

Choosing the 'Right' Device to Deliver Your New Therapy: Four Simple Steps

When you develop a new therapy, the device you develop or select to deliver it will be key to the overall success of your product. You may have spent considerable time and investment developing your drug; however, if your device doesn't perform technically, or the patient struggles to use it, then the chances of that drug successfully delivering the therapy to the patient are severely compromised.

So, how do you select the 'right' device to deliver your therapy? Typically, you will have one of two options: either develop your own from scratch, or license an existing or developing one from someone else.

There may be good reasons to embark on your own device development, such as the ability to tailor the device to your specific needs. Despite this, pharmaceutical companies often choose the latter option. Getting a new device approved takes time. In the United States, it can take an average of seven years, in fact. Finding something that is already available, either on or near to market, that can be licensed can be a

much more appealing option, offering a less time-consuming, less risky and often more cost-effective way of procuring a device than a ground-up development.

With so many devices available on the market, however, where do you start? This is where it helps to have an "ADEA" of how to identify promising devices for your therapy, following four initial steps: align, define, explore and assess.

Step One: ALIGN Your Stakeholders

When setting out to license a new technology, it is important that your stakeholders are united behind common goals and a shared vision. Doing this early on will make sure you stay on task and help to avoid any disagreements in the later stages of your project.

An effective way to align your stakeholders is to hold a strategic workshop with key individuals from across your business and other relevant parties. Try to get a breadth of representatives in this meeting to ensure everyone involved in the project has their say, including regulatory, clinical, formulation, devices and commercial.

It's important to set clear outcomes for your workshop, such as agreeing what your goals and objectives will be for your project,

therapy and device, as well as collectively identifying what you want to achieve. This is also a great opportunity to share knowledge between your different stakeholders and identify any gaps that need to be filled.

While these workshops are typically performed in person, the recent pandemic, alongside advances in collaborative software, has enabled successful, efficient and effective methods for engaging multiple stakeholders in disparate locations. It is now easier than ever to get many participants involved who may otherwise have not been able to attend, such as colleagues and contacts from different offices and locations.

Step Two: DEFINE Your Requirements

Once you've reached a consensus among your stakeholders, it's time to bring this group together once again to define your device requirements. The challenge here is making sure you find a balance between the commercial, technical and user requirements for your device, identifying which are essential and which are simply "nice to have".

As the user should be at the centre of any device selection or development, at this

ID	Requirement	Participant Number															Total Votes	Total Score
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15		
1	suitable for patients with limited abilities	1					3	10		3	3	1					6	21
2	Cost of goods less than x amount	2			1	2											3	5
3	device improves patient compliance			2													2	2
4	usability	3	1					3	3	2	2		2				7	16
5	device available in specific regions																0	0
6	device deliver x amount of therapy in y				2								3				2	5
7	on market by certain date		3	1													2	4
8	Device ready for clinical trials by x date						1				1	3					3	5
9	feasible scale up and filling of primary container						2	2	2								3	6
10	good working relationship with supplier																0	0
11	easy maintenance																0	0
12	ergonomics		2			1											2	3

Figure 1

stage it also pays to have established a clear understanding of the needs, behaviours and challenges of your target users. This can further help you to define your key requirements. Are there any particular user behaviours your device will need to address or change? Do your end users have any physical or cognitive challenges to take into consideration?

Putting together a simple spreadsheet with a scoring system for each requirement can be a helpful tool to carry out some prioritisation too. As seen in figure 1, each participant puts a score against each requirement, which is then totalled to provide a red, amber, green rating.

To make sure everyone is aligned on what makes a requirement “essential”, it can also be helpful at this stage to assign a weighting value to indicate the importance of each requirement. Say your device needs to deliver a payload of ‘x’ in a time of ‘y’. You might give this requirement a weighting value of ‘5’ as this is very important to the performance of the device, whereas the final cost of goods for the device might only get a total value of ‘3’ as it is less important.

