The Qfinity Autoinjector

A More Sustainable Solution by Design

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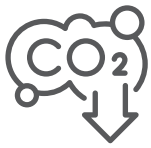
Executive Summary

The author describes how the Qfinity™ and Qfinity+™ autoinjector platform leverages design for sustainability (DfS) principles to deliver a virtuous circle — improving resource allocation and conservation across the manufacturing value chain, while also lowering the total cost of goods. Compared to market-leading single-use autoinjectors, the Qfinity Platform's patient-centric, drug delivery solution outperforms on the following key sustainability metrics:



Greater than **80%**
reduction in carbon footprint

50% smaller
manufacturing footprint

70% reduction
in CAPEX

Delivers a **VIRTUOUS CIRCLE** of sustainability

Sustainability — The Challenge of Our Time

The carbon footprint of the healthcare industry is increasingly analysed for its impact on the global environment. One frequently cited study, (by Pichler et. al.) published in Environmental Research Letters (2019), calculates that the healthcare sectors of 36 Organization for Economic Cooperation and Development (OECD) countries (plus China and India combined) are responsible for 4.4% of net global (CO_2) emissions. As reported by Healthcare without Harm, to put this into context, "if the healthcare sector was a country, it would be the fifth largest greenhouse gas emitter on the planet."

If the **healthcare** sector was a country, it would be the
FIFTH LARGEST
greenhouse gas emitter on the planet.

Healthcare without Harm

Also in 2019, a paper authored by Lotfi Belkhir and Ahmed Elmeligi, "Carbon Footprint of the Global Pharmaceutical Industry and Relative Impact of Its Major Players" concludes that emissions of the pharmaceutical industry are significantly more than the automotive industry. Furthermore, some estimates project that as much as 90% of medical device waste comes from single-use, single-use items. Within pharmaceutical delivery, the injector market is made up of 70% single-use products.

In June 2020, the European Federation of Pharmaceutical Industries and Associations (EFPIA) released a whitepaper speaking to these environmental challenges and calling for the pharma industry to increase adoption of circular economy principles to better preserve resources and maximise product lifecycles. Various approaches and opportunities for more sustainable solutions are identified in respect to drug products, devices, packaging, and raw materials. One point, however, is made quite clearly by the authors of the paper —

80% of a product's environmental impact is determined in its design phase.

Estimates suggest as much as
90% OF MEDICAL DEVICE WASTE
comes from **disposable, single-use items**

The **injector market** is made up of
70% SINGLE-USE PRODUCTS

Sustainability Objectives Locked in at Design

As illustrated in Figure 1, consideration of a product's design requirements and potential environmental impact should be accommodated in tandem and, critically, from the outset. Given that all but 20% of a product's carbon footprint is typically locked in at initial concepting, DfS must certainly be a paramount concern in this phase of the product's development. Even as a device moves from initial concept through prototype to production, these same disciplines must be maintained or risk reducing the product's overall sustainability performance.

Circular economy protocols, and in particular, device reusability, are fundamental to achieving sustainability objectives. A re-usable autoinjector is a compelling solution for the opportunities described within EFPIA's analysis and bears out advantages that single-use injector products just cannot match. The challenge is how such a design can be delivered whilst not comprising usability.

The injectable drug delivery market continues to expand. Today's growth is driven by the increase in biologics and by patients and payers' preference for in-home self-administrration. These drivers make it imperative for the industry to develop solutions that address sustainability challenges from an environmental and business case perspective, whilst also being intuitive and easy to use for the patient.

