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AUTOINJECTOR TRAINER INNOVATIONS TO ENHANCE THE PATIENT EXPERIENCE

In an increasingly crowded marketplace, the availability of realistic trainers can serve as a key differentiator that can set a pharmaceutical company ahead of its competitors. Noble has designed an agitator needle simulation tip to replicate the forces and feel of the needles that are used in manual insertion. Joe Reynolds, Research Manager, looks at the benefits offered by the simulation tip – which can be incorporated into several types of autoinjector trainers – and reviews the development process.

With competition among drug manufacturers steadily increasing, each company faces the challenge of effectively differentiating itself from its competitors. A smart solution could lie in adopting patient-centric strategies that can make a course of treatment less daunting for those who are prescribed a specific medication.

One area where this is particularly important is the administration of biologic drugs, as many patients have to use self-injection devices and may not feel comfortable with them or well-versed in their proper use. Studies have indicated that needle anxiety can play a significant role when patients are prescribed a medication that involves self-injection.1 Other studies suggest that, without proper training during the first 30 to 90 days of treatment, patients are more likely to drop off from therapy or use their devices improperly, thus receiving less than a complete dose.² To offer a truly patient-centric experience, it is important for drug manufacturers to ask what methods can be employed to rectify these problems.

THE AGITATOR NEEDLE SIMULATION TIP

One solution comes from the world of technology and engineering. Recent advances have made it possible to incorporate various special features into autoinjector training devices that can help patients achieve increased confidence and proficiency, giving them a solid grounding in self-injection before they begin using their actual autoinjector on a regular basis.

One recent feature-based innovation in autoinjector trainer design – known as the agitator needle simulation tip (Figure 1) – was introduced into the commercial market by Noble[®] in November 2017 and serves as a good case study on how autoinjector trainers can be made more realistic while providing multiple benefits for users.

USING AGITATOR SIMULATION TIPS IN TRAINING DEVICES

The agitator needle simulation tip feature can be incorporated into trainers that mirror the operation of manual autoinjectors, in which the patient applies pressure to insert the needle.

"...a trainer with an agitator needle simulation tip allows patients to experience the sensation of what it would be like to use an actual prescription autoinjector on their own body as closely as possible..."



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Figure 1: Noble's Agitator needle tip simulator replicates the force and feel of needle insertion.

Prior to the advent of commercially available autoinjector trainers, the onboarding process for self-injection patients relied on other methods, such as practising an injection on an orange. In contrast, a trainer with an agitator needle simulation tip allows patients to, as closely as possible, experience the sensation of what it would be like to use an actual prescription autoinjector on their own body by replicating the four phases of needle insertion into the skin:



Patient Benefits

There are three distinct benefits to the use of agitator needle simulation tips:

- Users have a better understanding of what to expect when injecting
- Patients gain confidence that they can self-inject correctly
- Needle anxiety is reduced.

The use of agitator needle simulation tips as a feature in autoinjector trainers can help relieve patient anxiety by replicating the actual sensation of needle insertion. In many cases, patients discover that the sensation of the needle is less painful than they had initially feared. This is significant because the perceived pain that is often associated with needle use can lead to a tendency among some patients to remove the needle almost immediately following insertion. This could result in them not receiving the full dose of medication.

Practising with a trainer that incorporates an agitator needle simulation tip can also prepare patients to the point where they are more comfortable with the initial sensation of needle insertion and keeping a needle inserted for the entire interval as recommended by the Instructions for Use (IFU).

Additionally, by training prior to an actual self-injection, the user gains familiarity with the IFU and how the device functions, which can help lower the risk of errors, such as needlestick injuries or wet injection.

Use with Other Self-Injection Devices

The use of agitator needle simulation tips is not exclusive to autoinjector trainers for a particular drug class or patient population. In fact, Noble conceptualised and developed agitator needle simulation tips to be compatible with a wide range of trainers that mirror the variety of commercially available autoinjectors, prefilled syringes and potentially other kinds of self-injection device as well.

Additional Components

Agitator needle simulation tips are just one of several "device-agnostic" features that can be easily incorporated into a wide variety of trainers, depending on a drug manufacturer's specific needs. Aside from the agitator needle simulation tips, a range of other preconfigured components can allow additional features to be integrated into autoinjector trainers – such as plunger speed simulation and actuation force simulation (Figure 2). These can further replicate the realistic experience of using the prescribed autoinjector.

