The Platform Effect:

Elevating Manufacturing Efficiency in Injectable Drug Delivery

"At its core, fill-finish involves taking a bulk pharmaceutical product – whether a vaccine, biologic, or small molecule – and precisely filling it into its final container for distribution. For some products, such as biologics, the complexity is amplified due to their sensitive nature. These treatments require highly specialised, sterile environments and precise handling to maintain their potency and safety. The demand for biologics, gene therapies, and cell therapies has rapidly accelerated, and so has the need for innovative solutions in fill-finish packaging and manufacturing."[1]

Emma Verkaik, CEO of the BCMPA – The Association for Contract Manufacturing, Packing, Fulfilment & Logistics

In the Summer issue of IPI, Emma Verkaik, CEO of The Association for Contract Manufacturing, Packing, Fulfilment & Logistics, writes, "The fill-finish phase in the pharmaceutical manufacturing industry is undergoing a significant transformation. Once primarily focused on the aseptic filling of vials and syringes, it has now evolved into a multi-faceted process requiring a high degree of technical precision, regulatory awareness and strategic foresight."1 The need for the integration of final combination device assembly into the production process has heightened the importance of device design to achieve optimal production process efficiency.

Delivery device partners must align with current manufacturing priorities. As the pharmaceutical industry innovates and enables greater self-administration of more complex dosing regimens, it needs appropriate drug delivery solutions, capable of handling a range of formulation types.

Many therapies and their dose regimens can be accommodated by flexible and de-risked platform devices. New drug formulations need ever more flexible solutions – but developers have to square the circle while containing costs, and ensuring performance and ease of use. Additionally, with patient populations growing, manufacturing efficiency is key for cost effective global market access.

Typical Assembly Scenarios

Pharmaceutical manufacturers will be familiar with a scenario where one drug requires six different fill volumes, and two or three different types of autoinjector. In this scenario, the manufacturer modifies assembly processes for each autoinjector, adjusting pre-filled syringe filling and stoppering, for instance.

Each of these variants will require individual assembly process validation steps; this additional validation requirement drives significant operational and quality complexity and therefore costs. Optimised device design reduces the line change requirements between product variants throughout a manufacturing campaign, improving overall capacity utilisation.

Innovative biologic therapies further increase complexity. Batch sizes for these therapeutic products are inherently smaller and more variable, resulting in more frequent changeovers, with filling lines adjusted for each batch. Small batch variations can also impact device performance, specifically injection time and plunger force. Inherently flexible autoinjectors can therefore streamline assembly activities for innovative products in development, and support consistent performance.

Wide Performance Envelope

Platform devices with a wide performance envelope are able to function with both low and high-volume drugs, and formulations of varying viscosity, while also accommodating broad user requirements such as lack of dexterity or needle phobia. As one device engineer puts it, "For pharmaceutical companies, platform devices offer a near 'off-the-shelf' solution to deliver their assets".[2] Delivery device manufacturers make the significant upfront investment to create this comprehensive device, which acts as the core product ready to be customised by pharma partners when putting together a combination product.

Given the extended timeline from initial discovery to market approval (often a decade or more), a robust platform device that flexibly adjusts to drug volumes and viscosities offers some relief to drug developers.[3] In one example of a modern platform autoinjector, the device's plunger rod auto-adjusts to the stopper position regardless of the fill volume, eliminating the need to change parts.

This means that if the required delivery volume or formulation changes (as it often does during drug development), the device design or configuration does not. The autoinjector's configuration flexibility allows for a fill volume range of 0.3mL up to 2.25mL from one device. Once assembled, the consistent distance between the stopper and plunger for all dosages reduces the need for individual verification and process validation. This is an example of an injector design optimised for both patient performance and manufacturing efficiency.

