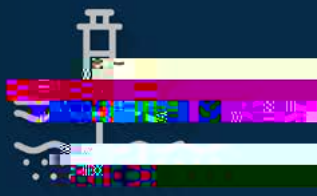
SOLVING DRUG DELIVERY CHALLENGES IN THE REAL WORLD



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Jabil's new Qfnity™ autoinjector platform provides a compelling solution to the many challenges facing the healthcare ecosystem today.

Norm, an 81-year-old widower living alone in Miami, is frequently on his daughter's mind. A busy software executive in Austin, Sara worries about her father sticking to the challenging treatment plan addressing his multiple chronic conditions, which include rheumatoid arthritis, hypertension, and high cholesterol.

Sara visits her father whenever possible and has someone check on him regularly, but oftentimes Norm is on his own to manage a regimen requiring six different medications, each with their own dosing schedule and two different drug delivery devices.

"My dad gets upset and confused by having more than one remote for the TV. Why can't this be easier?"

Norm is not alone; research shows that within the US, approximately 45% of the population suffers from at least one chronic disease, and these numbers are increasing with an ageing population[1].

People with chronic conditions account for 83% of healthcare costs. The challenges and concerns experienced by Norm and Sara are faced by millions of patients and caregivers every day[2].

Shared Goals Across the Ecosystem

Across the healthcare ecosystem, distinct, yet interdependent players are all working to achieve an optimal balance for Norm — and people like him — between efficacy, safety, and access to treatment that is non-disruptive to everyday life.

The Challenge of Adherence and Compliance

In parallel, pharma companies are increasingly employing digital tools in clinical development, providing a range of interrelated benefts. Digital technology enables more proactive management of studies with real-time data for improving patient engagement. This helps support smaller and/or shorter studies reducing product development cycle time and cost.

The Promise of New Therapeutic Classes

New therapy classes emerging from advances in biologics research are facilitating novel treatment strategies. In the last 15 years, approvals for biologics-based therapies have increased their share of the total pharma market from 16-25%[8]. There are some headwinds due to higher development and associated manufacturing costs, as well as usability challenges since these therapies are delivered as injectables and not as tablets.

The Promise of New Routes of Administration

Biologic formulations approved for parenteral administration have likewise increased in recent years, including drug products for intravenous (IV) and subcutaneous administration. For autoimmune diseases, there has been a transition to subcutaneous self-administration in the home setting, eliciting a strong preference from patients who value the convenience, as compared to IV administration in a clinical setting.

A similar trend in oncology may also be realised, as novel cancer therapies continue to reach maturity and safety profle improvements enable further exploration for approval of these treatments for administration in the home setting, either by healthcare providers and/or self/caregiver administration. This is evidenced by approval of Herceptin® in 2019 for subcutaneous administration, and the current late-phase clinical assessment of Keytruda®[9].

The key challenge for this direction of travel is the increase in dose concentrations and/or volumes, and their safety profle. There is, however, emerging evidence that the subcutaneous route has an improved safety profle with reference to the equivalent IV route and that adverse events reduce after the frst and second exposures, further securing the viability of self-administration in the home setting as part of a longer-term chronic disease management strategy.

What Makes Qfnity a Better Solution?

For patient and provider, a spring-driven unit ensures the dose is always available; Qfnity's drive system is not dependent upon the device being charged.

Qfnity's functionality is appropriate to requirements without adding redundant features that will likely not be used by a majority of users. Simple mechanical systems are well precedented, to the point that chronic disease patients are likely to have familiarity with the drive system employed by Qfnity from their experiences in other therapeutic areas. The result: increased user confdence with minimal additional training burden.

Regulators value a simple mechanical design for minimising user errors common to more complicated systems, as well as easing the oversight burden of lifecycle management changes driven by the component obsolescence issues associated with complex electromechanical designs. By keeping it simple, Qfnity is ideal for all players, since less can go wrong.

Qfnity's simple, intuitive, and reusable solution resonates with all players. The reduction, just in respect to materials used, is on the magnitude of circa 55% for a reusable autoinjector, like Qfnity, as compared to a disposable autoinjector's requirements.

In addition, there is a smaller, simpler cost in the manufacturing/assembly footprint, as well as lower carbon footprint to build and maintain such a facility. The smaller product footprint for Qfnity reduces the carbon footprint of cold chain storage through the supply chain. Reusability also drives lower cost per injection, by as much as 40% by some estimates.

Strategic
Aligned with pharma corporate strategy and portfolio direction of travel

Easy to use, easy to teach
Intuitive and familiar, facilitates patient/healthcare professional administration outside clinic

Robust
Mechanical system delivers essential functionality, simply and dependably

Versatile
Scalable platform fexibility supports a wide dose range (0.4 – 2.25 mL)

Sustainable
Reusability minimises waste/ lowers carbon footprint across the supply chain

Value
Lower total cost of ownership/ lower cost per injection

Integrated
Optional home hub assures charging/data transfer with no additional patient burden

Connected
Optional connectivity supports improved patient engagement with less burden

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Qfnity's one-size-fts-all modular design ensures a common form factor across a wide dosing range. For Patients, (many, like Norm, battling a range of chronic conditions) this eliminates the need for additional user training, resulting in more security and comfort in their - and/or their caretakers' - routines. Greater user confdence translates to a decrease in common user errors, a positive outcome benefting all Players.

Pharma companies benef t from the fexibility of a modular platform device with broad portfolio applicability. In fact, across the top 12 pharma companies worldwide, circa 80% of their assets cited for subcutaneous administration in all therapy classes (excluding oncology) are deliverable in volumes below 2.25mL. As more oncology assets are cited for subcutaneous administration, it is estimated that 30% of those could be deliverable in volumes up to 2.25mL.

All players can benef t from Qfnity's connectivity option which enables the power of connected health to be deployed throughout the product lifecycle.

As a connected device, Qfnity facilitates more informed discussions, improving patient engagement, either in clinical development (driving protocol adherence resulting in more cost-effective testing of the scientifc hypothesis) or in commercial supply, through improved adherence, compliance, and patient education, all of which improve health outcomes.

Maintaining the same form factor enables patients to transition from one version of Qfnity to the other without the need for retraining.

Qfnity's connected home hub solution improves usability as the system is not dependent upon co-location of the Qfnity autoinjector with a smartphone. The hub provides a convenient base station cradle for charging the device and delivering seamless data transfer functionality in near real-time.

Qfnity — The Opportunity is Now

Pharma manufacturers have a signifcant opportunity to infuence how the healthcare ecosystem evolves in solving today's challenges with tomorrow's solutions. The way forward is becoming easier for Norm and that should comfort his daughter, as well as everyone else seeking better tools for improving health and peace of mind.

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