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CHALLENGES AND CONSIDERATIONS IN CUSTOMISING PLATFORM DEVICES

How do you choose the best delivery system for your drug? Doug Boyd, Manager, Medical Devices at Battelle, explores the pros and cons of a cost-effective, off-the-shelf platform versus a custom drug delivery device. He also discusses the challenges and considerations of customising an existing platform device.

A well-considered drug delivery system can maximise the effectiveness of innovative small molecule and biologic therapies. But how do you choose the best system for your drug? Do you choose a cost-effective, off-the-shelf platform or invest in developing a custom drug delivery device? There are pros and cons for each option – and there is also a third path to consider. Adapting an existing platform device with a few custom attributes tailored to your molecule can offer the best of both worlds.

Adapting an existing device can enable faster timelines, lower costs and potentially smoother regulatory approval compared with custom device development, while still providing key attributes needed to optimise drug delivery and maximise the market potential for a drug.

> "Adaptation of an existing platform device is a practical and effective solution for drug developers who do not want to invest the time and money to develop a completely custom device but need specific attributes not available in an off-the-shelf model."

With many existing drug delivery platforms to choose from, chances are good that drug developers can find one that gets them 80% of the way to the optimal device. But how do you solve the technical challenges required to address the remaining 20%? For successful adaptation of a platform drug delivery device, you need a development partner who understands how to "innovate inside the box" to optimise outcomes and minimise risks.

WHAT IS INNOVATING INSIDE THE BOX?

Drug developers have three routes to matching a drug with a delivery device, each with its own trade-offs between cost and time to market and the degree of customisation desired:

- They can adopt an existing off-the-shelf device to use as is with their molecule
- They can create a brand-new, completely custom device from scratch
- They can innovate inside the box and adapt an existing platform device with custom attributes to meet unique drug, user and market requirements.

Adaptation of an existing platform device is a practical and effective solution for drug developers who do not want to invest the time and money to develop a completely custom device but need specific attributes not available in an off-the-shelf model.

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HOW TO 'INNOVATE INSIDE THE BOX'

When adapting an existing platform device, device engineers must:

- Work within the constraints and tolerances of the original platform device
- Innovate within those constraints to find the optimised delivery solution for the given drug formulation, user requirements and business needs.

First, we must prioritise and optimise the drivers for customisation. What attributes are essential for safe and effective delivery of the drug? These might include adaptations to account for the physics of the drug's formulation (e.g. high viscosity), the needs of the administration route or end-user needs uncovered through prior research. What attributes are desirable but non-essential? These might include things like a compact device or a particular form factor, which may be desired by end users but will not make a critical difference in drug administration or market opportunity. These drivers need to be weighed and balanced against each other – especially if some turn out to be mutually exclusive.

The next step is finding the appropriate device for customisation. Which platform is closest to meeting the requirements? Which platform offers the most potential for customisation in ways that would meet the essential requirements? How would each platform need to be changed to meet the desired characteristics?

Then, we must evaluate the impact of proposed changes to the device. Any proposed change must address two problems: the one you are trying to fix, and the one you create by introducing the change. For example, changing the physics of the device – such as making the spring stronger to accommodate a higher-viscosity drug – may put too much stress on other device components, leading to earlier failure or shelf-life issues. Additional changes may need to be made to compensate, such as choosing a stronger material for the housing or a different type of snap-fit or adhesive for joined parts. If the negative impact outweighs the benefit, you may need to look for alternative solutions.

Finally, the proposed solutions must be weighed and balanced. How well do they meet the requirements? What are the negative impacts? What are the costs, timelines and risks associated with each solution? There may be a tipping point where it becomes apparent that full customisation is a better option.

	Adopt (Use an existing box)	Adapt (Innovate inside the box)	Create (Build a new box)
Pros	• Likely lowest cost (a fraction of the cost of custom development) • Near immediate availability to speed time to market • Significant risk reduction (already tested and approved)	• Faster and less expensive than custom development with similar advantages • Reduces risks and timelines by starting with an approved platform • Enables platform device to meet specific requirements based on drug characteristics and patient population needs	• Addresses specific needs of patient population and unique drug characteristics • Creates a recognisable brand or unique market differentiator
Cons	• Not optimised for specific drug characteristics and target population • Does not deliver a differentiated market advantage	• More expensive than adopting an off-the-shelf device • Degree of customisation possible can be limited	• Higher development costs • Longer development timelines • Regulatory hurdles and risks
Best for	• Drug formulations with standard viscosity, dosage, delivery rates and administration routes (e.g. subcutaneous) • Patient populations without special needs • Markets where cost competitiveness is critical • Situations where taking the shortest path to market is essential	• Situations with modest formulation and special patient population needs, such as: – Formulation that needs slightly higher delivery force – Alternate dosing regimens or other preparation considerations – Minor grip or use enhancements – Need for competitive differentiation via user experience	• Situations with significant drug formulation and special patient population needs, such as: – Unique physical characteristics (e.g. high viscosity/high delivery rate) – Dexterity or cognitive needs, special connectivity, etc. • Treatments, or pipelines full of treatments, leveraging similar formulation/ delivery strategies with large market opportunities where product differentiation will deliver a substantial benefit

Table 1: Pros and cons of the adopt, adapt or create trade-offs.

