Innovating Drug Delivery to Carry Us to the ‘New Normal’

Rahul Thakar, Technical Key Account Manager

The growth of injectables, personalized medicine, anti-counterfeiting measures, and automation are a few trends that may follow the industry into a new normal.

Before the COVID-19 outbreak earned its designation as a pandemic, a December 2019 Market Study Report projected the global drug delivery systems market would grow at a CAGR of 7.2 percent to $2.3 trillion in 2027.1 While it’s unclear what the full impact of the virus will be, we can speculate the growth will continue. It’s important to remember, however, this expansion was originally propelled by many factors, including innovations and advancements to better service patients—for which need will not disappear any time soon. The growth of injectables, personalized medicine, anti-counterfeiting measures, and automation solutions are just a few trends that may follow the industry into a new normal.

Injectable Therapies on the Rise

The use of injectables has grown across treatments for a wide range of chronic diseases including cardiovascular, gastrointestinal, central nervous system, respiratory, oncology, infectious disease, and urological problems. A major factor propelling the growth of injectable biologics is the increased prevalence of the chronic diseases themselves. According to the CDC, six in 10 adults in the U.S. have a chronic disease and four in 10 adults have two or more.2 Additionally, advancements in the convenience, ease of use, and

reduced pain of today's injectables have made them less daunting to patients as well as safer and more ergonomic for medical professionals who must administer them. This trend poses certain challenges, however, to the industry at large. Injectable biologics contain less stable molecules, making them more difficult to manufacture than oral medications as they are more susceptible to contamination from particulate, silicone, and protein aggregation. This added risk can be mitigated with primary packaging solutions designed around these sensitivities, such as plungers and stoppers spray coated with a no-silicone-added fluoropolymer coating to prevent contact between the drug and naked rubber. Injectable biologics are also often highly viscous, requiring unique functionality requirements on parenteral packaging components to ensure the drugs can be delivered consistently.

Greater Personalization

To better address unique patient needs, the healthcare industry as a whole started to shift toward value-based care. As a result, pharmaceutical companies aim to provide drug delivery methods tailored to individual patients. However, personalized medicine requires unique delivery designs and functionalities that can take pharmaceutical companies two to seven additional years to commercialize depending upon the complexity of the mechanism, as well as resources, time, and equipment. Additionally, personalized drug delivery mechanisms are manufactured in smaller quantities in line with smaller batch sizes than standard drugs, requiring flexible manufacturing practices.

Despite the challenges that come with developing and manufacturing personalized medicine, the resulting solutions help companies better engage with patients to ensure drugs are being delivered in more effective ways. Personalized medicine also facilitates product differentiation and better brand recognition in the market, enabling drug manufacturers to better guard against 'copy cats.' Customized solutions such as stoppers and plungers used in prefilled syringes or autoinjectors can be designed in close collaboration between drug developers, device manufacturers, and components suppliers to ensure FDA requirements are being met while fulfilling the goal to personalize drugs and delivery methods. This collaboration implemented early in the process can help to speed time to market.

Autoinjectors for Convenience and Differentiation

According to an August 2019 study—Autoinjectors - Market Analysis, Trends, and Forecasts by Global Industry Analysts Inc.—the worldwide autoinjectors market is projected to grow by 22.5 percent between 2019 and 2025, with cases of rheumatoid arthritis representing a significant factor propelling that growth.3 Autoinjectors and on-body delivery devices require specialized designs for unique drug delivery needs, lifecycle management, or to improve patient experience. Increasingly, the companies that manufacture these devices seek customized solutions as to differentiate from the competition, which in turn, requires the use of customized rather than off-the shelf components. Specifying unique dimensions and functionality impacts elastomer requirements and rubber formulations. This dynamic alters the path to production, requiring the development of prototypes, testing for functionality and chemical compatibility, and further optimization based on the results. It can be a longer process to lock in the perfect design before scaling up for production, so efficiency in that process is critical. Companies ranging from the smallest biotech firms to the largest drug manufacturers, however, can find value in the differentiation. As patent cliffs approach,

companies of all sizes tend to innovate and invest their intellectual capital in the drug delivery mechanism to ensure superior performance.