As can be seen in Figure 2, you can then use the same system to define your scoring criteria and ranking scores for each requirement. For example, a device that can deliver your payload in the correct time without needing modifications might get a ranking score of ‘5’, while one that needs significant adjustment and modification to achieve this gets ‘1’. Using a set scoring system ensures that all the potential technologies are assessed on the same basis.

Step Three: EXPLORE Your Options

Now that you have defined your requirements, it is time to start searching for potential device candidates. As you explore the device technology landscape, keep in mind your prioritised requirements and try to find devices that would potentially meet them. Your search doesn’t need to be limited to devices on the market either – it can also include technologies that are still in development and nearing market.

There are a variety of sources you can use to explore the device technology landscape, including conferences, publications and supplier websites. If you’re unsure where to start, you can also speak to a device development expert to help.

Similarly to the requirements stage, creating a database to list the devices you identify can help ensure you capture the right information for each one. Think about the positives, negatives, key features, key performance attributes and potential risks

Requirements

Criteria	Weighting value
Technical/performance requirements	
Delivers therapy in the right dosage and amount of time	5
Feasible scale up and filling of primary container	1
User requirements	
Device suitable for use by patients with specific set of conditions	5
Minimal cleaning and maintenance needed	3
Commercial/strategic requirements	
Device ready for clinical trials by x date	5
Device meets regulatory requirements in target regions	5

Scoring criteria

Ranking scores		
☆☆☆☆	☆☆☆	☆☆
Meets requirements with no changes needed	Minor changes needed to meet requirement	Major changes needed to meet requirement
Meets requirement with no changes needed	Minor changes needed to meet requirement	Major changes needed to meet requirement
Device suitable for all specified conditions	Device only suitable for certain specified conditions	Device not suitable for any specified conditions
Minimal cleaning and maintenance needed	Some cleaning and maintenance needed	Significant cleaning and maintenance needed
Fits with timelines	Trials would be delayed by <3 months	Trials would be delayed by >3 months
Device meets regulations in all target regions	Device meets regulations in some but not all regions	Device does not meet regulations in any regions

Figure 2

for each device, and write this up into a short summary for an easy comparison. See Figure 3.

Step Four: ASSESS Your Options

Having established a list of candidate devices, it is time to assess them against the requirements and scoring criteria you set out in step two. By multiplying the weighting value you assigned against the ranking scores for each device, you can total up the scores and begin to see how they compare against each other. It can also help to map these results visually, by plotting the scores for any market and user facing criteria (attractiveness) vs. the scores for the technical and commercial criteria (fit) – as shown in Figure 4.

As you score each device, it will likely become apparent that there is no option that meets all your requirements perfectly. Some may score better from a user’s perspective, others from a technical or commercial perspective. It’s important here to consider any trade-offs or modifications you might need to make to improve the

device in areas where it scores weaker, to help inform your final decision.

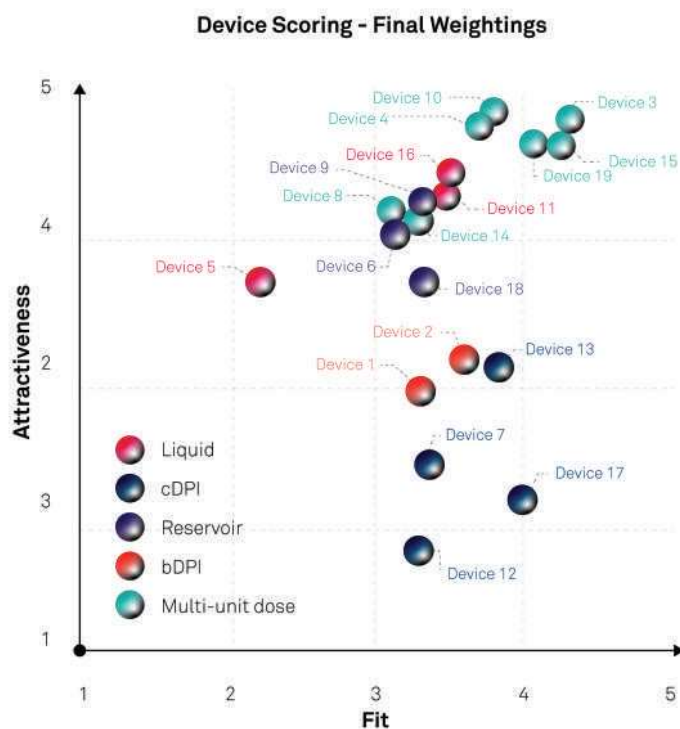
While you may need to commit some time and investment into modifying or developing your chosen device in order to bring it in line with your requirements, this can still be much more cost-effective and convenient than a ground-up development. The closer to your requirements and the more developed the devices in your shortlist are, the less commercial risk you might face. By taking on an effective device that has been tested and verified to deliver therapies, you will have a much easier route towards launching your therapy to your users with ease.

