalmic, nasal, dermal and injectable delivery devices.