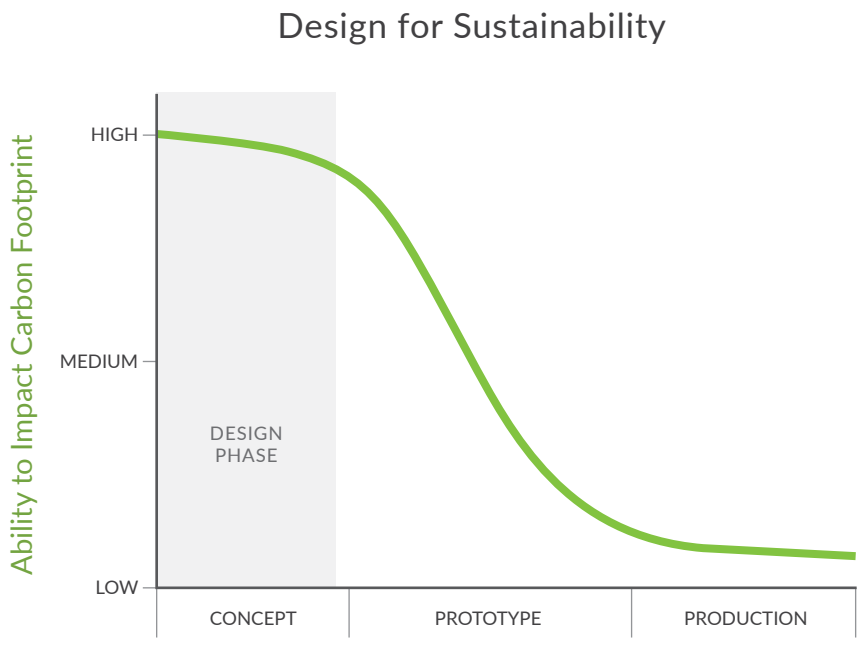


Figure 1

80%
of a product's
ENVIRONMENTAL
IMPACT
is **determined**
in its **design phase**

The Jabil Autoinjector Platforms — Qfinity and Qfinity+

Following extensive reviews of partner pharma company pipelines and strategic directions, Jabil identified an opportunity for the development of a subcutaneous autoinjector platform. Jabil's high-level product requirements brief for the platform include the following key objectives:

- Deliver the lowest cost, portfolio-enabling product solution
- Provide an option for connectivity
- Improve sustainability

The brief describes a future-facing autoinjector platform — ready for the connected world — that is intuitive and easy to use for patients while providing a flexible and more environmentally sustainable product solution for pharmaceutical customers.

The result — Qfinity and Qfinity+ autoinjectors.

How Qfinity and Qfinity+ Deliver

The Qfinity Platform enables the delivery of a broad range of therapies in a versatile platform solution. The platform features a simple spring-loaded, reusable drive unit and single-use, pre-filled single-use cassettes in 1.0-ml and 2.25-ml syringe sizes. The mechanical autoinjector allows pharma customers maximum flexibility for choosing the right solution for their target patient population across a range of dosing sizes. The attractive, handheld device operates with a single-button push to safely deliver medications at the optimal speed and pace across a range of formulation viscosities [Figure 2].

Qfinity Mechanical Autoinjector & Cassette

Mechanical Autoinjector

- Reusable, durable device
- 3-year (156 use) expected lifespan

Mechanical Cassette

- Pre-filled syringe for correct dosing and needle safety

Figure 2

The Qfinity+ Platform incorporates electronics, sensors and wireless connectivity and uses a Home Hub for automatic data transfer and device charging. However, the look, feel and function for both Qfinity and Qfinity+ autoinjectors are otherwise identical, which means patients can switch between the devices without any retraining.

Qfinity+ supports a seamless path to connected care without burdening the patient or those who care for them. The patient simply uses the device and places it back onto the Home Hub which then manages the data transfer from the device automatically and charging of the device's onboard battery, without any need for additional interaction by the caregiver or patient.

Designed to provide broad accessibility without requiring a smartphone, device pairing, or the downloading and management of an extraneous app, the Home Hub leverages nearly universal cellular communication coverage to deliver connectivity. Qfinity+ has been designed to function for the entire population — even those elderly groups who may not be tech-savvy and may not have the smartphone that is a prerequisite for most other connected devices. By way of example, Pew Research Centre reports that even in a technologically advanced country like the United States, smartphone ownership in people over 65 years old — a key market for healthcare — is only 61%, while cellular networks, globally, provide coverage accessibility to more than 95% of the world's population.

In **clinical trials**, the Qfinity+ Platform eliminates any requirement for participants to own a smartphone and in essence, extends access to those who might otherwise be excluded due to socioeconomics, demographics, or geography. Qfinity+ makes real-time monitoring of clinical trial adherence and compliance in long-term patient care and clinical trial applications easy — for program managers, care teams, and patients [Figure 3].

