

## **SPECIAL FEATURE - Prefilled Syringes & Parenteral Contract Manufacturing: Biologics Present a New Set of Challenges**

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Parenteral drug delivery is the second largest segment of the pharmaceutical market and accounts for nearly 30% of the market share. Currently, around 3.5 billion prefilled syringes are produced each year and that number is growing between 9%-10% annually. The *Future of Alliances and Partnerships in the Prefilled Syringes Market to 2020* forecasts that the global market for prefilled syringes will hit \$6.6 billion in 2020, up from \$3.9 million in 2014.<sup>1</sup>

The surge is being attributed to an increasing geriatric population, increasing demand for vaccines, increasing prevalence of chronic diseases, and technological advancement in prefilled syringes. In addition, the demand for point-of-care administration and regulations regarding needlestick injuries are driving the growth of the global prefilled syringes market.<sup>2</sup>

There is also a shift in demand for biologics and biosimilars. In fact, nine of the top-10 drugs available in prefilled syringes are now biologics and the majority of these are used for treating chronic diseases such as diabetes, rheumatoid arthritis, and multiple sclerosis.

As the parenteral drug pipeline continues to move from small molecules to complex biologics such as monoclonal antibodies (mAbs) and antibody drug conjugates (ADCs), biological therapies provide unique challenges for parenteral drug delivery, such as volume and viscosity.

Other challenges are prevalent as well, including quality concerns, strict regulatory requirements, interaction of prefilled syringes with drugs, manufacturing complexity, combination therapies, and lyophilization. Additionally, aseptic processing of parenterals involves challenges such as protecting the sterility of a product as it moves through each phase of formulation, filtering, filling, and packaging.

Due to the complexities of syringe manufacturing, the contractor market is growing. According to Frost & Sullivan, sterile parenteral contract services make up about 82.8% of the total sterile CMO market. This includes small-volume parenterals (vials, ampoules, and syringes), which make up the majority of sterile CDMO services with 88.9% of market share. The sterile parenteral manufacturing sub-segment is expected to reach a market size of \$6.5 billion by the end of 2016.<sup>3</sup>

In this exclusive *Drug Development & Delivery* report, syringe developers and contract manufacturers discuss how they are overcoming the challenges discussed above and provide a look at some advancements in prefilled syringe technology.

## **ALTHEA: KEEPING UP WITH THE INCREASED PREFERENCE FOR PREFILLED SYRINGES**

During the last few years there has been tremendous growth in sales and units of prefilled syringe versus other injectable dosage forms. Althea prepared for this favorable market condition by investing in a new syringe line, which became commercially approved last year. “Our capacity utilization has increased substantially over the past year and we have seen a marked increase in the number of biosimilar/biobetter-based drug programs,” says Don Paul Kovarcik, Technical Marketing Specialist, Althea. “We anticipate this trend to continue as more branded drugs go off patent.”



Initially in the biologics segment, vials were the gold standard. After conducting trials, the developer would switch to prefilled syringes just before commercial launch, explains Mr. Kovarcik. In cases where clients use alternative primary container systems, Althea works with them to ensure they are compatible with automated filling systems.

Recently, however, many developers have decided to simply start out using prefilled syringes. “Because of this change, Althea has started to do a lot more prefilled syringe work much earlier in the development process and sometimes even in the preclinical stage.”

Critical to prefilled syringes is manufacturing high-quality product the first time. Manufacturing success is dependent on a robust and reproducible process. To this end, Althea has been advocating for its pharmaceutical partners to bring forward their prefilled syringe programs in the earlier stages of development. “That way we can identify any gaps in the production processes, which allows us sufficient time to work through any issues prior to clinical studies and commercial launch,” says Mr. Kovarcik.

## **APTAR STELMI: ELASTOMERIC CLOSURE SYSTEMS FOR SENSITIVE INJECTABLES**

Aptar Stelmi designs and manufactures elastomeric closures: stoppers for vials, and prefilled syringe and cartridge components such as plungers, needle shields, and tip caps for all parenteral applications. The most recent addition to its product portfolio is the PremiumCoat™ coated serum stopper designed for the protection of sensitive and high-value drugs, including biopharmaceuticals.

