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Prefilled Syringes & Parenteral Manufacturing

The science & business of drug development in specialty pharma, biotechnology, and drug delivery

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for lyophilized/solvent drugs and liquid/liquid drugs, and offer many advantages for sensitive compounds," says Dr. Feussner. "Benefits include enhanced product safety provided by an all-in-one closed system, precise dosing because the drug is premeasured, and simple administration users."

Vetter also offers a syringe closure system, Vetter-Ject®, which is a tamper-evident system for prefilled syringes. The device combines an integrated staked needle with a baked-in siliconization process for standard glass barrels that is suited for highly sensitive compounds.

As a CDMO, Vetter's services span early development support, including clinical manufacturing, through to commercial manufacturing and secondary packaging services. Vetter works with customers by asking a variety of questions to determine how to move forward. Is the product liquid or lyophilized? What are the therapy requirements? Is it a self-administered therapy? What does the product lifecycle and competition look like? What are the different drug concentration presentations to be brought to market? Other critical issues to be considered include the use of non-flurotec or flurotec stoppers, glide and release forces, and shelf-life issues.

West Pharmaceutical Services, Inc.: Systems to Deliver High Volumes and High Doses

Combination products, those that combine the drug, its primary packaging, and delivery system, are becoming more prevalent as biologic drugs present the challenges of higher viscosities and increased dose volumes. "As dose volumes go up and the frequency of dosing associated with new therapeutic regimens goes down, we've seen a trend toward the use of combination products," says Karen Flynn, SVP & Chief Commercial Officer, West Pharmaceutical Services, Inc. "Manufacturers of injection technologies are addressing this trend by developing systems that are capable of delivering up to 2.5ml using systems such as autoinjectors and volumes even greater than 10ml using on body wearable technologies."

West is addressing this trend by extending the platform of its wearable injector technology, SmartDose®, to include doses of up to 10ml. "West developed the SmartDose platform of devices to meet a variety of delivery needs," says Ms. Flynn. "With three device options, the platform features pre-programmable user-loaded and preloaded variations."

Additionally, West is commercializing its patient-assisted injector, SelfDose®, in collaboration with several pharmaceutical customers. The SelfDose injector offers a self-controlled injection option to patients. "An off-the-shelf delivery system that is ergonomically designed for optimal patient administration, the SelfDose injector was developed using extensive human factors studies that helped to confirm the intuitive design, and support ease of use and patient acceptance," she says.

Primary containment systems are also trending towards specialized components that are engineered to enhance functional performance. West supplies elastomer components used with glass prefilled systems, and also supplies Daikyo Crystal Zenith® PFS systems. For complex molecules, West provides NovaPure® syringe plungers for PFS/autoinjector delivery systems across various injection volumes and higher viscosity ranges in glass systems. "NovaPure plungers are designed to maintain container closure integrity while minimizing the contact area between the plunger and syringe, reducing friction and break-loose force," explains Ms. Flynn. "When a non-glass system is preferred, West offers Crystal Zenith syringe systems to maintain purity, integrity, and efficacy of biopharmaceutical therapies. It minimizes potential contamination issues associated with glass systems and reduces breakage, protecting high-value drugs."

Aptar Pharma: Ready-to-Use Program Facilitates Development Time

Pharma customers serving the biologics market require smaller runs as these markets have a smaller subset of patients. As a result, contract partners must be able to provide Ready-To-Use (RTU) products that allow for faster and more flexible runs.

