SIX TECHNIQUES FOR RAPID EARLY-STAGE MEDICAL DEVICE DEVELOPMENT

Here, Stuart Curtis, Consultant Mechanical Engineer at Cambridge Design Partnership, runs through six techniques which, in his experience, are invaluable for accelerating the early development stages of drug delivery device design and can therefore be of great use when trying to accelerate a product's time to market.

INTRODUCTION

There has always been pressure in pharmaceutical companies to be first to market, thus gaining a key edge over competitors. In the so-called "Age of Impatience", this is more important than ever before. So, how best to achieve it? One approach, discussed here, is accelerating design development in the early phases of a device programme to get ahead of the normal timeline. Looking back at some recent programmes I've worked on, I've highlighted some of the techniques that have helped accelerate early-stage development.

SIX TECHNIQUES

One – Get the Project Scope Right from the Start

The crux of early development is that it's all about learning. The earlier in the process that learning can happen, the faster development can occur. Critical learning can start as soon as a project is initiated, long before any design work starts. Being able to collect information from a range of stakeholders, whether internal product owners or, best of all, from direct front-end user research, allows for building a solid foundation of evidence to support the rationale behind the development brief. Such a foundation communicates and validates the project vision throughout the team, and often provides new insights that can have a profound impact on the project's overall success.

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Two – Get the Team Right

I work in a team of multidisciplinary engineers who regularly work on projects from sectors outside healthcare, so we have the ability to cross-fertilise expertise and experience (Figure 1). Taking proven design solutions from other sectors, rather than developing them from scratch every time, is a great timesaver. For example, some of the manufacturing volumes that are encountered in the injection device space, mean that high-speed manufacturing techniques from the fast-moving consumer goods (FMCG) world can be a good point of reference.

Three – Use the 80/20 Rule to Your Advantage

Some of the many steps required in a regulated medical device development process can be time consuming, making it tempting to leave them until the number of concepts has been reduced. Considering the Pareto principle, which states that 80% of an effect comes from 20% of the cause, it can make sense to start some of these tasks early, intentionally leaving them unfinished until later phases. This can accelerate learning and reduce the effort required in subsequent phases. For example, just reviewing the potential failure modes in a design

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Figure 1: Cross-pollinating ideas and expertise with team members who are active on projects outside of healthcare can open the way to interesting, and often time-saving, approaches to early-stage design problems.

failure mode and effects analysis (dFEMA) template (20% of the effort) and discussing where team members see major unknowns, allows you to address these in this early phase of development when concepts can still be easily adapted, compared with later phases. Formal dFMEA scoring can occur later (the remaining 80% of the effort).

The same is true of mathematical modelling. When working on a mechanism for an injection device, we might put together the first-pass of a dynamic model with just a subset of interfaces (20% of the effort) whilst multiple concepts are still being developed. This quickly delivers insights into the designs, such as the largest contributing factors to accurate motion and where the largest forces will occur. Not only does this help to refine the design earlier in the development process, but it allows for a more accurate estimate of the effort required to complete to model in later phases (remaining 80%).

Four – Build It Early

Getting designs into a physical form usually finds unexpected issues, as well as helping to present a more compelling case to stakeholders. With the explosion in 3D printing technologies and their ever-decreasing costs, a working model can be made overnight and tested the next day with relatively little investment. Model making is a key part of the learning and development process and should be used freely whilst the design is still in rapid development. The burden of costly and time-consuming design reviews can be kept low (remembering the 80/20 rule once again), as the impact of parts not working is low and it is almost certain something useful will be learnt. A model does not need to be feature complete, or even functional, for it to be worthwhile. Just getting a sense of size, forces and assembly steps is useful to guide the design forwards and can help mitigate some of the effects of computer-aided design (CAD)-eyes, where everything looks simple, perfect and tough on a computer screen. Making models early on can be particularly useful for picking up "unknown unknowns", providing valuable insights with very little time or resources.

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Five – Use Agile Methods

Setting regular short-term reviews helps focus the team and keep the development pace up. An agile approach, borrowing techniques from the world of software development, can be applied in early-stage development. This involves short-term sprints, with regular face-to-face team meetings to encourage an iterative design approach with rapid build and test cycles. This is a very effective method at a stage when design process lead times are conveniently short and it is important to make any big changes that may be required quickly. At the end of each sprint cycle, a review with the stakeholders allows time to reflect on the progress, direction and discussions, and assess if changes to the requirements or vision are needed.