**With Aptar's PremiumCoat serum stoppers, a barrier film covers the drug contact area. (Photo courtesy: Aptar Stelmi)**



Based on an approved, pure, state-of-the-art formulation, the surface of the elastomer is coated during manufacturing with an ETFE film. This coating acts as a barrier to many of the extractables and leachables that can be released from the elastomer. As a result, compatibility of the drug and the closure is improved. The first design released in 2015 was the 20-mm coated stopper, and a 13-mm coated stopper will soon be available.

## **CATALENT PHARMA SOLUTIONS: HELPING CLIENTS COMPLY WITH CGMPs FOR DEVICES**

A notable trend in the market for sterile injectables has been toward self-injection or autoinjector devices, which have become increasingly popular over the past few years as a means of improving patient compliance and helping prevent needlestick injuries. Catalent has actively supported customers in this market segment by implementing the necessary steps to fully comply with Current Good Manufacturing Practice regulations for devices [21 CFR 820 (cGMP)] from a quality and regulatory assurance viewpoint.

“These regulations require a focused approach, with design reviews performed across the different parties involved: the assembly site, the final customer, primary component supplier, autoinjector parts supplier, and the machine manufacturer,” says Wim Blendeman, Director New Product Introduction, Advanced Delivery Technologies at Catalent. “These reviews are important to determine the Critical Quality Attributes (CQAs), Critical Process Parameters (CPPs), and to put final design controls in place in order to supply the final product reliably.”

The majority of the investment in a typical project is made prior to starting the assembly process and the design is checked and verified prior to starting clinical assembly. Using information gained through the executed process, In-Process-Controls (IPCs), Acceptable Quality Limits (AQLs), Process Control Limits (PCLs), and process reviews need to be implemented and checked for effectiveness. These data must also be supported by a risk assessment and facilitate the drafting of a User Requirement Specification (URS) for a fully automated assembly line. “Due to the precise and unique nature of the autoinjector market, equipment is, in most cases, specifically designed to support each type of autoinjector,” says Mr. Blendeman.

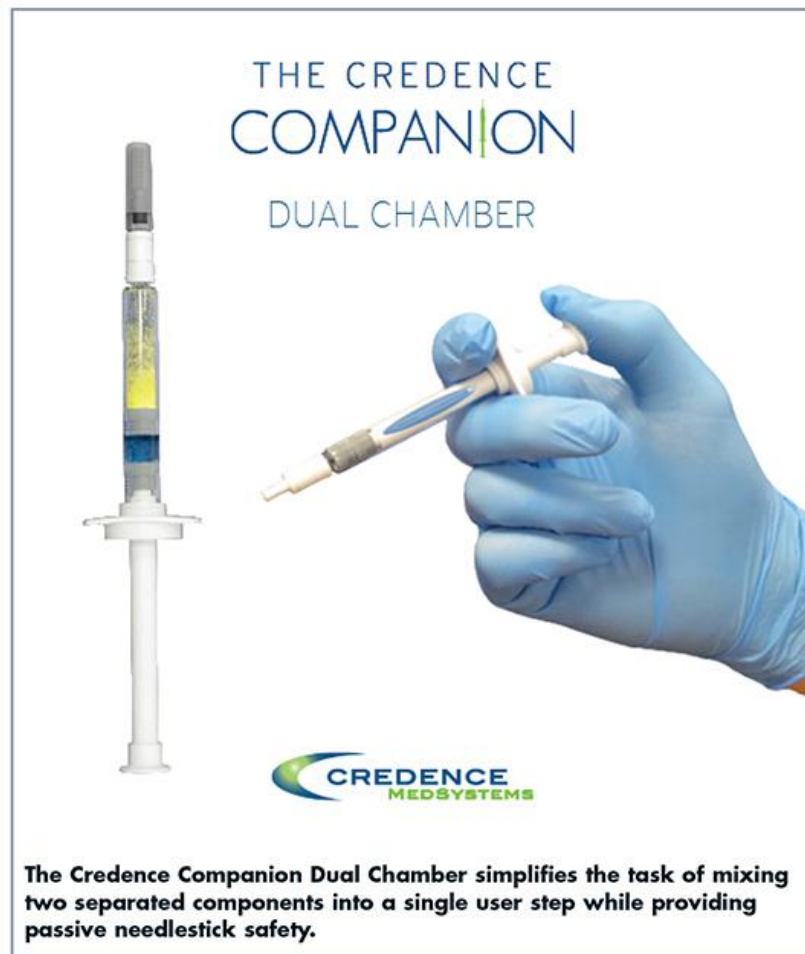
## **CREDENCE MEDSYSTEMS: ADDRESSING THE NEED FOR INNOVATION IN RECONSTITUTION SAFETY DEVICES**