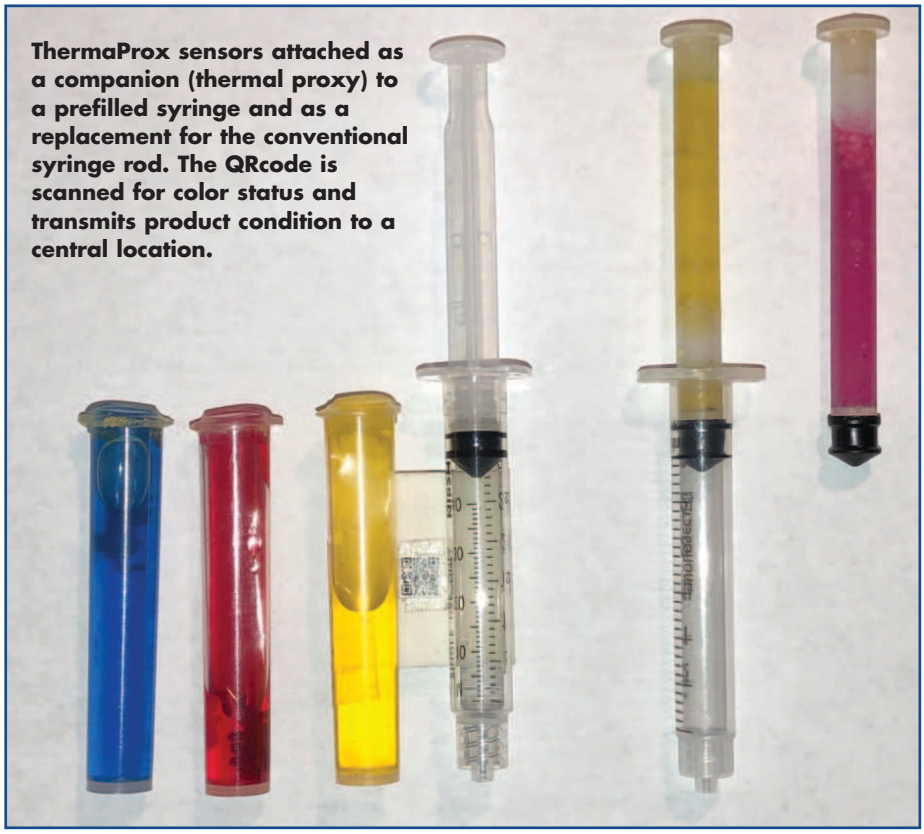
Aptar Pharma fulfills this request for customer by providing RTU stoppers. The stoppers, along with vials, and seals are available through Aptar's recently launched QuickStart™ for Injectables, a one-stop-shop, ready-to-use sterile solution, designed specifically to accelerate the development time for start-ups and early-stage development, R&D, biotechs, and university research organizations.

Launched in October 2018, this injectable development package comes with gamma-sterilized stoppers and push-off caps from Aptar Pharma and EMA Pharmaceuticals respectively, and ETO sterilized vials from Schott.

"We facilitate customers who require speedy developments with an immediatly available and easy-to-use online ordering platform," says Adam Shain, Director, Global Business Development - Injectables, Aptar Pharma.

Addtionally, as the developer and

manufacturer of Rigid Needle Shields (RNS) for autoinjectors, Aptar fulfills customers' mandate for optimal performance. Mr. Shain says that customers are choosing the design of their RNS early in the process to ensure optimal removal in the device. "Previously, the device was designed around the RNS; today customers realize that they can remove gripping features in their autoinjectors by utilizing the right RNS," he says. "Our patented RNS allows for optimal gripping by any autoinjector and minimizes components within the device while providing a consistent pull-off force and a prevention method for fragmentation during removal."



ThermaProx sensors attached as a companion (thermal proxy) to a prefilled syringe and as a replacement for the conventional syringe rod. The QRcode is scanned for color status and transmits product condition to a central location.

ThermaProx, Inc.: Navigating the Cold Chain's Last Mile with a Prefilled Syringe

Much effort is being placed on the quality control of the containers in which a medication will reside. However, little has changed in the transport of finished, prefilled medications from manufacturer to patient. The same technology for vial shipments stands for prefilled syringes. They are packaged and shipped, with coolants, inside insulated containers and handled multiple times under all types of storage and weather conditions.

Nat Cooperman, CEO, ThermaProx Inc., explains that large quantities (pallets) of syringes are shipped with electronic recorders measuring the temperature and shock to which the syringes are exposed, but once the pallets are broken down to the carton level those recorders disappear and reliance is now on label or card indicators to record temperature and limit occurrences. "Shipments get broken down further to the box level and, often, no temperature or shock records are available. Even worse, when the box arrives at a pharmacy or patient's home ("the last mile"), there is little record of how the syringe is handled or stored."

The challenge becomes even greater with regard to highly temperature-sensitive biologics, gene therapies, vaccines, and cancer chemotherapeutics becoming more prevalent. The more of these products being sent directly to a patient's home, where receipt and storage conditions are often unknown, the greater the possibility for unknown temperature limit excursions to occur, says Mr. Cooperman.

ThermaProx, Inc. has developed a multi-patented temperature excursion sensor that mimics the temperature characteristics (thermal mass) of the monitored medications up to the point of the injection site. "Existing sensors (electronic, card or label) monitor the ambient temperature surrounding the medication, resulting in many false positives indicating temperature excursions that the product never experienced," says Mr. Cooperman. "The ThermaProx sensor is triggered only when the medication is definitely questionable."

Reference

1. Dermal Filler Market Worth Over $8.5 Billion by 2024, Global Market Insights, December 11, 2018, https://www.globenewswire.com/newsrelease/2018/12/11/1664912/0/en/Dermal-Filler-Market-worth-over-8-5-Billion-by-2024-Global-Market-Insights-Inc.html.

BIOGRAPHY

Cindy H. Dubin is an award-winning journalist who has been reporting on the pharmaceutical industry for more than 18 years about a variety of topics, including formulation development, drug delivery, and drug quality.