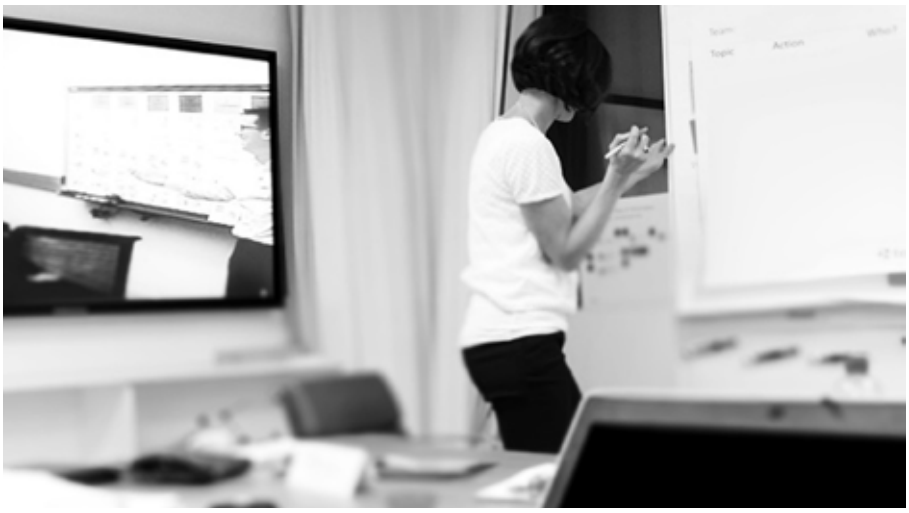
# Five Questions You Should Ask when Developing an Inhalation Device: How to Develop the 'Right' Device

Developing a medical device is no easy task and knowing where to start is the first hurdle. At the start it's not always clear what to do or what direction to take. This is called the "fuzzy front end" for good reason. The opportunities could seem endless, and there could be many different directions that the project could take – and it can be hard to know which is the 'right' one to pursue. Spending time early on working out which is the right path will not only help avoid costly changes later in the programme, when the design is set and you have made significant investment, it can also determine the success of the project. During these early phases, it's important to not only make sense of what you know, but also to discover what you don't – and we recommend taking time to explore and prioritise the opportunities and requirements as a group, with input from all relevant stakeholders, before making a decision on project direction.

Ask the following five questions to better explore the key factors which may have an influence on your programme. The answers will ensure you and your team are making informed decisions as you progress through the early development stages and will set you on the path to a successful device that meets your commercial, user and technical requirements.



**1. Is the *whole* team aligned on the objectives of the programme?**
It is really important to gain consensus and alignment on project goals right from the word 'go'. This prevents surprises and disagreements later on in the programme and means everyone involved is on the same page from the start. That's why kicking off the project with a strategic workshop attended by multiple stakeholders from across the business is so important.

The workshop is firstly a forum for all interested parties to share their own individual views on the project. Some of the essential attendees will likely be located around the globe, but you can't beat meeting face to face if possible. The ultimate aim of the workshop is to get all those busy people in a room together working as a team to agree objectives and develop and agree a shared vision for the project. This vision then becomes an anchor for the programme – a stake in the ground for what you are striving to achieve and something tangible you can keep referring to throughout the projects as scope creep inevitably happens.

During this workshop, participants share what they know already and identify what they don't, both individually and as a group, and agree a plan for filling any gaps in knowledge.

We have found that it isn't always easy to get a group of stakeholders with potentially very different views to a) share what they really mean and b) agree on what they want to achieve. Therefore, we often recommend using tools to aid communication and discussion during this workshop. There are numerous tools available, but some examples we've used are; Lego Serious Play – where participants are encouraged to communicate by creating metaphors in Lego; or Hopes and Fears – where participants are individually asked to write down their hopes (e.g. what do they hope to achieve with the new inhalation device?) and their fears (e.g. what are the barriers they see ahead?). In both these tools, individuals are encouraged to have their say and the facilitated discussion around these will help to generate an understanding of the group's shared views.

**2. Do you want to develop your own inhalation device or license one that's already available / in development?**
You may not be able to answer this question right from the start – the answer is likely to be heavily influenced by timelines, resources, in-house experience and other factors which may not be clear until you've explored the other four questions.

**Licensing an Existing Inhalation Device:**
If you already know your best option is to license a technology, you need to start the process of exploring what is available, either on the market or in development.

As a first step, device technology requirements should be defined and prioritised, and scoring and selection criteria agreed that will be used to select frontrunner device candidates. When defining requirements for an inhalation device, it's just as important to define commercial requirements such as 'time to clinic/market' or 'device to be marketed in regions x, y and z' and user requirements such as 'suitable for use by patients with 'x' condition' or 'suitable for use by paediatrics' as it is to define the key technical performance characteristics such as 'fine particle fraction of <x%' or 'must be digitally enabled'. The final list may be lengthy, and these should be prioritised, but by considering the

needs of multiple stakeholders, you can be sure you haven't missed out any key requirements which could influence the success of the project.

