

Drug Delivery Trends to Overcome Industry Challenges

Navigating the Rise of Injectables, Quality Control Measures, and Personalization

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As of May 2019, the global drug delivery systems market was expected to reach US\$ 2,302.2 billion in 2027 from US\$ 1,243.1 billion in 2018 with a CAGR of 7.2 percent from 2019-2027.¹ That was prior to the COVID-19 outbreak and it is unknown exactly how the virus will impact the global market. Up until recently, much of the growth could be attributed to a range of developments over recent years—particularly innovations and advancements in healthcare for the modern patient. The growth of injectables, personalized medicines, and customized drug delivery solutions are just a few trends that have emerged to address industry challenges.

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Chronic Disease and Key Advancements Propel Injectables

Increased prevalence of chronic diseases is a significant factor driving demand for injectable biologics.² Others include the enhanced convenience, ease of use, and reduced pain of today's injections, which add to the merits of injectable biologics. However, the growing use of injectables pose certain challenges to drug manufacturers.

Compared to oral medications, injectable biologics are less stable molecules and difficult to manufacture. This characteristic makes them more susceptible to contamination with a particular sensitivity to particulate, silicone and protein aggregation. Increased risk for contamination requires companies to implement primary packaging solutions designed with these sensitivities in

mind. Examples include plungers and stoppers spray coated with a no silicone-added fluoropolymer coating to prevent contact between the drug and naked rubber. Injectable biologics can also have high viscosity, necessitating unique functionality specifications on parenteral packaging components. By using a fluoropolymer coated plunger, highly viscous drugs can be delivered in a consistent manner without the introduction of silicone.

Quality Takes Control

Since injectable biologics also present a higher immunogenicity risk to patients, authorities' expectations for quality control are escalating. As such, manufacturing environments must meet the more stringent regulatory and quality demands placed on the primary packaging solutions for these applications. Implementing 100 percent camera inspection minimizes the accidental use of defective components. Utilizing vacuum sealed bags for Ready-to-Use (RTU) components add a layer of security by indicating—through the absence of vacuum—if a bag may have been compromised in transport. This enables a manufacturer to reject a single bag if it were jeopardized as opposed to rejecting the entire batch. When coupled with flexible production capabilities to accommodate smaller batch sizes, these measures help to better preserve the drug, protect patients and uphold the reputation of the company.

Value-based Care Drives Personalization

The healthcare industry has begun to shift toward value-based care in an effort to better address patient needs. This has prompted pharmaceutical companies to place a greater emphasis on providing drug delivery

¹ <https://www.marketstudyreport.com/reports/drug-delivery-systems-market-to-2027-global-analysis>

² <https://www.marketsandmarkets.com/Market-Reports/injectable-drug-delivery-market-150.html>

methods tailored to individual patients. As such, personalized medicine has become a natural step in this direction.

Personalized medicine requires unique delivery designs and functionalities. It can take medical device manufacturers two to seven years to commercialize a prototype such as prefilled syringes or autoinjectors, depending on the complexity of the design as well as resources, time and equipment. Moreover, these products would come in much smaller batch sizes than standard drugs, which also requires flexible manufacturing.

Though this move from standardization seems daunting, personalized medicine comes with a myriad of benefits. Most importantly, companies will be able to better engage with patients to ensure that drugs are being delivered in more effective ways. Beyond that, personalized medicine offers product differentiation for better brand recognition in the market. This opens the door for patented products and better equips manufacturers guard against 'copy-cats.'

Customized solutions such as stoppers and plungers used in prefilled syringes or autoinjectors, can be designed from the ground up with close collaboration to ensure FDA requirements are being met while fulfilling the goal to personalize drugs and delivery methods. This approach can also speed time to market for components created for personalized medicine delivery.

Drug Delivery Innovation Rests on the Details

With these emerging drug delivery trends, companies need to be equipped to catch up or stay ahead of the curve. Companies can implement superior primary packaging and streamline their production processes in cleanroom environments. This allows manufacturers to mitigate contamination threats and even improve personalization and customization capabilities. Careful consideration of what materials and processes are used to develop components like plungers and stoppers, make advancement in syringes, autoinjectors, and other medical devices possible.

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