Auto-injectors: A Revolutionary Leap in Drug Delivery

In recent years, the biopharmaceutical industry has experienced a paradigm shift with the increasing prominence of auto-injectors. In 2023 the global auto-injector market size is USD 9.34 billion and is expected to grow at a CAGR of 16.05% to USD 19.67 billion by 2028.[1]

This rapid growth is driven by the increasing adoption of self-administration devices across various therapeutic areas for allergies and lifestyle and chronic diseases such as psoriasis, diabetes, multiple sclerosis, and rheumatoid arthritis. Biopharmaceutical companies are actively incorporating auto-injector drug delivery technology into their product portfolios, recognising the competitive advantage these devices offer in terms of differentiation and patient satisfaction. As a result, the auto-injector market is witnessing a surge in innovation, with companies investing in research and development to enhance device features and compatibility with a diverse range of biologic drug products.

These user-friendly drug-device combination products have revolutionised drug delivery, offering patient's greater convenience, accuracy, and control over their treatment regimens. As the demand for biologic therapies continues to grow, auto-injectors are emerging as a key drug delivery mechanism in enhancing patient adherence, reducing healthcare costs, and improving overall treatment outcomes.

Benefits of Auto-injectors

1. **Precision in drug delivery:** auto-injectors are designed to administer precise doses of biologic drug products, ensuring accurate and consistent delivery. By automating the injection process, auto-injectors minimise the risk of human error, providing a level of accuracy that is paramount in the treatment of complex conditions such as autoimmune disorders and chronic diseases.
2. **Safety and reduced risk of contamination:** auto-injectors are designed to minimise the risk of contamination and infection associated with traditional methods of drug administration such as vials and syringes. The sealed, prefilled cartridges or syringes used in auto-injectors protect the medication from external contaminants, ensuring the integrity of the drug product. Additionally, the automated injection process reduces the likelihood of accidental needle stick injuries, enhancing safety for both patients and healthcare providers.
3. **Patient-Centric Approach:** The surge in auto-injector usage can be attributed to the growing emphasis on patient-centric healthcare. These devices empower patients to self-administer medications in the comfort of their homes, eliminating the need for frequent hospital visits. The user-friendly design of auto-injectors, often featuring intuitive interfaces and ergonomic grips, enhances patient compliance and reduces anxiety associated with traditional injection methods. This change towards at-home administration not only improves patients' quality of life but also reduces the burden on healthcare infrastructure.

Market Expansion and Technological Advancements

The global auto-injector market has experienced remarkable growth, driven by continuous technological advancements and collaborations between pharmaceutical companies, device manufacturers and partnering Contract Development and Manufacturing Organisations (CDMOs). Companies are investing in research and development to enhance the capabilities of auto-injectors, including features such as connectivity for real-time monitoring and dose tracking. The expanding market is also witnessing the integration of smart devices and data-driven solutions, further optimising patient care and treatment outcomes.

Advanced Drug Delivery Solutions at PCI Pharma Services

With the pharmaceutical industry's growing pipeline of biologics, the need for technically advanced sterile manufacturing and specialised advanced drug delivery assembly and packaging support has grown considerably. Committed to being a market leader in the packaging of biologic drug products for our global clients, our goal is to support our customers in safely, and efficiently bringing their novel therapies to patients.

Driven by innovation and patient-centricity, our design and development expertise combined with our device assembly and advanced drug delivery packaging capabilities offer flexible solutions for a diverse portfolio of conventional and specialty injectable drug-device combination products. We have the scalability to handle the dynamic volumes of biopharmaceutical therapies, whether large or small, from niche personalised medicines to large-volume treatments.

Expert Advice from Device Strategy to Packaging Design

With a global network of experts with experience in advanced drug delivery, PCI can provide guidance at critical time points to assist you developing an optimum patient-centric drug-device combination product.

Our deep industry experience can help determine the best device strategy for your patient and drug product, from the use of established well-accepted platforms that have received regulatory approval as part of a drug-device combination product, which may be deemed lower risk for a new program, or alternatively, a more innovative device approach which may be deemed more attractive for specific patient populations compared to that of more traditional and readily available platforms.

PCI's pharmaceutical packaging design department provides an innovative and value added service. Our dedicated team of in-house design specialists deliver insightful packaging design and practical knowledge to deliver differentiated and cost-effective packaging solutions. Working with our client partners as early as possible during their drug products clinical phases, our design department together with a cross-functional network of experts in sterile drug product manufacturing, engineering, operations and approved vendors develop expert design processes focused on

human-factors engineering and technical functionality, and deliver optimised designs for manufacturability, scalability and automation. This seamless solution ensures that key considerations are addressed at the right time, leading to both cost and time efficiencies and ultimately ensuring speed to market.