The growth of biologic parenterals in the commercial and pipeline portfolios of drug manufacturers has been well documented. These biologics are often formulated as powders, in lyophilized or spray-dried form, when unstable in solution. Additionally, there are an increasing number of applications requiring separation of two liquid components during storage. Because of this, the number of drugs that require reconstitution or mixing at the point of injection has increased.

The conventional approach to reconstitution includes multiple vials, syringes, needles, and/or vial access components, and an arduous mixing and administration process that contribute to inefficient workflow, dosage errors, wasted drug product, and needlestick exposure, explains John A. Merhige, Chief Commercial Officer, Credence MedSystems. The industry has seen attempts to improve upon this approach with vial mixing devices and multi-chamber syringes and cartridges.

“While the dual-chamber offerings that are available or in development have been evolving, there remain limitations with regards to efficient manufacturability, supply chain availability, cost, usability, and safety that have placed barriers on adoption,” he says. “With the delivery of

healthcare moving from formal medical settings to the home, and medications increasingly being administered by self-injectors, the industry is in need of an injection system that allows those complex biologics requiring point-of-care mixing to be injected easily and safely by less experienced users.” To address this market need, Credence MedSystems has developed and recently introduced its Companion Dual Chamber Reconstitution Safety Syringe technology. “The Companion Dual Chamber shares the *Innovation Without Change* design philosophy that is seen across Credence’s other safety syringe systems, maximizing the usability and safety of the device while minimizing the change from existing primary package components and supply chain dynamics,” says Mr. Merhige.



The Companion Dual Chamber simplifies the task of mixing two separated components into a single step. The user advances the plunger rod as in a conventional injection, creating a newly formed center channel through the standard stopper, and allowing the contents of the rear chamber to pass into the front chamber where they are combined together for mixing.

Beyond the simplification of the mixing process, the Companion Dual Chamber provides important safety and usability features. A pre-attached needle reduces yet another user step, but also provides the key to an integrated passive safety system; the user simply completes the injection (marked by an end-of-dose click) and then the needle automatically disappears

through the stoppers and into the plunger rod and syringe barrel. The syringe cannot be reused and is now rendered safe for disposal.

Existing approaches to dual chamber devices all use some combination of customized primary package components: bespoke glass barrels with external or internal bypasses, stoppers with specialized internal channels or wiper blades, etc. “These customized components drive high costs, long lead times, captive supply chains, and the potential for product failure and complaints stemming from a dependency on primary package components that do not have a proven history in the field,” says Mr. Merhige.

The Companion Dual Chamber uses a standard, uniform diameter glass barrel (syringe or cartridge), standard stoppers, and standard needle shields from well-known component suppliers. Additionally, the Dual Chamber is glue-free, eliminating any risk of interaction between glue and the drug product. “The combination of single-step mixing, end-of-dose cues, passive needlestick safety, and reuse prevention makes the Companion uniquely suited to enable a broader utilization of point-of-use mixing devices in the home and healthcare provider markets,” he says.