WORKING WITH DRUG DELIVERY MANUFACTURERS

To date, Noble has forged industry collaborations with some of the world's leading drug delivery device manufacturers "Incorporating special features such as agitator needle simulation tips into autoinjector trainers can provide benefits not only to the patients for whom they are designed, but also to the pharmaceutical companies that choose to have them produced."

to ensure the highest quality trainers are produced. Many such companies have come to appreciate the importance of improved patient training and, in particular, the benefits of realistic training devices. Consequently, the demand for training devices within this market space is likely to continue to rise in the years to come.

A positive "word of mouth" reputation has been fuelled in part by feedback from those in the industry who have had the opportunity to see a trainer up close and observe first hand how Noble's agitator needle simulation tips and other features work, as well as from participants in various market research forums. Noble has the capability of working with a company at every stage – from establishing product requirements to concept development, prototyping and ultimately product manufacturing.

THE DEVELOPMENT PROCESS

Once a pharmaceutical company has opted to work with Noble to offer a training device in tandem with the release of a new self-injectable drug, the process of developing a realistic autoinjector trainer – one that integrates an agitator needle simulation tip or additional special features - begins. The Noble team collaborates closely with the company to develop the precise product requirements that will drive its design and concept development. Noble has vast in-house prototyping capabilities and will produce various high-quality, fully functioning prototypes for evaluation.

Some advanced training devices that have been developed by Noble incorporate electronics that allow for real-time feedback and instruction for patients who are selfinjecting. Accordingly, these products require the use of printed circuit boards (PCBs) and other components that Noble can integrate as well. These capabilities are applied on a per-project basis when the pharmaceutical manufacturer has specifically requested such features.

Final product assembly of the trainers can be conducted either manually, semiautomatically or fully automatically, depending on the specific features of a product and the quantity of trainers required. Once again, product assembly protocols are determined on a per-project basis in advance by the requirements of the pharmaceutical manufacturer.

An integral element in the overall production process is printing and packaging. These initiatives are conceptualised early in the development process and produced in tandem with the production of the training device itself. For the most realistic experience by the patient, the trainer must resemble the prescribed autoinjector as closely as possible, so Noble works to replicate the colour and other features specified by the manufacturer for the exterior of the trainer. Similarly, Noble can produce packaging for the trainer that matches the packaging of the actual device to make the patient experience as realistic as possible.

Quality practices are incorporated into every stage of the development process of the autoinjector trainers, from initial conceptualisation through commercial production. Testing is conducted early in

ABOUT THE AUTHOR

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the development process to ensure that the trainer meets all of the requirements specified by the pharmaceutical manufacturer.

CONCLUSION

The technical advances that allow the production of realistic autoinjector trainers, and Noble's proven ability to work with leading drug delivery device manufacturers to ensure the highest-quality products, can serve as a win-win for drug companies, healthcare providers and patients alike. Incorporating special features, such as agitator needle simulation tips, into autoinjector trainers can provide benefits not only to the patients for whom they are designed, but also to the pharmaceutical companies that choose to have them produced.

ABOUT THE COMPANY

Noble[®] works closely with the world's leading pharmaceutical and biotechnology companies to develop autoinjector, prefilled syringe and respiratory device training solutions designed to provide positive patient onboarding experiences, reduce errors and improve patient outcomes. Cross-disciplinary designers and engineers provide fully customised solutions from the first concept sketch through production, in both regulated and non-regulated environments.

REFERENCES

- 1. Noble, "The Relationship Between Anxiety, Injections and Device Training." Poster session. 2015. Presented at PDA Universe of Prefilled Syringes and Injection Devices Conference, Huntington Beach, CA.
- Reynolds J, "Best Practices & Considerations in Developing Effective Training Devices for Injectable Healthcare Markets." Drug Development & Delivery, October 2016. (drug-dev.com/Main/ Back-Issues/TRAINING-DEVICES-Best-Practices-Considerationsin-1169.aspx Accessed April 2018)
- Bhagwat P, "Study of needle insertion forces." 2009. (www1.coe.neu.edu/~smuftu/ docs/2009/ME5656_Term_Project_ Needle_Insertion_Forces_(Bhagwat). pdf Accessed April 2018)

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