Qfinity+ Connected Autoinjector, Home Hub & Cassette

Mechanical Cassette with Optional RFID Tag

- Single-use component containing pre-filled syringe with drug
- Optional RFID tag for drug identification

Connected Autoinjector

- Reusable, durable device
- 3-year (156 use) expected lifespan
- Contains electronics to capture time of activation and success of drug delivery

Home Hub Charging Station

- Reusable, durable device
- 6-year (312 use) expected lifespan
- Contains electronics for wireless charging of autoinjector
- Connects with autoinjector and automatically transmits data to cloud-based software

Figure 3

Qfinity and Qfinity+ Lifecycle Assessment

The Qfinity and Qfinity+ Platforms were evaluated by a third party per the following carbon footprint lifecycle assessment criteria:

ISO 14067

2018

Greenhouse gases

Carbon footprint of products

Requirements and guidelines for quantification

ISO 14040

2006

Environmental management

Lifecycle assessment

Principles and framework

ISO 14044

2006

Environmental management

Lifecycle assessment and requirements

Supplemented with information from a leading European trade association, Plastics Europe, the study utilized the ecoinvent 3 Database, a lifecycle inventory database that supports various types of sustainability assessments.

This lifecycle assessment considered the carbon footprint for raw material extraction, materials manufacturing, conversions, and disposal. It did not consider the assembly, cold chain storage, and transportation through the pharma supply chain which, in the case of Qfinity and Qfinity+, would have offered further comparative benefits versus single-use autoinjectors [Figure 4].

System Boundaries Flow Diagram

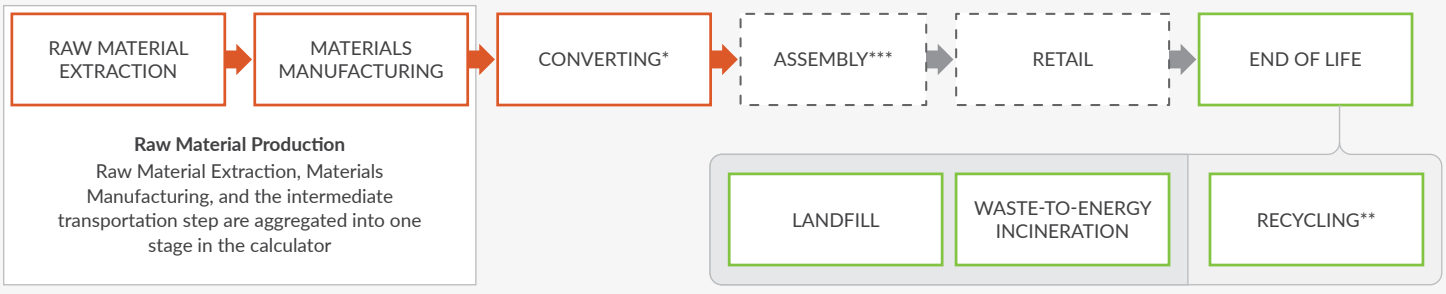
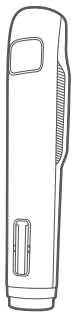


Figure 4

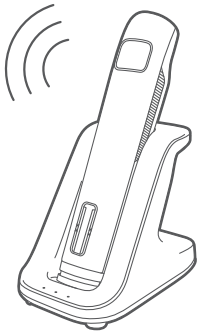
In order to compare the sustainability performance of the Qfinity Platform versus other autoinjectors, a list of input assumptions was established. Those assumptions referenced here as 'base case scenario', represent a fictitious drug product with a 100K patient population, for a chronic disease, requiring fortnightly dosing and assumes that the reusable injector and Home Hubs have an in-use life of 3 and 6 years, respectively.

When comparing the carbon footprint of the Qfinity and Qfinity+ Platforms to a marketed, unconnected 2.25mL single-use autoinjector, the Qfinity and Qfinity+ Platforms have a reduction of circa 65% and 60%, respectively.