MAKING THE CHOICE: ADOPT, ADAPT OR CREATE

What are the pros and cons of the "adopt, adapt or create" trade-offs (Table 1)? How do you reach the optimised balance of feature sets and time/cost to market (Figure 1)?

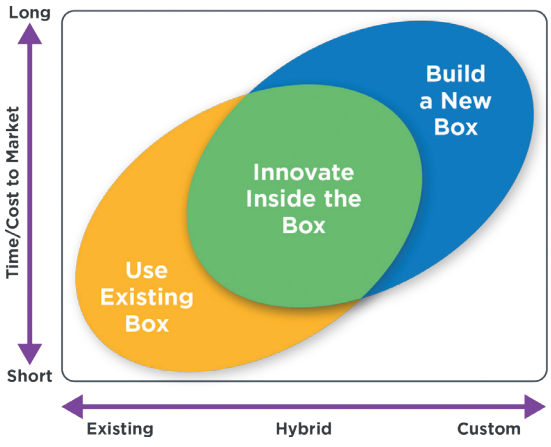

Figure 1: Innovating inside the box – time/cost versus customisation trade-offs.

DRIVERS FOR CUSTOMISATION OR ADAPTATION OF DRUG DELIVERY DEVICES

There are many reasons why an off-the-shelf drug delivery platform may not be right for a given therapy. These can be broadly grouped into three areas (Table 2):

- **Drug formulation considerations** – the physics, dosage, injection rate, administration route and storage requirements of the molecule are key drivers for customisation. For example, a device may need to be adapted with a stronger spring to accommodate a very high-viscosity drug formulation.
- **User requirements** – special populations such as children or patients with cognitive or dexterity challenges may require adaptation of a device to make the device easier or less confusing to use.
- **Business drivers** – adaptation may also be used to deliver a business advantage, such as providing a clear market differentiator. The decision to adapt or customise may also be driven by market size and pipeline considerations; the larger the market opportunity, the more it makes sense to invest in adaptation or customisation.

The decision to customise or adapt comes down to weighing the various drivers. Imagine this as a seesaw, with unique and special needs stacked on the right and ordinary, off-the-shelf attributes on the left. A large number of significant uniqueness drivers – e.g. high viscosity, non-standard administration route, special storage requirements, a special patient population and a large market opportunity – will tip the balance towards a full custom development as the best solution. Likewise, having very few or no uniqueness drivers will tip the balance towards a fully leveraged platform device. Often, however, the blend of common and custom features desired leaves the balance more even, leading to a best choice of adapting an existing design (Figure 2).

> "There are many reasons why an off-the-shelf drug delivery platform may not be right for a given therapy."

Customisation drivers		
Drug formulation	User requirements	Business drivers
• High viscosity (greater than 15 cP) and/or delivery volume (greater than 2 mL) • Non-standard delivery speed • Non-standard administration route (e.g. intramuscular, oral, intrathecal, intradermal, ocular) • Special storage requirements (e.g. refrigeration) • Requires reconstitution prior to delivery • Frequency/complexity of dosing regimen	• End-user characteristics (child versus adult, patient versus caregiver, etc.) • Physical and cognitive abilities of end users • Lifestyle considerations • Sustainability/disposal requirements • Visibility requirements for drug or delivery mechanism • Storage/portability requirements • Weight/ergonomics • Value of connectivity/ apps for condition management	• Time-to-market requirements • Importance of device to branding/market differentiation • Patient preference • Pipeline considerations (similarity to launched or pipeline molecules) • Market size/opportunity

Table 2: Drivers for customisation of drug delivery devices.

Real-World Example: A Low-Tech, Low-Cost Solution to Reduce Patient Anxiety

- An autoinjector needed a window to allow patients to see the liquid inside, as per regulatory requirements. Adding the window also unmasked the needle, which caused increased anxiety and lower levels of acceptance for some patients.
- Adding an opaque façade over the tip re-obscured the needle while still allowing the liquid to be seen clearly through the window.
- Adding the façade was a low-cost solution with no negative downstream effects. The façade did not require a redesign of the device and only required a minor change to the manufacturing process. Obscuring the needle improved patient acceptance of the device.