#### **ENABLE INJECTIONS—WEARABLE DEVICES MAKE BIOLOGIC SELF-ADMINISTRATION POSSIBLE**

Recent discussion in the industry has centered on reducing overall healthcare costs by eliminating waste associated with excess drug that is thrown away. For example, many biologic drugs must be infused intravenously by a healthcare professional, typically at a hospital. Healthcare costs could be significantly reduced, compliance increased, and patient convenience vastly improved if patients could safely and easily self-administer such drugs subcutaneously at home without the aid of a healthcare professional, believes Mike Hooven, CEO and President of Enable Injections.

To that end, Enable Injections is developing a new class of wearable on-body drug delivery devices capable of delivering higher volumes and viscosities with minimal discomfort.

The new generation of wearable injectors feature improvements in construction materials, injections process, and safety features, meant to overcome the challenges of delivering large-molecule and high-volume biologics. For example, Enable Injections’ on-body delivery system (OBDS) is designed with a proprietary S.E.T. (sequential elastomeric toroid) mechanical drive system. The force required to deliver the drug does not change with the volume, and the needle size is the smallest available, typically 31g.



**The Enable OBDS features improvements in materials and safety features for in-home delivery of large molecules.**

“Advancements with wearable injectors offer the opportunity to revolutionize biological therapy treatments, especially those treating chronic conditions that struggle to attain positive clinical outcomes due to patient adherence,” says Mr. Hooven.

While the Enable OBDS is not yet approved or commercialized, independently conducted User Preference studies demonstrate a high acceptance of the technology by patients and caregivers, says Mr. Hooven. “Obtaining this information provides confidence that development of larger volume biologics for in-home use will not be an impediment to product uptake and acceptability.”

### **GERRESHEIMER MEDICAL SYSTEMS: CUSTOMIZED SOLUTIONS FOR BIOTECH DRUGS**

The specific requirements of biologics development and production, the obligation to better understand the final product, as well as the latest revision of the FDA Combination Product Guidance have resulted in the more complex qualification of prefillable syringes as the container closure system for new products, says Claudia Petersen, Global Director Business Development Medical Systems, Business Development, Gerresheimer Medical Systems. To address these trends, she believes close and early interaction in the product development cycle between the packaging and/or formulation development departments and the supplier is key to increasing patient compliance.

To date, most development-stage and marketed biopharmaceuticals are either monoclonal antibodies or recombinant proteins, each with specific requirements/sensitivities, and need to

be administered by injection. “Protein-based drug products have complex requirements that demand customized prefilled syringe solutions,” she says.

Custom drug delivery devices with prefilled syringes are a must in the parenteral market because of the vast number of parenteral drugs that exist. That’s why Gerresheimer offers a comprehensive portfolio of high-quality products in glass and cyclical olefin polymers (COP), and adapts the syringe system to the customer’s individual requirements profile.

“Gerresheimer is one of a few companies in the world to offer its customers both glass and COP syringes,” says Bernd Zeiss, Medical Systems, Technical Support Manager at Gerresheimer. COP’s barrier properties effectively protect the content of the syringe. COP is also transparent, which means that COP syringes are similar in appearance to glass syringes. This transparency makes it easy to visually check the content for clouding, particulate, and other defects. COP syringes can be used as a primary packaging for biotechnologically derived drugs.

“These are some of the most expensive drugs on the market and highly susceptible to external influences. They are manufactured in high-tech processes and involve complex development and production methods,” says Mr. Zeiss. “The very precise injection molding process permits more exact tolerances than the free-forming process used for glass syringes. Exact geometries are very important if the syringe is destined for use in an autoinjector. These exact geometries also reduce the syringe’s dead volume so that less drug residue is left inside the syringe after use. This is a persuasive argument for manufacturers of expensive drugs.”

## **NEMERA—A NEW VERSION OF A PROVEN DEVICETO ADDRESS SAFETY & BIOLOGICS**

Since the early 2000s, prefilled syringes have gained popularity due to their ease of use, improved user safety, and the reduction of potential dosage errors. Self-administration, at-home administration, and the rise of biologics are the main drivers of this growth. Indeed, needlestick injuries remain a global concern with more than 3 million exposures to blood every year, according to the World Health Organization. In order to overcome those problems, regulation/recommendations have been established to improve users’ conditions. As a consequence, devices such as safety devices for prefilled syringe or autoinjectors have emerged.

