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Empowering Self-Administration

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SPECIAL FEATURE

Injection Devices: Wearables, Connectivity & Patient-Centric Designs Empower Self-Administration

By: Cindy H. Dubin, Contributor

The global self-injection devices market is expanding at a rapid pace due to high prevalence and incidence rate of chronic diseases, technological advancements, new product development and commercialization, and product differentiation strategies adopted by leading pharmaceutical companies worldwide. In terms of revenue, the global market was valued at \$3.7 billion in 2017 and is projected to reach \$11.3 billion by 2026.¹

“The high numbers of new injectable drugs projected to reach the market in the coming years, as well as the trend to move therapies from clinics into home settings to save costs and provide more convenience for patients means increasing demands for injection devices,” says Hans Jensen, Global Business Development Director, Consort Medical, Bespak Drug Delivery Devices.

The global self-injection devices market is also driven by a significant rise in demand for home health care, owing to low cost of treatment and improvements in overall patient experience.

The ability of self-administration is a key factor fueling demand for pen injectors. The pen injectors segment held a significant share of 67.6% of the market in 2017 and research indicates that it is likely to be the leading product segment, owing to the applications in diabetes, easy availability, and low cost, according to a report from Transparency Market Research.

Technological advancements in self-injection devices, especially in autoinjectors and wearable injectors, for the administration of high viscosity and large-volume drugs represents a potential business development opportunity for leading players. Reports suggest that the wearable injectors segment is projected to expand at a CAGR of 20% between 2018 and 2026.¹

“Traditional spring-based autoinjectors have previously been sufficient to deliver the drugs being developed, however many biologics by nature need higher doses to have an effect, which leads to higher viscosities and/or higher volumes to be delivered,” says Mr. Jensen. “Furthermore, others are working on viscous long-acting formulations to decrease frequency of injections, thereby increasing patient convenience. Finally, a number of drugs initially developed for IV administration in clinics are being re-formulated to allow home administration, but that also can result in high viscosity and/or higher doses which may not be appropriate for traditional autoinjector devices.”

This exclusive *Drug Development & Delivery* report highlights the innovation in injection devices – from wearables to connectivity to varied dose administration – that have occurred in the past year.

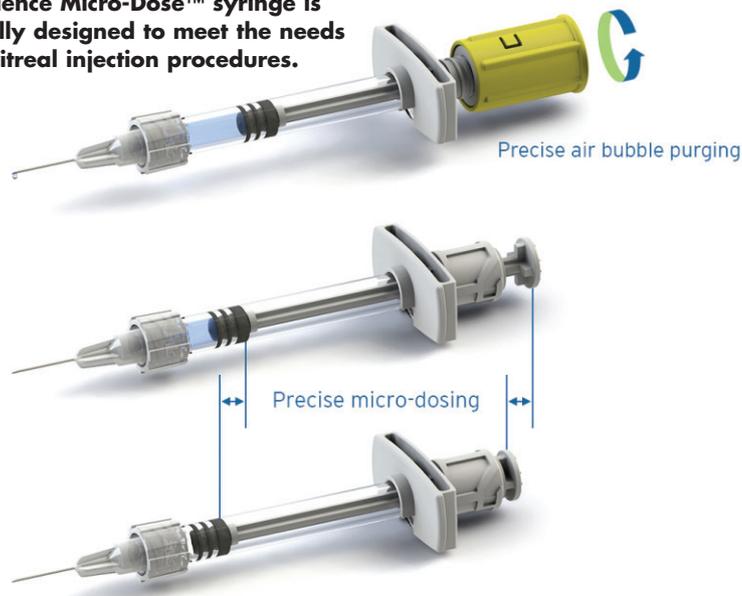
Credence MedSystems, Inc.: Overcoming the Challenges of Intravitreal Drug Delivery

With approximately 1.3 billion people worldwide victimized by some form of blindness due predominantly to macular degeneration, diabetic retinopathy, ocular vein occlusions, endophthalmitis, and re-tinitis,² and with the booming growth of the over-65 population from 630 million today to 1.2 billion in 2030, the pharmaceutical industry's focus on therapies delivered via intravitreal injection continues.³ This is leading to a forecasted growth in the intravitreal injectables market of 4.8% CAGR from 2018 to 2026.⁴

As with any therapy, delivery systems for intravitreal injections should seek to minimize safety risks, facilitate administration of the correct dose, and minimize disruption to pharma's established processes, says John A. Merhige, Chief Commercial Officer, Credence MedSystems, Inc., which has developed the Micro-Dose™ Syringe System. Mr. Merhige says the design of Micro-Dose reduces the unwanted variability during use that can lead to patient risk. "Intravitreal injections have specific challenges related to the sensitivity of the injection site and the extremely low dose volumes, which are in the 50µL range for conventional indications and even lower for newer therapies," he says.

For example, air injected into the eye causes significant pain for the patient. With Micro-Dose, the clinician purges the air bubble in a controlled manner by turning the safety cover until it automatically detaches, revealing the thumbpad. In addition to adding a greater level of certainty that the air will be purged, this process eliminates the drug spillage that can occur in conventional debubbling from overcoming

The Credence Micro-Dose™ syringe is specifically designed to meet the needs of intravitreal injection procedures.



the plunger break-loose force. With such low volumes, any significant spillage will lead to underdosing, says Mr. Merhige.

"The conventional procedure is further susceptible to mis-dosing due to its inherent variability," he says. "With the conventional injection process, the clinician is required to eyeball the correct dose by attempting to place the plunger adjacent to a dose line on the syringe," he explains. "This variability leads to the risk of under or overdosing."

With Micro-Dose, the clinician simply presses on the plunger rod until it stops moving. The permitted travel length of the plunger rod determines the dose 'by design,' enabling an extremely precise delivered dose. Additionally, Micro-Dose allows the clinician to achieve a comfortable grip, unfettered access to the injection site and efficient completion of the procedure.

The system is compatible with conventional needles or can incorporate Credence's proprietary needle-retraction system. An additional option exists to include a feature that reduces the user force required for injection of viscous products. Mr. Merhige adds that Micro-Dose has been designed to allow implementation

without disrupting already validated primary package choices or manufacturing operations. The design incorporates few additional components and is compatible with any prefilled syringe. Secondary assembly on already-filled syringes is straightforward in implementation on existing processes.

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