Expanding Our Drug-device Combination Capabilities and Capacities

Complementing the continued growth and investment across our sterile manufacturing network, we continue to expand our European, North American and UK Centers of Excellence for clinical and commercial packaging. These state-of-the-art facilities are equipped with advanced drug delivery packaging technologies for the assembly and labeling of vials, cartridges, standard pre-filled syringes, advanced safety syringes, auto-injector and pen devices complete with integrated top-load cartoning and in-line serialisation.

Most recently we announced an investment of $150M in a new 200,000 sq ft facility at our Rockford, IL, site to meet the growing biologic market need of specialised assembly and packaging for injectable drug-device combination products. With over 20 dedicated suites, the new facility will support the assembly and packaging of vials, pre-filled syringes, auto-injectors, on-body injectors and pen-cartridges such as those for glucagon-like peptide 1 agonists (GLP-1) for treatment of diabetes and obesity as well as those needed for oncology treatment and autoimmune diseases.

Flexible, Scalable Auto-injector Assembly

As a global leading CDMO, PCI provides highly flexible, reliable advanced drug delivery packaging solutions to meet the dynamic needs of our client's. Meeting the exponential growth in the development and use of auto-injectors, PCI continues to invest in innovative scalable auto-injector assembly and labeling technologies.

Although many auto-injector devices have similar components, their design varies in terms of size, material and shape. With true customer focus and flexibility at the core of our injectable packaging service offering, our technologies can adapt to the unique requirements of each global market from concept to commercialisation.

For example our specialised clinical and low-volume commercial auto-injector assembly line provides a multi-platform auto-injector solution including Ypsomed Ypsomate, SHL Molly, Becton Dickson (BD) Physioject alongside other platform devices. It also has the capability to assemble and label needle safety device platforms such as BD Ultrasfe/Plus and Nemera Safe & Sound making it the ideal technology for development studies, clinical trials and niche orphan drugs.

Providing an integrated scalable solution, our mid- to high-volume commercial assembly technologies are also able to accommodate various auto-injectors types from different manufacturers at a larger scale for product launch and commercial market supply. Supporting true customisation, the RDA can easily and cost-effectively be retooled for future new auto-injector types allowing us to respond quickly and efficiently to technological changes and future innovation.

Seamless Solutions

At PCI, ensuring life-changing medicines reach those who need it most is our highest priority. As a truly integrated global CDMO, we are manufacturing, packaging and supply chain experts, harnessing our experience and expertise to deliver seamless solutions with the ultimate aim of improving the lives of patients.

Providing expert sterile fill-finish and lyophilisation solutions from development to commercialisation together with integrated custom assembly and packaging solutions for sterile injectables allows for ultimate knowledge sharing and communication between teams to ensure the drug product packaging is optimised for the product, patient and production.

With in-house laboratories we provide a range of packaging and analytical services to support client's development, clinical and commercial supply of medicines globally. From product ID testing, method transfer, release and stability testing to auto-injector system testing with ISO 11608 functional tests such as cap removal force, activation force, extended needle length, dose accuracy, injection time, and lockout force, we ensure your life-changing therapy meets regulatory guidelines and is safe for patient use.

Conclusion

The widespread adoption of auto-injectors represents a transformative leap in the biopharmaceutical industry's approach to drug delivery. These devices offer a compelling solution to the challenges of precise dosing, patient adherence, and safety, particularly

in the context of the rising prominence of biologics. As technology continues to advance and regulatory frameworks evolve, auto-injectors are poised to play an increasingly integral role in shaping the future of drug administration, offering patients a more accessible, convenient, and personalised healthcare experience.

As a leading global CDMO, as part of our strategy to support advanced drug delivery for novel molecules, PCI's integrated sterile drug manufacturing and injectable packaging solutions supports our client partners in optimising dosing and providing convenient, easy to use, patient-centric therapies to patients. We not only want to meet growing demand for scalable sterile manufacturing and advanced drug delivery packaging, but through innovative value add solutions we aim to exceed our customer expectations, delivering flexibility and excellence in all that we do to accelerate the development and commercialisation of life-changing therapies.

REFERENCES

1. https://www.mordorintelligence.com/industry-reports/auto-injectors-market

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Bill Welch is Executive Director of Services for PCI's advanced drug delivery segment, with focus on injectable drug-device combination products. Bill has over 30 years of contract development and manufacturing experience, with over 20 in drug delivery devices and combination products. Prior to joining PCI, Bill served as Chief Technology Officer at Phillips-Medisize, leading a 900 person global innovation, development and new product introduction services segment. Bill holds a B.S. in Industrial Engineering from the University of Minnesota, Duluth.