While 1-ml prefilled syringes are the common primary container, over the last years—with the rise of biologic drugs—larger volume containers (2.25 ml) have emerged. Those biologics have raised new challenges. “Indeed, on one hand, biologics are adding complexity to the parenteral segment due to the nature of the drug (more viscous and with larger filling volume), while on the other hand biologics are targeting patients suffering from chronic diseases who have to self-inject,” says Adrien Tisserand, Global Category Manager at Nemera.

In response, Nemera has developed a 2.25-ml version of Safe’n’Sound<sup>®</sup>, an open, adaptable, and customizable platform of add-on passive safety devices for prefilled syringes to help prevent needlestick injuries. As a passive safety device, the safety feature activates automatically at the end of the injection, easing the use.





User interface has been integrated from the beginning in the design and development of the device, integrating many ergonomic features: a large thumb pad surface to smooth the injection; large built-in finger flange to facilitate handling; a round shape for more comfortable handling; and a spring located at the syringe flange position to provide good visibility of the tip of the syringe and enable inspection of the drug, even with low-filling volume drugs. An optional add-on ergonomic extended finger flange has also been developed to improve the handling, gripping, and comfort for the user.

Safe'n'Sound has been designed to give flexibility to the laboratories being an open and customizable platform. Indeed, Safe'n'Sound is compatible with syringes of different filling volume (1 ml and 2.25 ml), flange type, and suppliers. "The device provides pharmaceutical companies flexibility on their dosage formulation, and an innovative safety device solution to equip small- and large-volume drugs while responding to patients' needs in terms of ease of use and safety," says Mr. Tisserand. "Moreover, Safe'n'Sound is a patented, 510(k) cleared product, which can be sold worldwide."

