



SOLVING DRUG DELIVERY CHALLENGES IN THE REAL WORLD



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HEALTHCARE

Jabil's new Qfinity™ 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 population¹.

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 day².

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.



Figure 1: The healthcare ecosystem

What Are the Specific Objectives of These Players?

- Patients seek effective treatments
- Healthcare professionals strive to improve patients' lives; they additionally hope that their treatment plans will be followed, as directed, with minimal intervention
- Regulators work towards a balance between clinical outcome and safety
- Payers and insurance companies work to balance clinical outcome and total healthcare costs³
- Pharmaceutical companies seek approval and reimbursement for therapies that will be clinically successful, as well as commercially viable⁴

In addition, there are other factors that must be considered.

The Challenge of Adherence and Compliance

“Drugs don’t work in patients who don’t take them.” Former US Surgeon General, C Everett Koop’s 1985 statement remains relevant today.

Research reports that adherence/ compliance to long-term therapy for chronic illnesses in developed countries averages 50%⁵. The causes of this reality are myriad, including impaired motor skills and/or cognition, complicated regimens, and inadequate patient education, as well as socioeconomic and psychological factors.

The expense of increased hospitalisation and other interventions resulting from adherence/ compliance failure are financially staggering, ranging from \$100 billion to \$290 billion annually, while the human cost is tragic, contributing to excess deaths of 125,000 patients every year in the US alone⁶.

The Environmental Challenge

Consideration must also be given to sustainability goals and efforts from all the players in the ecosystem to lower their carbon footprint by reducing waste streams, such as those arising from disposable functionality. By some measures, approximately 90% of all medical device waste consists of disposable, one-time-use products, or components⁷. Addressing these costs and concerns is a multi-faceted challenge.

The Promise of Digital Health

Digital health — the use of computing platforms, connectivity, software, and sensors for healthcare and related uses — has the potential to address some of the compliance, adherence, and patient education challenges, while enhancing health outcomes and reducing total healthcare costs for marketed products through improved patient engagement.

Connected, digital health tools continue to provide an invaluable combination of oversight and insight with increasing capabilities for filling the roles (for people like Norm) that can’t always be attended to by family or caretakers via personalised alert and reminder platforms, as well as other remote medication management tools.

In parallel, pharma companies are increasingly employing digital tools in clinical development, providing a range of interrelated benefits. 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 profile 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 profile. There is, however, emerging evidence that the subcutaneous route has an improved safety profile with reference to the equivalent IV route and that adverse events reduce after the first and second exposures, further securing the viability of self-administration in the home setting as part of a longer-term chronic disease management strategy.

A Real-World Opportunity

Given the growth in biologics, the emergence of newer classes of biologics with improved safety profiles and patient preference for self-administration, there is a clear opportunity for a drug delivery system enhanced by digital technology, with improved sustainability metrics, that is reliable and easy to use whether in clinical development or commercial supply.

Looking through the lens of each of the ecosystem players, and how each of their objectives weighs upon the other in the balance of efficacy, safety, cost, and access, how do we improve the path for Norm and millions of others using the subcutaneous route of administration?

Introducing Qfinity™ — the Best Solution for Delivering this Win-Win Scenario

A mechanical, reusable, modular platform autoinjector with a common form factor, capable of supporting volumes up to 2.25mL and the optionality for connectivity, via a home hub.



Figure 2: Qfinity™ Cassette, Reusable Autoinjector and Connected Charging Hub

What Makes Qfinity a Better Solution?

Mechanical

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

Qfinity'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 Qfinity from their experiences in other therapeutic areas. The result: increased user confidence 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, Qfinity is ideal for all players, since less can go wrong.

Reusable

Qfinity'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 Qfinity, 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 Qfinity 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 flexibility 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

Figure 3: Solution benefits across the healthcare ecosystem

Modular Platform Autoinjector Capable of Supporting Volumes Up to 2.25mL

Qfinity's one-size-fits-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 confidence translates to a decrease in common user errors, a positive outcome benefiting all Players.

Pharma companies benefit from the flexibility 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.

Qfinity Offers Optionality for Connectivity in the Same Form Factor

All players can benefit from Qfinity's connectivity option which enables the power of connected health to be deployed throughout the product lifecycle.

As a connected device, Qfinity facilitates more informed discussions, improving patient engagement, either in clinical development (driving protocol adherence resulting in more cost-effective testing of the scientific 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 Qfinity to the other without the need for retraining.

Connectivity via a Home Hub

Qfinity's connected home hub solution improves usability as the system is not dependent upon co-location of the Qfinity 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.

Qfinity — The Opportunity is Now

Pharma manufacturers have a significant opportunity to influence 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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ABOUT THE AUTHOR

Oliver Eden is a Business Unit Director at Jabil Healthcare focused on the development and commercialization of drug delivery devices for the division's pharmaceutical delivery systems business. Operating from the UK, Oliver earned his Master's in Mechanical Engineering and a PhD in Biomaterials Engineering, both from the University of Exeter.

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