Combatting Counterfeiters

Furthermore, all drug manufacturers have a good reason to invest in highly differentiated drug delivery solutions: fighting the avalanche of counterfeit drugs. In 2019, American doctors published a piece in The American Journal of Tropical Medicine and Hygiene stating that “falsified and substandard medicines are associated with tens of thousands of deaths, mainly in young children in poor countries” and “exact an annual economic toll of up to $200 billion.4 In March, the U.S. Justice Department issued a temporary restraining order against a website marketing a fraudulent coronavirus vaccine.5 The growth of counterfeit drugs on the market can be considered its own pandemic. Aside from the necessary vigilance of the World Health Organization and government agencies around the world to identify and remove counterfeit drugs from the marketplace, companies can also combat counterfeiters through product differentiation and product education.

Developing highly differentiated packaging for parenteral drugs with nuanced identifiers, serial numbers, barcodes, custom color components, and other design measures enhances the trackability of legitimate drugs as well as the identification properties for doctors and patients to verify the authenticity of medications.

Enhancing Quality Control

Injectable biologics present a higher immunogenicity risk to patients, escalating authorities’ expectations for quality control and mandating that manufacturing environments meet the more stringent regulatory and quality demands. These requirements inevitably extend to primary packaging solutions for these applications. Measures such as 100 percent camera inspection of components can minimize the accidental use of defective components. The use of vacuum sealed bags for ready-to-use components also adds a layer of security by indicating—through the absence of vacuum—if a bag may have been compromised in transport so that a drug or medical device manufacturer can reject a single compromised bag instead of rejecting the entire batch. Additionally, cellulose is a common contaminate found in medications that can be reduced by removing paper, paperboard boxes, and wooden pallets from manufacturing floors of medical devices and related components. Combined with flexible production capabilities and small-batch production, these measures boost both drug preservation and patient protection.

Decentralizing Supply Chain Resources

We are living in what will undoubtedly be a defining case study to support the decentralization of medical supply chains. As COVID-19 extends its toll across the world and countries implement social distancing and other sanitation and testing measures to “flatten the curve,” we see a staggered impact across the globe. As nations like China relax regional quarantine measures, others are implementing stricter restrictions to shrink the peaks in cases and deaths. Realistically, no single company has the capacity to produce billions of dose units by 2022 unless many work together.

Collectively, companies can play a significant role in helping the world overcome this global challenge. However, scaling of production and ensuring a fluid supply of chemically compatible components requires the navigation of workforce and supply chain challenges from the lab to transportation of the final product. It takes a sophisticated supply chain network as well as plug-and-play sourcing solutions around the world to keep the operation running through all the regional obstacles to project and proactively mitigate shortfalls.

Small Details Can Solve Big Problems

When the world emerges from the COVID-19 pandemic, there is sure to be high-level theorizing about sweeping changes that will prevent the next crisis. However, those professionals who work closest to the actual development of medical devices and drug delivery solutions also know attention to detail drives the innovation that makes critical medications accessible and effective—from material selections to design criteria to the behind-the-scenes supply chain modifications. Drug delivery innovation is built on the details.

References

https://www.marketwatch.com/press-release/at-72-cagr-drug-delivery-systems-market-size-to-reach-23022-bn-by-2027-2019-12-03bit.ly/mpo200522

https://www.cdc.gov/chronicdisease/resources/infographic/chronic-diseases.htmbit.ly/mpo200524

https://www.businesswire.com/news/home/20190812005342/en/Global-Autoinjectors-Market-Set-Grow-22.5-2019-2025

https://www.ajtmh.org/content/journals/10.4269/ajtmh.18-0981

https://www.justice.gov/opa/pr/justice-department-files-its-first-enforcement-action-against-covid-19-fraud

Rahul Thakar, Ph.D., is a technical key account manager with Datwyler, and has over 10 years of product development experience in pharmaceutical and chemical sciences. In his current role, Dr. Thakar consults with pharmaceutical and medical device companies on parenteral packaging solutions to develop safe and efficacious drug-delivery systems. He holds global responsibility for several key clients, where he is responsible for technical projects from the ideation to the commercialization stage. Within Datwyler, he is also leading strategic collaborations with external partners for product portfolio expansion and product innovation. Dr. Thakar received his B.S. in chemistry (major) and business (minor) from St. Stephens College, University of Delhi. He was awarded his Ph.D. degree in material science and analytical chemistry from Indiana University, Bloomington. His graduate research was focused on design and microfabrication of bioanalytical devices for electroanalytical measurements.