Inclusive and Intuitive Design

The initial investment from the device maker entails inclusive design and testing strategies,

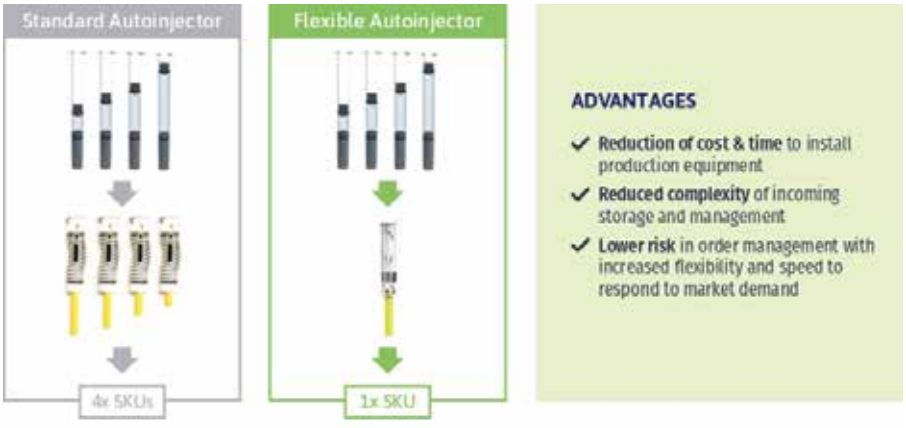

Figure 1 Advantages of a new, flexible autoinjector compared to a standard autoinjector

covering patients with differing physical and cognitive abilities (including some very small patient cohorts). As the specific user group is not known during design, platform devices must accommodate multiple patient groups – from carers administering medication to family members, to self-injecting elderly patients with limited dexterity.

Audible and visual notifications – e.g. audible clicks at the start and end of dose delivery and a clear viewing window – provide reassurance to users, for instance. Obscuring the needle during injection not only prevents needle exposure but may offer relief to patients with needle phobia. The effectiveness of platform products in meeting diverse needs can make them pivotal to commercial differentiation.

Streamlined, Sustainable and Scalable Manufacturing

With a platform product, the manufacturing scenario described above (one drug, six different fill volumes, two-three autoinjectors) is no longer a necessity. Line changes for each batch are simpler. The same lines can be used without modifying machinery like assembly equipment, labelling, blister packing, and uniform carton packaging.

Currently, in many organisations, line availability is reduced as manufacturers handle the numerous product Stock Keeping Units (SKUs) and device combinations needed for diverse dosage forms, along with manufacturing line changeovers. Optimising resource use, reducing waste, and strengthening efficiency can also help to minimise environmental impact in a sector where sustainability is often complex and even counter-intuitive.

Design-enhanced production efficiency is a prerequisite for effective scaling – a necessity as demand for autoinjectors grows, with populations ageing, incidence of chronic diseases rising, and pressure on healthcare systems deepening. Device manufacturers must therefore have robust scaling strategies in place. Demand and risk management may require supply chain strategies such as dual sourcing. Partnering with suppliers that have a global footprint to combine capabilities and increase manufacturing capacity ensures device makers' security of supply, allowing them to optimally manage demand.

Customisation Possibilities

How might platform devices be customised? As described above, such devices inherently adapt to different drug delivery requirements,

from fill volumes to user groups, ideally with minimal change parts needed. For higher viscosity formulations, manufacturers may consider customised spring force options – i.e. high drive for high viscosity and/or larger volumes, or low drive for lower viscosity and volumes.

With various syringe and RNS (Rigid Needle Shield) options available in the market, it is convenient if the drug delivery device is designed to accommodate a broad range. For drug filling, platform products enabling both vented or vacuum filling may also widen the choice of contract filling partners. Drug developers often have further specific criteria, such as branded labelling or patient information to communicate. Greater choice throughout eases the burden on manufacturers as they come closer to commercialising the final combination product.

From Afterthought to Forethought

In the long and pressurised drug development process, and with pharma teams primarily concerned with drug formulation and efficacy, device selection is often an afterthought. Earlier device assessment could however facilitate planning for future pipelines, in addition to current development drives. Identifying a platform device that functions with multiple drugs in a portfolio produces future efficiencies and simplifies decision-making. Versatile, thoroughly tested platform products offer drug developers reliable and consistent performance, reduced risk, and a more efficient path to market – even as the market evolves.

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