A thorough exploration of the technology landscape is the next step. Searches should include already marketed inhalation devices that may be able to be licensed for a different respiratory condition, as well as devices that are still in development. There are many different types of inhalation device such as metered dose inhalers, dry powder inhalers (capsule-based, multi-dose etc.), soft mist inhalers and a variety of different types of nebuliser. So, if from your earlier requirements definition activities (and most likely driven by the potential drug formulation(s)), it is possible to focus the search on a subset of these, then this will reduce the effort needed for this stage.


We recommend starting with finding device information that is available in the public domain. Often it can be harder to find detailed information about devices still in development, but contacting the suppliers or attending respiratory conferences where new devices are being showcased can often be good ways to find out more information.

Once you have your inhalation device longlist, each device technology should be scored and assessed against the requirements and selection criteria defined by your stakeholder group. This allows a systematic comparison and assessment of the technologies and will help you to filter down to a shortlist. A more structured process of further technical and commercial assessment will follow, but this initial activity will identify the most suitable technologies for your specific application and help assess the impact of any modifications that may be needed.

**Developing a New Inhalation Device:** You might have decided to develop a new inhalation device. Maybe you've done something similar before or have some proprietary technology that you want to use. However, before you start innovating, you need to identify and prioritise your 'design challenges' by exploring technical, commercial and user needs. These needs can be identified using some of the techniques outlined in this article, and by phrasing them in such a way that they become a question (e.g. '*How might we ensure that the user can co-ordinate inhalation with activation of the device?*') they become a 'design challenge' that drives your innovation activities and helps to focus development effort.

Once you start generating ideas, a rapid iterative development cycle can be a good way to create multiple ideas and assess both their technical feasibility and likely user acceptance. Using a 'design sprint' process helps to keep things moving quickly and involves going from 'nothing' to a user-tested prototype in just a few weeks.

Following this process means ideas can be mocked up very quickly and functional elements of concept prototypes can be tested by using foam board form, rapid 3D prototypes, a quick piece of breadboard circuitry, mock app screens or the lashing together of development boards. Doing it this way means you fail fast and early (if you're going to) and the technical merit of ideas can be assessed without investing lots of time and money developing them.

**3. Do you know your target users and understand their needs, behaviours and preferences?**
Applying a user-centred design approach will ensure you are developing a device which meets the needs and desires of the people who will ultimately be using it. Engaging patients, caregivers and HCPs in a programme of design research will provide rich insights. It will help you to understand existing behaviours and the challenges that end users face in managing their health.

Some common research techniques include focus groups and in-depth interviews, as well as more ethnographic approaches such as contextual enquiry where we use cultural probes and visit participants in their home or clinic environments. Online approaches can be a good way to access more participants and include Skype interviews or online threaded communities where multiple patient groups can be asked to assess ideas via an app-based platform.

Once you have your initial ideas or a shortlist of possible device technologies, it is important to consider what you want to test with users and design stimulus material accordingly. There's immense value in putting physical prototypes in the hands of users, but you need to ensure that each of your concepts are presented with equal fidelity so as not to bias the research. This can sometimes be difficult when testing 'licensed' solutions which may be at different levels of technical maturity. It

is often sensible to focus your study on the key attributes you want to test and if prototypes aren't feasible, you can gain great value in showing sketches, PowerPoint animations, videos or mock screens to demonstrate the functions of a device and gather feedback.

**4. Do you understand the business/commercial/regulatory drivers and requirements?**

The commercial drivers and strategy for a device development will be unique to each company. For some it may be all about timelines and being the first to market. For others it may be about differentiation in a crowded market, or delivery of a new chemical entity, so it's important to consider the business drivers and strategy as part of your development process. Identifying your likely competition, understanding what devices they are marketing/developing and how they position themselves in terms of features and unique selling points will help identify what you'll be up against when you get your own device to market (even though in some cases that could be 5–10 years away).

Other commercial drivers to consider include reimbursement strategy and market access, and a thorough understanding of the device classification and regulatory pathway to approval are also critical to success. In the later stages of development, you will need to assemble a device technical file for presentation and scrutiny by the relevant authorities, so getting this right is essential.

Whatever the commercial strategy, it's important that the wider team have at least some top-level knowledge of the key commercial drivers and timelines, and an understanding of how the whole programme fits together in terms of drug development, clinical trials, time to market and key decision points along the way.

**5. Do you have the evidence and confidence you need to move forwards?**

As you progress through the early stages of device development it is important that you gather enough information and evidence to make an informed decision of how to move on to the next stage of the process.

At each key decision point asking your team 'have we explored all the opportunities?', 'have we got enough evidence to make an informed decision?' and 'do we feel confident in the decision we're making on how to progress?' will help to ensure that you stay on track. If the answer is no to any of those, then more work needs to be done before you're ready to move on.

**Conclusion**

Each device development is different – as is each company developing it. However, to ensure that you set off on the right track, it's important to consider each of the five key questions above. Answering these will form the basis of the business case for your device and help to ensure that you are on the path to developing the 'right' device.

**Charlotte Harris**

Charlotte is Head of Front End Innovation at Team – focused on helping clients set off on the right path in the early stages of product development. Her goal is to ensure that all opportunities are uncovered, considered early on and to prevent the wrong product to be developed too late in a costly development programme. Charlotte has over 20 years' experience in the medical device industry and is an experienced project manager and facilitator. Alongside a wealth of experience in contextual/design research, she has many innovation tools under her belt to help navigate through the fuzzy front end of product development.