Qfinity™

65% CARBON FOOTPRINT REDUCTION



Qfinity+™

60% CARBON FOOTPRINT REDUCTION

Simplistically, the benefit of the Qfinity and Qfinity+ Platforms derives from its reusable design. At each dosing event, the patient now only consumes a small, lightweight cassette comprised of only four moulded parts, whereas a single-use autoinjector is discarded after each dosing event and must be replenished in full.

Lowering Footprint and Cost by Design

Having established the carbon footprint benefit, Jabil next reviewed the impact of this design approach in respect of other key business drivers using the base case scenario previously described, specifically the contribution from:

- Manufacturing footprint
- Capital expenditure required to install high-volume manufacturing capacity

Finally, Jabil considered all these attributes and their aggregate impact upon cost per injection.

REDUCED FOOTPRINT & COST

Manufacturing Footprint Reduced by 50%

Based upon Jabil's experience quoting installed manufacturing for single-use autoinjectors at volumes of up to circa 5M units per annum (i.e., similar volumes to our base case), it was assessed that the manufacturing footprint at the CMO and Pharma partner is reduced by circa 50%. This manufacturing footprint saving is driven by the relative simplicity of assembling the Qfinity Platform's four-component single-use cassette versus the complex manufacturing solution associated with assembling a 15 to 20 component single-use autoinjector.

It should also be noted that the Qfinity Platform offers further efficiencies for cold chain storage because the pre-filled syringe is assembled into the compact single-use cassette which offers more efficient packaging than a single-use autoinjector.

50%
REDUCED MANUFACTURING FOOTPRINT

Capital Expenditure Reduced by 70%

Based upon Jabil's experience of industrialising single-use autoinjectors with capacity of 5M units per annum (i.e., similar volumes to our base case), it was assessed that such a solution would drive a 70% reduction in CapEx.

As in the earlier cost projection, these calculations are based upon the relative differences in scale between the Qfinity Platform cassette with four components and the single-use autoinjector comprising 15 to 20 components. Requirements to accommodate the single-use injector design drives higher costs in moulding and manufacturing equipment as well as the carbon footprint required to build and maintain their respective facilities.

70%
REDUCED CAPITAL EXPENDITURE

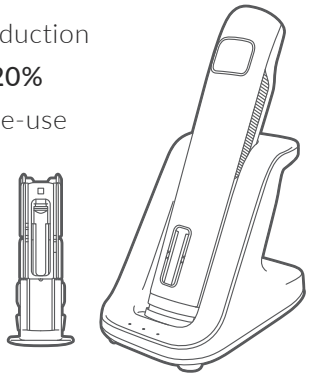
Cost per Injection Reduced Significantly

Basing our projections upon a reusable injector platform, Jabil considered costs of the following elements:

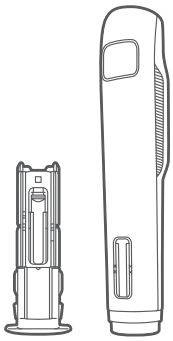
design | **manufacturing solution** | **manufacturing facility**

The result is not only a significant reduction in carbon footprint, but also a much lower projected cost per injection.

For **Qfinity+** Platform, the reduction in cost per injection is circa **20%** versus an unconnected, single-use autoinjector.



For **Qfinity** Platform, the reduction in cost per injection is circa **65%**, on a like-for-like basis.



A Virtuous Circle Achieved

Lowering carbon footprint by reducing waste streams, such as those arising from single-use products, is certainly an achievable goal. Injection devices are indispensable for patients managing their health. As long as these devices deliver easy to use, patient-centric solutions, the more 'eco-friendly' options, the better. Qfinity and Qfinity+ Platforms are designed to do both.

The Qfinity autoinjector design choices were made intentionally — from the outset — to improve sustainability. The platform's delivery of a 60% reduction in carbon footprint bears out the success of these early design-stage commitments.

At the same time, the Qfinity autoinjector is exceptionally supportive of the growing trend for at-home treatment of chronic disease. Simplifying care delivery by reducing the need for travel to clinic or hospital is another way the platform reduces impact upon the environment while simultaneously accommodating patients' lives.

Next-generation autoinjector devices, like the Qfinity Platform, that improve care, cost, and environmental impact in a virtuous circle, will help biopharma companies meet their goals in addressing the sustainability challenges facing the industry, and indeed, the planet.