The specific approach: the advantage of customization for wearable delivery systems

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Considering the overlapping needs of a drug therapy delivered via wearable injectors, each project benefits from its own specific approach. This means that involving customization from the outset can not only optimize the patient outcome, but can also streamline the development timescale for device engineers. Involving motor design expertise ensures a holistic approach throughout the development of the delivery system.

Portescap's Business Development Manager for medical applications, Dave Beckstoffer, explains.

In the arena of on-body injector and auto-injector development, more and more companies are creating devices paired one-to-one with a specific drug. While injector developers are still producing devices to handle a range of different drug types, the advantage of developing a specific injector is in matching the unique therapy and patient profile to the given drug.

The push from pharmaceutical brands is the need to optimize the actual delivery of the drug to match the demand in improving drug efficacy. The expertise and timescale required to create the latest, most effective drug treatments, requires high investment; in turn, to optimize therapy efficacy demands the most appropriate delivery methodology.

As a result, the capability of the delivery system, based on an electric motor, a gear, a connecting actuator, and potentially a feedback device, must also be customised to suit the drug and its criteria in delivery. Drugs that do not, relatively speaking, have the highest need for volumetric precision, such as a diuretic like furosemide, could be still delivered by a generic device.

However, in the burgeoning market of biologics, precision in delivery is often crucial to treatment efficacy, and there might be less margin for error in harmful overdosing. In these cases, customization of the delivery system ensures precision over delivery force, dependent on drug viscosity, as well as the injection time profile. The frequency of administration and the total required lifespan of injector use are the other key considerations. While the growth in the biologics market has pushed the move towards the customization of delivery system designs specific to each drug, the tendency to aim to standardize for subsequent or similar drug types can still remain. A device developer might invest resources in establishing a customized delivery system for the first contracted drug or set of biologics but might then aim to use the original design platform across a broader drug range. As a result, the outer portion of the device and the software can be tailored to each specific drug and therapy, while the core delivery system remains the same.

Typically, this could mean adjusting the force to suit the viscosity, substituting the original motor and gear specification with an off-the-shelf selection of standard products. There's logic to this approach, where repeating tried and tested designs, making only the necessary adjustments, can quickly achieve reliable results.

The danger, however, is moving too quickly with the re-design, and neglecting important decisions that can impact wider aspects of the on-body injection device. This can result in the need for re-work later down the line, elongating the overall project timescale.

Form factor and drug delivery requirements

Form factor is an important aspect that can be adversely impacted by abandoning the full range of customization considerations at a premature stage, or by moving directly to selection of off-the-shelf motors, gears, and lead screws. However, by maintaining a customization approach at the concept phase of every new project, a designer can make fine adjustments to the delivery system's components, adapting to different drug viscosities and delivery requirements as necessary, while keeping the form factor, and weight, practically the same.

The gearing system has the biggest impact on form factor, and if greater force is needed, customization can achieve more specific ratios than off-the-shelf designs will usually provide. For the most compact footprint, the gear housing can also be modified to mould perfectly with the device architecture. A spur gear is typically preferred as this arrangement allows an offset lead screw output, enabling an improved fit within the typical rectangular layout of the on-body injection device.

With the gear design optimized, the motor can also be customized to provide the required output characteristics while maintaining the desired footprint. While motor size might have to increase to meet output torque requirements, should increasing the gear ratio alone not be sufficient, using alternative motor technologies could be advantageous. Switching from a brushed DC motor to a brushless DC (BLDC) motor increases the speed potential, increasing the delivery capability while reducing the footprint for the equivalent output. Changing the motor technology can also be useful to handle different drug delivery profiles. For example, if the drug needs to be delivered rapidly, the higher speed of a BLDC design could be more appropriate. To achieve precise dosing and enable exact management of the delivery phase, the encoder pairing is also crucial, with careful consideration over the feedback technology type and its resolution. Alternative technology could also be used, considering a delivery profile where the drug needs fine incremental volumes administered over a longer duration. In these cases, stepper motor technology might be preferable, which can be run open loop thereby focusing the feedback on the drug delivery.

Design consideration must also be made for the lead screw, with customization available for the diameter and pitch leading to an optimized system. This way, in combination with the appropriate motor technology, a higher pitch could deliver several times the force capability from the same footprint drive mechanism.

