



Nemera's Safe'n'Sound® is a 2.25ml customizable platform that addresses the challenges of administering biologics.

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 (1ml and 2.25ml), 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."

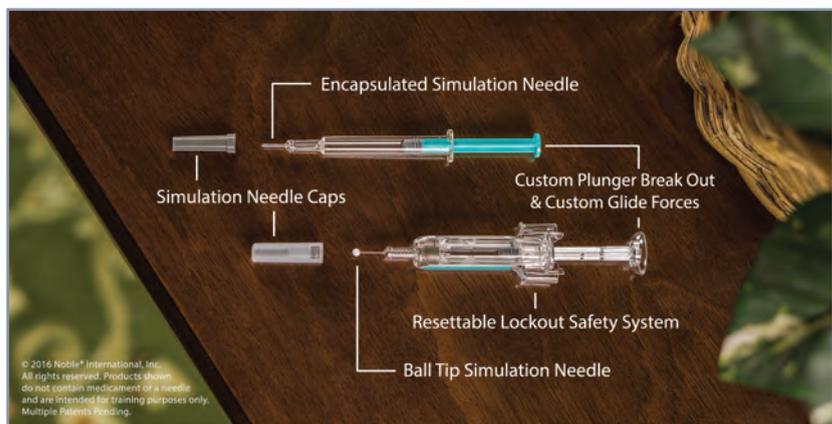
Noble—Providing a Positive Patient Onboarding Experience

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



Training and educating users about prefilled syringe use and safety have been shown to improve patient compliance, according to Noble.

traditional patient educational materials have proven to be ineffective, as studies reveal 78% of the patient population lacks proficient health literacy⁴, 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.⁵ 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 pre-sterilization.”

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