The Next Steps

Following these steps will help ensure your team are united and invested in the device(s) you choose to move forwards with. By exploring your options from a commercial, technical and user perspective, you will be able to filter a potentially large number of options down to a shortlist that best fits your needs.



Figure 3



Of course, the journey doesn't end here, however. Once you have selected a shortlist of devices, you will still need to carry out a detailed programme of technical and commercial assessment to further refine the list.

For example, depending on the development status of the devices under consideration, and if there any design modifications required, a further programme of development and testing will be needed.

Development and Testing

From a technical perspective, the key performance criteria of each device will need testing with your drug formulation to ensure compatibility, including consideration of any changes to the primary pack and any stability testing that may be needed. Modifications to device components and functionality might also be required to improve delivery performance.

Modifications

Likewise, modifications to the device form, packaging, instructional material and overall look and feel could also be beneficial. This can help you ensure the device is designed to meet the needs of your target user group, while also addressing some of the other big drivers we see in our industry at the moment, such as improving adherence or sustainability.

Market Research

Whether any modifications are required or not, you may wish to undertake market

research to assess your users' likely acceptance and/or preference for the devices you have selected. Having established a clear understanding of the needs, behaviours and challenges of your target users prior to defining your key requirements is particularly helpful here; however, this presents another opportunity to assess your device selection against these requirements.

Usability testing

Usability is another key area to consider. Different user groups may have different cognitive or physical challenges as a result of their condition or age, such as dexterity, hearing or eyesight problems, or just learned behaviours from using other devices to manage their condition. An assessment of device usability with your target end users will be beneficial at this stage to highlight any areas of concern.

At first this initial engagement with users may be used, alongside the other technical and commercial assessments, to further refine and filter your shortlist of devices. But as you progress further along the process and start to make modifications or improvements, end users should be consulted at several points in the development to inform your design and ensure their needs continue to be addressed. This can also be extended to assessing the device packaging and any printed or digital information or accompanying app/software, with your target users. Reviewing all the interactions and touchpoints a user may

have with the system can further help to identify any opportunities for improvement and differentiation.

Due Diligence

Separate from the device technology itself, a programme of technical and commercial due diligence will also need to be initiated to help you determine the suitability of the supplier. For example, the capabilities of the device supplier should be assessed to determine a good fit with you, the investor. This might involve assessing their development and manufacturing capabilities and facilities, the abilities of their staff and leadership team, and their openness to sharing documentation and processes. You may also wish to conduct a review of their quality systems and relevant accreditations.

From the commercial side, a programme of commercial due diligence should be undertaken to assess the supplier's commercial activity, viability and potential, along with their commercial position, revenue, and competitive dynamics. It should not be underestimated the time it might take to agree a deal!

Conclusions

Device selection can be a lengthy process and the early stages can be the most confusing and critical. Putting the user at the centre of the process and exploring and assessing the full range of options that meet your specific needs will ensure you set off on the right path. By working through the above steps with a multi-disciplinary team, you will gather the evidence you need to make an informed decision on how to progress and feel confident that the choice you make will be the right one for you.



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