However, it’s crucial to remember that changes to any one of the components can impact the output or footprint of the delivery system as a whole. This reiterates the point that any design changes should be considered, with due expertise, as early as possible in the design and development process.

Duty cycles, efficiency and reliability

From the patient perspective, and hence the needs of the device designer, energy efficiency is also crucial, and this is another area where involving motor engineering expertise can offer an advantage. Although each drug has a specific therapy profile, the motor's operation to achieve it can be adjusted to match its optimal operation.

This is key because the duty cycle has a significant impact on motor efficiency, where high speed operation for a short duration is generally more efficient than continuous low speed operation. Take a drug delivery profile of six hours; a motor could run for two seconds every minute at high speed and still achieve the same effective delivery profile as a continuous low speed operation. This approach demands high precision in motor control but will result in a marked efficiency increase.

Close attention to duty cycle management in delivery system design can also improve another key area: lifespan. If a device designer assumes continuous duty operation, this could be a difference in a lifecycle of requirement of hundreds of hours, or even several thousand hours, down to just tens of hours of intermittent operation, spread over the required months or years of use. Considering materials selection, this means that specifying the most durable, and most expensive, options may not be required, and instead, sufficiently robust, yet significantly less expensive materials could be used.

The other key advantage of utilizing intermittent duty cycles to minimize the total required lifetime is the benefit to testing. Typically, a delivery system is tested for two cycles of its total lifespan, but with a lifetime reduced from hundreds to tens of hours, life testing duration can be significantly reduced. This time advantage can be used to test an additional range of parameters, as well as allowing testing to failure, enabling a more comprehensive test procedure, resulting in a more reliable device long term.

The future needs in delivery system design

Optimizing sustainability is another design aspect where customization is looking to push boundaries. Specifically, there's an increasing drive to convert disposable devices to reusable designs. Coinciding with the boom in weight loss drugs and GLP-1 receptor agonists, there's significant waste with single-use syringes.

While improving recyclability of materials is one option, a further potential is to look closer at the balance of the drive mechanism profile with the therapy profile, increasing the lifespan that can be achieved from delivery devices. As a result, delivery system developers are creating cost-effective ways of converting disposable devices to re-usable options, capable of delivering therapies for several years.

Yet whether developing a wearable drug delivery device to meet new trends like sustainability, through to adapting an existing design to deliver a new drug, the role of the motor, gear, actuator, and feedback will remain fundamental. Considering the significance of its impact, it's important to ensure that all design considerations are covered as early as possible in the development timescale, starting from the concept phase. In doing so, the involvement of device customization for each project adds the security that drug delivery to optimize the patient outcome can be realized, while the timescale of development can be minimized – reducing the potential for late surprises emerging during the project.

Image captions:

Image 1: A spur gear type is typically preferred for a wearable injector.

Image 2: Portescap provides brushless and brushed DC motor technology.

Image 3: Device developers gain through early input from delivery system engineers.

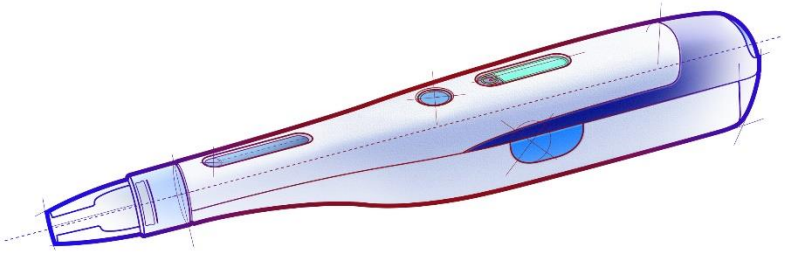

Image 4: The capability of the delivery system must be customised to suit the drug and its criteria in delivery.

Image 5: High speed stepper motors are also an option alongside BLDC and brushed motors.

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Portescap offers the broadest miniature and specialty motor products in the industry, encompassing coreless brush DC, brushless DC, stepper can stack, gearheads, digital linear actuators, and disc magnet technologies. Portescap products have been serving diverse motion control needs in wide spectrum of medical and industrial applications, lifescience, instrumentation, automation, aerospace and commercial applications, for more than 70 years.

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