Real-World Example: An Alternative Solution to Reduce the Negative Impacts of Change

- An autoinjector needed a spring with more force to push a more viscous drug. Using a larger spring would have required a complete redesign of the device, with a larger barrel and other significant engineering changes.
- A double spring with right-hand and left-hand springs coiled together provided double the push in approximately the same diameter.
- The existing device could be easily retrofitted with the new double spring. This solution avoided major engineering and manufacturing process changes and got the new molecule to market faster.

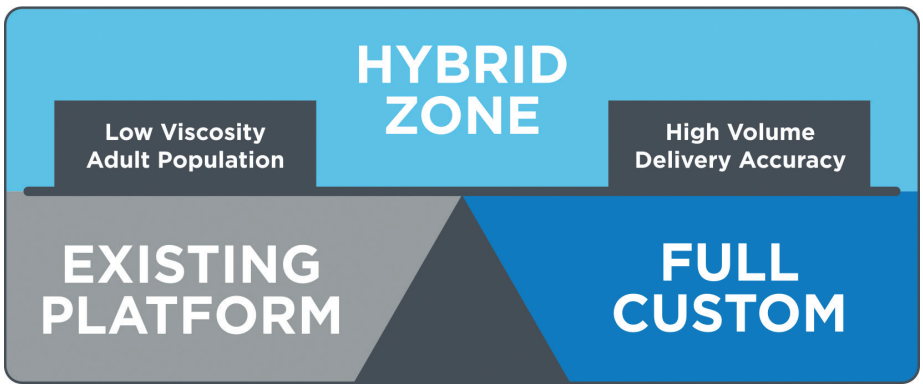

Figure 2: Weighing the drivers to determine customisation or adaptation.

FINDING THE RIGHT PARTNER FOR PLATFORM CUSTOMISATION

When customising a platform device, you need a partner who understands all the parameters and constraints, including the engineering and physics of the device, downstream effects, user impacts and business requirements. The right partner will be able to:

- Help you pick out an appropriate platform, suggest the changes required to meet essential and desired device characteristics, predict the potential negative impacts of each change and provide mitigation solutions.
- Find solutions that will be feasible in the real world and minimise potential downstream effects on supply chains and manufacturing processes.
- Understand how proposed changes impact the usability of the device and provide solutions that work for the target patient population.
- Help you perform a cost/benefit analysis for adaptation versus creation of a custom drug delivery device so you can make an informed decision based on business, market and patient needs.
- Help you understand and reduce risks, including safety, performance and market and regulatory risks.

Battelle has the right combination of expertise and experience to innovate inside or outside the box. We can help you select the right platform for your molecule, adapt a platform to your needs or develop a fully customised drug delivery device from scratch. We bring you decades of expertise in:

- **Device design** – our 25+ years of experience in custom device design, combined with our continual evaluation of dozens of drug delivery platforms each year for human factors evaluations or technical due diligence, has informed our team of designers so they can optimise the balance between user needs and commercialisation needs.
- **Device engineering** – we have decades of experience in all facets of drug delivery device design and engineering, from materials selection to Internet of Things connectivity. Our team brings specific expertise in state-of-art injection, patch pump and inhalation technologies, and is behind three of the most successful drug delivery platforms of the last decade.
- **Human factors evaluations** – with the patient always in mind, our team applies human-centric design principles and has deep experience in human factors studies and device usability. We can help you understand how proposed changes may impact the usability and acceptance of your drug delivery device and can develop solutions that better meet the needs of your end users.
- **Regulatory experience** – we understand the range of applicable regulatory processes (e.g. BLA, NDA, 505(b)(2), etc.) and can predict how proposed changes to a platform device may impact approval. We will help you make the right decisions and gather the right information to reduce regulatory risk and ensure a smooth submission process.

Our experience and multidisciplinary approach give us the ability to foresee the positive and negative impacts of a proposed change – not just from a device engineering perspective but also from the regulatory, commercial and market perspectives. The Battelle team can be relied upon to provide unbiased, expert advice to help you maximise your opportunities and reduce the risks, costs and timelines for device development.

ABOUT THE COMPANY

Battelle is one of the world's largest, independent, non-profit research and development organisations. It is a US$8.2 billion (£6.3 billion) enterprise with a mission as relevant today as it was when it opened its doors more than 90 years ago – to translate scientific discovery and technology advances into societal benefits. Headquartered in Columbus (OH, US), Battelle focuses its contract research efforts on three main areas: health, national security and environment.

ABOUT THE AUTHOR

Doug Boyd has dedicated his career to helping people by making new medical technologies a reality. He leads Battelle's multidisciplinary medical device and health analytics business, encompassing experts in programme management, systems engineering, electrical, mechanical and software engineering, human centric design, advanced data science and quality/regulatory compliance. Mr Boyd holds 22 patents and has been involved in the development of dozens of complex medical devices for commercial and US government clients, including surgical equipment and tools, *in vitro* diagnostic systems, self-administered drug delivery devices and in-hospital drug administration systems.

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