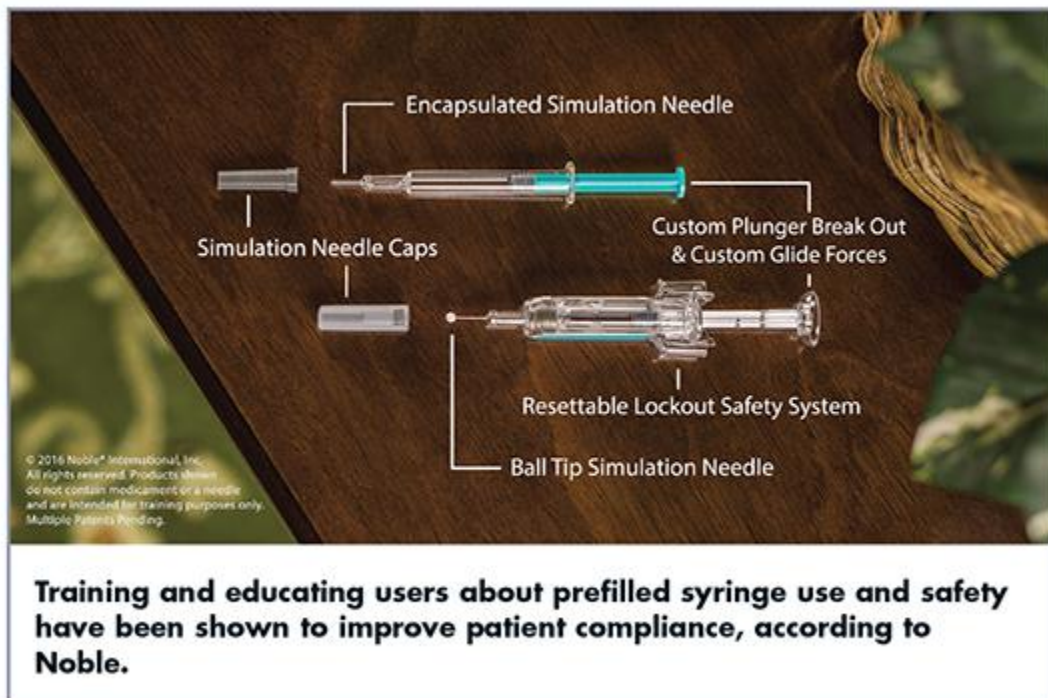
## **NOBLE: PROVIDING A POSITIVE PATIENT ONBOARDING EXPERIENCE**

The demand for prefilled syringes continues to grow as more patients are being required to self-administer medications, such as the increasing number of biologics and biosimilars entering the market. As these products continue to augment and launch into new therapeutic sectors, training and education will remain a critical success factor that will determine a patient's ability to safely and effectively use prefilled syringes and adhere to therapy, explains Paul Sullivan, Associate Director of Business Development at Noble.

Noble is a full-service, patient-centered product development and manufacturing company that specializes in onboarding and device training. Noble works closely with pharmaceutical and biotechnology companies to develop educational and training solutions designed to provide positive patient onboarding experiences, reduce errors, and improve patient outcomes.

"There are psychological factors that self-injection patients face, such as anxiety and confidence," says Mr. Sullivan. "Over the past decade, advancements in the industry have given us a better understanding of patient adherence and the benefits of training and education. The traditional patient educational materials have proven to be ineffective, as studies reveal 78% of

the patient population lacks proficient health literacy<sup>4</sup>, resulting in treatment barriers for prefilled syringe users.”



Mr. Sullivan adds that training devices have been shown to be effective for improving patient outcomes and adherence.

Findings also reveal patients who use a training device are more compliant.<sup>5</sup> Novel training technologies like simulation needles help promote positive onboarding experiences and empower patients to lead healthier lives.

“In the modern era of patient-centric care, products that are able to provide superior onboarding and patient experiences will be well positioned to reduce patient errors, while improving patient satisfaction and outcomes,” he says.

### **REVOX: STERILIZATION CAN MEAN THE DIFFERENCE BETWEEN SUCCESS & FAILURE**

Biologics and more complex delivery devices are sensitive to the high temperatures associated with traditional sterilization processes. The REVOX vaporized peracetic acid (VPA) sterilization process is conducted at room temperature (21°C), allowing full sterilization of the device without affecting the drug.

“Sophisticated delivery systems like combination devices require greater simplicity for the patient and the manufacturing process, which in turn requires the integration of diverse components with variable suitability to standard sterilization processes,” explains Mason Schwartz, Operations Manager and Co-inventor of REVOX. “High temperature sterilization methods often necessitate separation of components and assembly either post-manufacturing

or with the patient. With more than 100 materials tested for compatibility with the REVOX VPA process, the product can be fully assembled presterilization.”

Elevated temperatures in the sterilization process may affect the medication itself. And “surface sterilization” with lower temperature methods is often more challenging than the term implies, he says. “With the goal being sterilization of every component of the device while not touching the drug, the method needs to have the capability of penetrating mated surfaces, such as the threads on a plunger-to-stem assembly, while providing variable controls to limit the penetration to just short of reaching the drug itself.”



Add to this the issues such as strict regulatory requirements, recalled prefilled syringes, manufacturing complexity, and the cost associated with prefilled syringes. “All of this demonstrates the obvious preference and potential advantages, from various standpoints, to have a combined, single device for medication delivery,” says Mr. Schwartz. “If vial/syringe packaging was ‘good enough,’ manufacturers wouldn’t be challenging that status quo with the costs and risks associated with prefilled syringes. The sterilization method used on prefilled syringes can be the difference between success and failure.”

From a cost standpoint, depending on the standing infrastructure of a manufacturer, contracted sterilization is the standard sterilization process. REVOX enables on site, in-line sterilization that can significantly reduce per unit costs associated with sterilization. Sometimes cost savings aren’t enough to make a convincing argument. Mr. Schwartz recalls one client that wanted to launch its product as a prefilled syringe. However, project timeline pressures were intense. “We demonstrated the feasibility of REVOX VPA sterilization of the prefilled syringe,

but the client didn't want to trade off an on-time launch with potential delays associated with a novel sterilization method of a prefilled syringe."

