

EG-GILERO: Partnering with Pharma to Design Devices

EG-GILERO doesn't market its own products, but partners with pharmaceutical and device companies to design, develop, and manufacture devices. Most devices are disposable, both multi- and single-use, but occasionally they work with reusable systems like IV pumps, syringe pumps, and novel variants, explains Jim Fentress, Director of Engineering, EG-GILERO. Therapeutic applications vary, typically addressing parenteral routes, as well as ophthalmic and implantable systems.

Human engineering inputs and patient preference research affect EG-GILERO's designs, depending on their intended use. "For example, dental syringes need to inject into tissues with substantially higher back pressures than intradermal or intramuscular syringes," says Mr. Fentress. "This drives designs, which lower the required application force while still achieving injection pressures. Simultaneously, the higher injection forces drive ergonomic considerations that will make the syringe easier to activate and maintain position during injection."

Self-administration devices are always driven by specific needs of target populations, Mr. Fentress says. "When designing these devices, a fundamental understanding of the population and concomitant health problems is critical. The most effective solutions start out by exposing device concepts and variants to the target population early in the process. This kind of development effort avoids making mistakes that are expensive to correct later."

As important as the design is the packaging. Packaging is product specific and driven by primary considerations. Does the packaging have to be a sterile barrier? Does the package prevent some

form of device activation (i.e. preventing a permanent needle guard from triggering)? Does the package provide long-term device protection (i.e. an autoinjector that might be carried in a backpack)?

Typically, disposable devices gravitate towards the most cost-effective solutions. An exception exists for devices intended for non-clinician use. For these devices, the packaging often becomes an integral part of the instructions for use, directing untrained individuals towards safe and effective application. Most disposable injection devices developed by EG-GILERO incorporate needle shielding or lock-out to prevent injury.

Enable Injections: High-Volume Drug Delivery Supplants IV Infusion

Enable Injections has been developing large-volume (up to 50mL) wearable injectors for subcutaneous delivery of high-viscosity formulations. In addition, Enable Injections is developing easy-to-use systems that facilitate the rapid transfer of biologics and drugs from their original primary container closure to its wearable injectors.

"Our transfer systems were designed to warm the refrigerated biologic/drug products to room temperature through simple convection (no heating elements), thus reducing the typical 30- to 45-minute patient wait time," says Mike Hooven, President and CEO of Enable Injections.

Although the wearable large-volume injection systems are not yet approved or commercialized, Enable Injections' devices have undergone numerous human factors tests and evaluation protocols as well as user market research. The wearable large-volume injectors are purely mechanical

and designed for ease of use with the ability to initiate injections in three simple steps, explains Mr. Hooven. The injection device has a smooth, low-profile exterior with rounded components that prevent the device from catching on clothing. The device adheres readily to the skin. Patients then press the injection button to initiate subcutaneous injection. When the injection is complete, the button and needle automatically retract with an audible "click" and the device is then easily and safely removed. The device also allows patients to actively pause their injection by holding down the button.

"Of note, Enable Injections' system is designed to supplant the need for IV infusion of biologics in many cases, and reduce monetary costs and time burden of



The new Enable handheld syringe transfer system minimizes waste and volume.

establishing an IV infusion of a biologic by healthcare professionals,” says Mr. Hooven. “Our ability to use any standard pharma industry container closure with a delivery system that is preferred by patients and caregivers saves costs and reduces drug development time by months. Also, by pairing standard container closure systems with our injection system, the clinician is afforded the flexibility to establish effective dose regimens tailored to the individual patient when needed.”

Mr. Hooven adds that Enable Injections has designed its packaging around the concept of simplicity of use, which reduces the volume of hardware and requisite instructional material compared with more complex electro-mechanical drug delivery systems. “Ultimately, the products’ packaging focuses on minimizing waste and volume while accommodating a single-use, disposable device that ensures a safe and sterile environment for biologic/drug delivery.”

Enable injections has partnered with Flex to develop the Enable Smart Device, a next generation communication device that uses Bluetooth Low Energy technology by means of broadcast mode. The Enable Smart Device can be pre-integrated into a company’s Digital Health Platform, giving Enable’s pharma partners immediate access to patient data across multiple devices and gaining direct engagement with patients to drive adherence. “The Enable Smart Device adheres to our overall strategy of designing simple systems for maximum effectiveness with minimal interaction,” Mr. Hooven says.

Gerresheimer: Reducing Interactions Between Drug & Container

Primary packaging for parenteral formulations has strict requirements with regard to the likelihood of component/dosage form interactions, especially for biotech-based and other sensitive drug products. New product developments at Gerresheimer reflect this trend.

Gerresheimer offers a range of prefilled COP syringes produced by its long-standing Japanese partner, Taisei Medical Co. Ltd. The company is now extending its portfolio of the new Gx RTF® ClearJect syringe, available in a 1mL-long version, using standard rigid needle shield and fluoropolymer-coated plunger stoppers.

“Biotechnologically developed drugs

pose challenges for the container, as they can be very sensitive,” says Bernd Zeiss, Manager Technical Support Medical System, Gerresheimer. “There may be interactions with syringe components such as tungsten, silicone oil or the barrel material itself. Using a barrel material such as COP may have advantages with a drug compared to a glass syringe.”

Addressing the unmet needs in prefilled syringes is the key to successful pharma products. The metal-free syringe with a high quality luer lock adapter (TELC) is a good example of how Gerresheimer finds solutions for its pharma clients. “Solving the tungsten issue is an important step to minimize syringe container-induced interactions with a sensitive drug,” says Mr. Zeiss. “Substituting the tungsten pin used in the manufacturing of glass syringes with an abrasive-free and non-cytotoxic ceramic extends the range of biopharmaceuticals that can be administered by means of a prefilled syringe.”

Reducing silicone oil is another customer need addressed by Gerresheimer. The Gerresheimer Gx RTF baked-on silicization reduces the silicone levels significantly and make the syringe suited for sensitive biopharmaceuticals as well as for the stringent ophthalmologic USP requirements with regard to subvisible particle loads, Mr. Zeiss says.

Gerresheimer will complete its product portfolio of prefilled syringes made of glass and plastics with an integrated, passive syringe safety solution, acquired through an exclusive license from West Pharmaceutical Services, Inc.

Gerresheimer offers a syringe with an integrated safety system to avoid needlestick injuries.

