

Designing Auto-Injectors for Multiple Drug Viscosities

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Components—specifically springs used for device activation and needle retraction—play a key role in creating a flexible design. Pharma and biopharma OEMs need to engage spring suppliers at the very onset of new device planning.

The global injectable drug delivery market and, more specifically, the auto-injector market is booming. And that growth is predicted to continue skyrocketing through the next decade. According to a June 2016 report by Roots Analysis—a biopharmaceutical industry market research firm—the global auto-injector market is predicted to grow at a rate of more than 8% per year for the next 10 years. Another biopharma industry market research company, Mordor Intelligence, says the global injectable drug delivery market overall “... is estimated to be USD 40.5 billion for the year 2016. The market is expected to grow at a compound annual growth rate (CAGR) of about 18.1% during the forecasted period [edit.: 2016-2021] and reach USD 92.65 billion by the end of 2021.”

That data bears out in the real world as evidenced by increases in production at MW Life Sciences. Case in point: in 2016, MW Life Sciences produced 40-60 million springs across all drug delivery systems it supplies (including auto-injector devices), and in 2017, the company expects to double that figure, making 80-100 million springs.

With such a huge market in play, and given the range of physical properties of drugs and biologics being administered via auto-injectors, it is crucial for pharma and biopharma industry OEMs to optimize device designs to be as adaptable, and thereby as cost-effective, as possible. And that means bringing on board metal spring component manufacturers in the initial design phase.

How an Auto-Injector Comes to Market

A sizable portion of the global injectable drug delivery market’s predicted growth is due to the widespread increase in the self-administration of drug therapies, propelling the manufacture of auto-injectors like the EpiPen. The proliferation of that practice began at the behest of health insurance and managed care companies, which aimed to reduce the number—and expense—of physician office visits by enabling patients to inject themselves with treatments for chronic conditions. While the medical community pushed back, the pharmaceutical and biopharmaceutical industry saw the writing on the wall.

Pharma and biopharma OEMs began investing in the research and development of devices that could safely and effectively accommodate the self-injection of drugs and biologics. They enlisted and aligned world-class New Product Development firms (NPDs) and plastics and molding Contract Manufacturers (CMs) to design and produce new auto-injectors. Soon, that practice became routine.



Typically, a pharma OEM would contract an NPD to create an auto-injector around a new drug or biologic it is bringing to the market. The NPD would then begin research to plan the device design. The OEM would also contract a CM to mold the plastic components, specify and source the metal components, and send those to the OEM for final assembly, at which point the syringe is installed and the drug loaded. (In some cases, final assembly and drug-loading takes place at the CM, provided it has the capability to maintain the drug in a stable, climate-controlled environment. Due to their extreme sensitivity, biologics are nearly always loaded at the OEM.) Once the NPD locks down a working design, the CM typically manages manufacturing while the NPD shifts into a support and consulting role.

The Challenge: Creating One Design for Multiple Drugs and Biologics

Proper design of the plastic housing and specification of the material and size of the springs for any single-drug auto-injector are essential, but those tasks become even more vital and complex if an OEM wants to repurpose that same device for multiple drugs and biologics with varying viscosities. And that's where experienced metal component manufacturers are invaluable. The springs that control introduction of the surgical sharp or syringe needle, the delivery rate or dosage of the drug, and the automatic retraction of the needle are the most critical metal components of any auto-injector.

In practice, several big pharma OEMs have successfully launched a new auto-injector for a specific drug. But when they attempted to repurpose that device to accommodate other injectables, particularly biologics, they encountered problems largely due to differences in the viscosity of distinct medications. Drugs with different viscosities require springs with different physical characteristics—composition, length and thickness—to create spring rates that provide enough power to push higher viscosity drugs and biologics through the syringe to the needle, and achieve the precise amount of drug delivered. This includes the specified length of time for the syringe to be fired and the timely retraction of the needle at the end of that time period. Without knowledge of this complex science of metal performance and how it translates into the successful and accurate delivery of injectables with dissimilar viscosities, pharma OEMs (and their NPDs and CMs) are at a loss to use an existing auto-injector design for different drugs.

The Critical Role of Metal Springs

Auto-injectors come in many forms—pen-style (like the well-known EpiPen), trigger-activated, twist-and-depress, and more—but the majority require metal spring components designed to control the needle and achieve precise delivery of the drug.

Most auto-injectors contain a main spring and a return spring. With each application, a delicate dance occurs between the two. The rates of both springs work in concert to control the amount of medication delivered and the length of time it is administered. When engaged, a main spring must provide the necessary force to depress the syringe plunger within a specified time frame and surmount the device assembly friction to properly deploy the needle into the skin. A return spring must be able to counterbalance the remaining force of the main spring to safely retract the needle at an exact time. Both must be designed so they don't damage the plastic parts that comprise the rest of the device. If the metal springs are not meticulously fabricated to accommodate the viscosity of the specific drug or biologic involved, as well as to work smoothly within the confines of the device's plastic components, then the medication simply cannot be self-administered accurately and safely.