Another client, however, saw the "writing on the wall" in terms of the ever-lowering Ethylene Oxide (EtO) residual standards. As the residual limits are lowered, the WIP (work in process) time and volumes increase with the need for greater EtO post-processing aeration times. "We continue to work with this client to demonstrate the efficacy and economic benefits of transitioning from EtO to in-house VPA sterilization."

Mr. Schwartz continues: "We are seeing a tremendous increase in the need for sterilization of advanced combination and prefilled syringes. We've seen commercialization plans compromised with vial versus prefilled syringe packaging simply because of traditional sterilization constraints."

### **SCHOTT PHARMACEUTICAL SYSTEMS: POLYMER SYRINGE EASES VISCOUS DRUG DELIVERY**

With regards to syringe manufacturing, significant achievements have been made in recent years. This leads to an overall reduction of cosmetic defects (which otherwise could have an impact on filling operations) and enhanced mechanical strength of the syringe. For example, syringe barrels can be produced with tighter dimensions, which ensures a better fit with safety devices; tungsten residues and siliconization can be controlled in a better way, the latter by diving nozzle technology, resulting in a uniform distribution of the silicon oil inside the barrel; and highly automated handling of the syringe during production helps to further reduce defects.

"Looking ahead, patient comfort and safety will become even more prevalent," says Anil Busimi, Director Strategic Marketing and Innovation, SCHOTT Pharmaceutical Systems. "A very important point is drug container interaction and the determination of extractables and leacheables (E&L).

To address this, SCHOTT introduced a new prefillable polymer syringe, designed to improve the safety and stability of sensitive drugs. The product, SCHOTT TopPac<sup>®</sup> SD, offers new features for a reduced E&L profile, such as an inert COC (cyclic olefin copolymer) barrel that releases no ions or heavy metals; cross-linked silicone for barrel lubrication that reduces the amount of subvisible particles and still ensures optimal functionality; and the syringes are sterilized with an ETO (Ethylene Oxide) method, rather than irradiation.



To address the topic of patient comfort, a new syringe (TopPac SD) was designed with one of SCHOTT's clients to make the application of hyaluronic acid safer and more comfortable. "Given that hyaluronic acid is highly viscous, doctors need to apply a great deal of injection force when they use conventional luer lock syringes to give the injections," explains Mr. Busimi. "It is not uncommon for that to cause patients to feel pain. In extreme cases, the high pressure can even disconnect the needle hub from the syringe and, in a worst-case scenario, lead to breakage of the luer lock adapter. For that reason, highly viscous drugs (HVD) require packaging that allows a consistent gliding/injection force. The newly designed syringe comprises a smaller inner diameter, as well as optimized siliconization. This ensures that the plunger slides evenly with low injection force and that the medication can be administered in precise dosages. The syringe also features an integrated luer lock that prevents leakage, breakage, and needle pop off."

SCHOTT also added new closure systems for its prefilled syringe portfolio. "These rigid caps ensure the integrity of the container, yet can easily be opened by healthcare professionals or patients," he says. "The closure adds a great deal of flexibility to our customers' supply chain, and speeds up time to market for new or already existing drug products."

#### **VETTER: TACKLING THE CHALLENGES OF PACKAGE DESIGN & MATERIAL**

Large (bio-)pharmaceutical companies often focus their efforts on core competencies, such as late-phase development and drug marketing. To improve their efficiency in these areas, they are making efforts to reduce and simplify their network of different service providers.

“Whenever possible, they purchase a solution that equates to ‘one-stop-shopping,’” says Bernd Stauss, Senior Vice President Pharmaceutical Production/Engineering, Vetter Pharma-Fertigung GmbH & Co. KG.