Six – Knowing When to Pivot

As noted prior, the early design phases are all about learning quickly. Typically, a project will start with a wide number of early concepts that could work. As more is learnt about the individual concepts,

some of these are then dropped to get a shortlist of concepts that should work, usually determined by those that best fit the requirements. As the design of these mature, it often becomes apparent some aspects are more challenging than first thought, or that priorities on requirements have changed during the process. Ceasing development of an imperfect concept and pivoting, apparently jumping backwards to a previously discarded concept, may appear counterintuitive on the surface (Figure 2), but whilst it may look like a time-consuming process to bring previous designs up to the same level, it is likely that the majority of the learning gained so far is applicable, so the effort required may be less than it initially seems, and certainly much less than could be wasted trying to get a fundamentally flawed concept to work.

CONCLUSION

By using the techniques described here, in my experience it is possible to get from an initial brief to fully functional working models of miniaturised devices in around three months. Clearly it depends on the levels of innovation inherent in the device, but by introducing some of these practices into your device development programmes, especially at the early stages, you may be able to shorten development timelines and get ready-to-test prototype devices earlier than ever before.

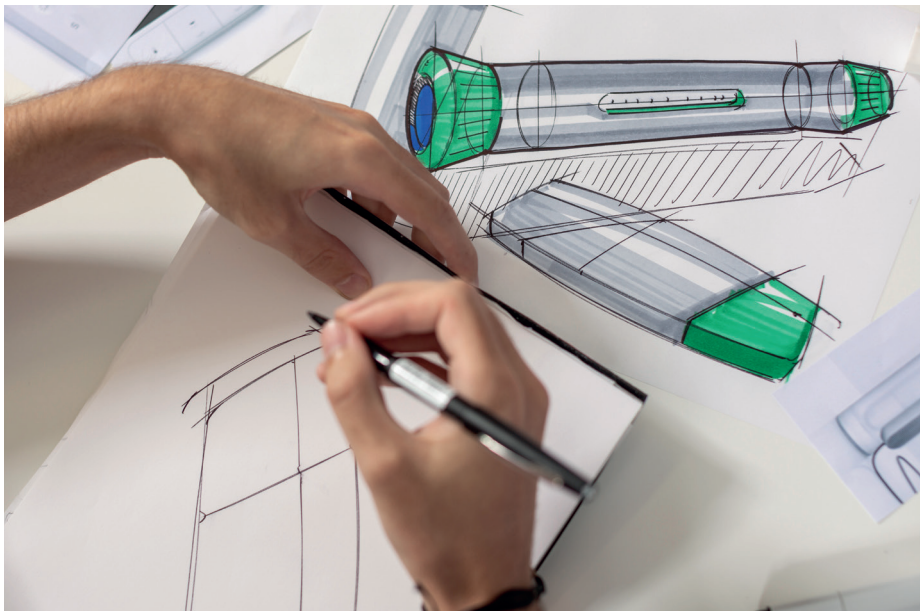

Figure 2: Pivoting from a matured design after a key flaw is uncovered to an older, previously discarded, one, may in fact save significant time and effort in the long term.

ABOUT THE COMPANY

Cambridge Design Partnership is a technology and product design partner focused on helping clients grow their businesses. Some of the world's largest companies trust CDP to develop their most important innovations. Located in both Cambridge (UK) and in Palo Alto (CA, US), CDP specialises in the consumer products, healthcare, energy and industrial equipment markets. Its multidisciplinary staff have the expert knowledge to identify opportunities and tackle the challenges its clients face.

ABOUT THE AUTHOR

Stuart Curtis is a Consultant Mechanical Engineer at Cambridge Design Partnership. He is a chartered mechanical engineer who has worked on product development across consumer, industrial, medical and FMCG markets over the last six years. As well as leading projects, he regularly works on the technical and creative aspects of engineering and has several successful on-the-market products to his name from a wide range of projects, from industrial printer design for manufacture through to hot chocolate dispensing. More recently, he has been concentrating on leading fast-paced projects involving early-stage medical devices.