When you understand the interplay between the metal springs in an auto-injector and the correlation of their characteristics to the viscosity of the drug or biologic being delivered, it becomes obvious that there's no such thing as a one-size-fits-all auto-injection device. But that doesn't mean that a pharma OEM with a variety of drugs eligible for self-administration needs to design a completely unique device for each medication.



For such pharma and biopharma industry OEMs, the plastic housing and components of a device can actually be designed to accommodate springs with rates that vary by as much as 30-40%. Simply put, an auto-injector can be designed so that the metal spring components are interchangeable. In such cases, OEMs need to be thinking from the get-go about these possibilities and need to get a qualified metal component manufacturer involved in the device design process as early as possible. Doing so can save millions of dollars in R&D and production costs.

The Solution: Interchangeable Design

According to the National Center for Biotechnology Information (NCBI), “Recent studies confirm that the incidence of anaphylaxis ... is increasing world-wide.” The first line of defense for an anaphylactic reaction is the administration of epinephrine, often via an EpiPen. That rising need—combined with the growing trend to treat other common chronic conditions like diabetes, rheumatoid arthritis and multiple sclerosis via injectable drug self-administration—translates to an escalating need for auto-injection devices.

Given the vast number of auto-injectors projected to be produced in the future, the cost-savings that can be realized by using a single injector design with interchangeable springs is indeed remarkable. And the importance of having a collaborator that understands the material science of spring design— at the initial design phase—cannot be understated. That knowledge allows for:

- Producing precision springs and other metal components that perform consistently from device to device without failure
- Specifying the springs with the metal characteristics that allow the precise and accurate delivery of a drug or biologic of a given viscosity
- Understanding how springs with varying rates impact plastic housing and component design

All of that (and so much more) requires years of specialized experience, investment and research— not traditionally areas of expertise for NPDs or plastics and molding CMs. Only an experienced, highly- qualified metal component manufacturer can offer that knowledge. It is incumbent upon pharma and biopharma OEMs to directly engage such firms at the onset of device design. OEMs are starting to understand the importance of springs and other precision metal components in auto-injector design, and they want direct access to those fabricator-suppliers at the earliest stages of product development.

Using an example from MW Life Sciences, the company was brought on board early to work with a high-profile pharma OEM, its NPD and molding CM on a device design project whose final phase is launching now. With the metal spring manufacturer’s help, the NPD conceived an auto-injector to use with two completely different drugs under the OEMs purview. MW Life Sciences fabricated and is now supplying two different main springs with distinct rates to the molding CM to assemble into that same plastic device housing. To the naked eye, the springs look exactly the same, so MW Life Sciences came up with a brilliantly straightforward solution to prevent mix-up during assembly: It delivers the springs to the CM in different colored trays. The CM’s automation system can detect if the correct spring is being used simply by monitoring the tray color on the line. This example clearly illustrates the importance of including the spring manufacturer in the initial design, resulting in substantial savings in time and money.



Not Only Springs

Auto-injectors often have other metal components such as anti-fire mechanisms that prevent the device from accidentally triggering if dropped, or prematurely activating during self-administration and harming the patient. Many auto-injectors must be cocked or twisted to release these safety components so the trigger is free to release. Others have a built-in tip that acts as a trigger so the device won't fire until a certain level of force is achieved pushing it against the patient's skin. Numerous auto-injectors also are designed to be tamper-proof so that, if taken apart, they become inoperable and impossible to reassemble. It is wise to discuss the use of these types of components at the beginning of the design cycle so that the device can successfully accommodate all safety and performance requirements necessary.

Conclusion

The inclusion of the metal spring component manufacturer, along with the NPD and CM, in the initial design phase of injectable drug delivery systems— particularly auto-injectors, with their massive growth forecast—represents a huge potential savings in time and money to pharmaceutical and biopharmaceutical industry OEMs. It's a methodology that is being repeated more often today and will continue to spread in step with the market boom.

About MW Life Sciences

We act as a **close partner throughout development** to optimize product designs with collaborative solutions that help you deliver the best patient care at the highest total value.

We have the **advanced manufacturing capabilities** needed for medical device component and product manufacturing. We have the ability to engineer and manufacture metal components and assemblies such as springs, stampings, ultra-high precision machined parts, bellows and laser technologies.

We deliver a level of innovation that reduces partner-customer risk and supplier-managed quality that **simplifies your supply chain**, allowing you to bring your products to market faster.

Finally, because we have over 100 years of experience as well as a **commitment to quality** and to **developing long-term partnerships** with our customers, you can be confident in MW Life Sciences as your manufacturing partner.



MW LifeSciences

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