But it’s not just single sourcing in partners that matters to pharma. An all-in-one concept is also appealing with regard to prefilled syringe technology and the issue of lyophilization. Dual-chamber systems offer advantages in this sector. The Vetter Lyo-Ject® dual-chamber syringe is designed for sensitive drugs that will not degrade in a lyophilized state. The actual active ingredient is lyophilized in one chamber, while the other chamber of the syringe contains a solvent that is mixed with the active substance immediately before application.

“This all-in-one concept enables a long shelf life as well as easy handling. This also means higher yields of your active product ingredient and precision in dosing,” says Mr. Stauss.

In addition to package design, packaging material plays an important role. For instance, Mr. Stauss says it can be a challenge to determine the right amount of silicone that will enable the correct movement of the plunger rod while avoiding any form of interaction between the silicone and the drug substance.



Consider this real-life example. High-value products are often based on very complex compounds. This means that these compounds demand a high degree of accuracy on the filling line. As a manufacturer, Vetter has to deal with the increased sensitivity to manufacturing processes and environmental conditions. One highly sensitive API required very small fill volume in a syringe device. “Small filling volumes create an increased demand on all production areas, including process design, technical equipment, and packaging material,” he explains. As such, packaging material and processes needed to be adapted to meet the requirements of this product.

“Reaching the right amount and correct application technique of the silicone coating the syringe is but one example of the challenges we face in fill/finish projects like this one,” says

Mr. Stauss. “Comprehensive project management is also needed to handle such a project successfully, taking into consideration the needs of both the product and the customer.”

## **WEST: DELIVERING DELIVERY DIFFERENTIATORS FOR BIOLOGICS & COMBINATION PRODUCTS**

Last year saw the first FDA-approved biosimilar. Advanced drugs, like biologics and biosimilars, require sophisticated packaging and drug delivery systems, and the market has responded with offerings that address this new need. In the case of biosimilars, with many companies competing for the same therapy, the mechanism of administration can be a key differentiator. West’s contribution to this evolution has included Daikyo Crystal Zenith<sup>®</sup> cyclic olefin polymer (COP), which is used to produce a technologically advanced COP containment and delivery system. Crystal Zenith is proven to complement biopharmaceuticals and other complex, high-value medicinal products because it addresses the need for clear, biocompatible material that helps mitigate the chemical interaction and breakage risks inherent in glass, says Mike Schaefers, Vice President, Global Product Management and Marketing Operations, West Pharmaceutical Services, Inc.

“For injectable biosimilars currently in the pipeline, it will be important to examine drug delivery options that can improve the patient experience while ensuring, when possible, a delivery format with which patients are familiar and comfortable,” says Mr. Schaefers.



“Together, device and drug manufacturers can work seamlessly as partners to provide innovative solutions that help mitigate risk, encourage patient adherence, and enhance value.”

Focusing on enhancing quality from early development through commercialization, West adopted Quality by Design (QbD) concepts in the design and manufacturing of packaging components. QbD delivers an improved, data-driven output, providing superior product and process understanding that minimizes risk, emphasizes patient-critical quality requirements, and enhances drug product effectiveness. For example, West’s NovaPure<sup>®</sup> plungers incorporate functional performance parameters like gliding and breakloose forces, which are very important to ensure consistent injectable drug administration when syringes are used in combination with an injection device.

And when it comes to the popularity of combination products, drug manufacturers are more heavily relying on companies like West to offer insight into the regulatory process related to components. “Our expertise around how drugs may interact with the delivery systems can help

to avoid regulatory delays, increase safety and expedite the process of getting combination products to market,” says Mr. Schaefer.

Additionally, combination products have also brought to the forefront the importance of flexible manufacturing, which enables drug companies to quickly transition fill lines from vial format to cartridge to prefilled syringes, depending on the needs of the injectable medicine.

Finally, the popularity of combination products has raised the bar in terms of developing drug containment and delivery systems that are safer and enhance the patient experience. “West strives to manufacture packaging and delivery systems that are easy-to-use, minimize discomfort, and work in a way that is compatible with patients’ lifestyles, as they need to easily assimilate these devices into their daily routines.”

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