

Drug Development & Delivery

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Issue: September 2014, Posted Date: 9/15/2014 (Exclusive Online Content)

Implementing Innovations in Injectable Drug Delivery With the User & Pharmaceutical Manufacturer in Mind

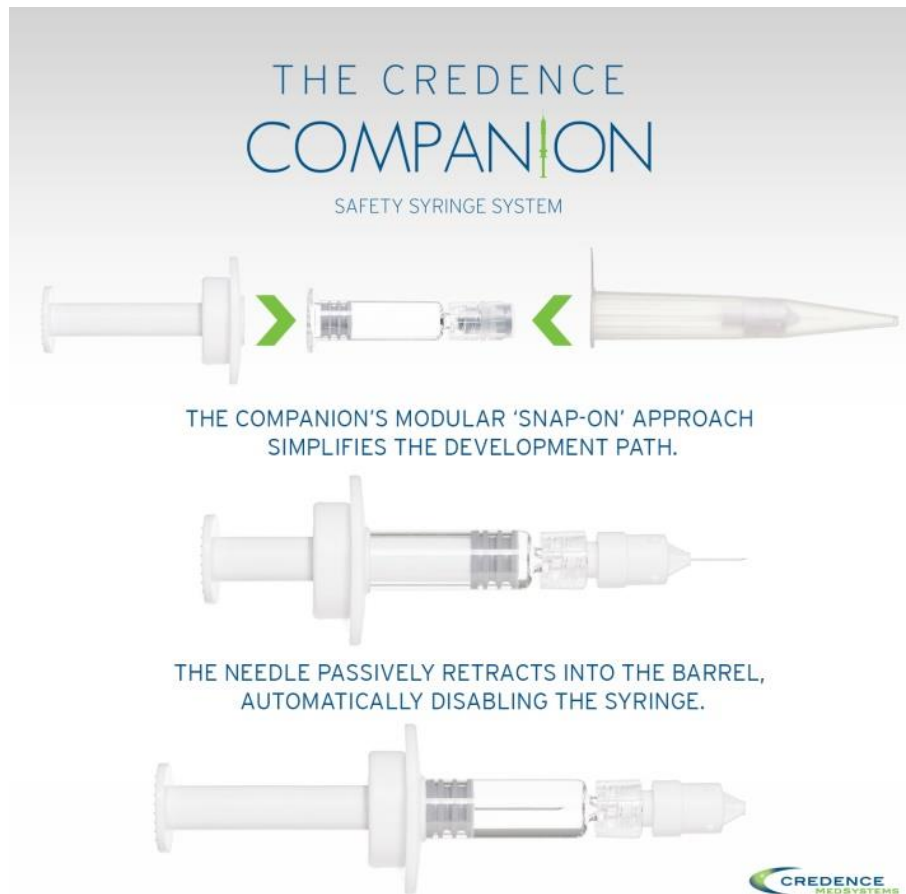
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The Current Climate

Change is hard. This is true in so many aspects of our personal and professional endeavors, and it is certainly true in biotech and pharmaceutical drug development. Drug manufacturers spend billions of dollars to develop a drug and perform extensive clinical studies evaluating safety and efficacy, an effort characterized by immense risk, all with the hope of achieving the exceptional result of taking the drug to market in its tailored delivery device. Adding unnecessary risk into the development process, even if it comes with anticipated benefits, is unwise. And once the drug is commercialized, the risks and expense commonly associated with making changes to the combination product often overshadow the end-user advantages that can come with the change. While this resistance to change is understandable (and, traditionally, often warranted), it has the undesirable effect of excluding technological advances in delivery systems from the market.

These excluded advances consist of potentially lifesaving safety improvements that are increasingly required to achieve compliance or gain access to tenders. They consist of human factors improvements that promote more accurate dosing and more efficient healthcare. And in a world where both the therapeutic magic and the majority of the development effort surround the molecule, these meaningful advances in the delivery system can not only help release the full potential of the molecule but also provide pharma companies a practical source of market differentiation and life cycle extension.

The very real benefits of any proposed change are therefore dutifully weighed against the very real pitfalls that may accompany the change. While much of the recently authored literature speaks to the need for simplification of the commercialization path for new delivery technologies, historically the new devices being introduced don't live up to this mandate. Each has its own opportunities for differentiation, user benefits, etc., but each comes burdened with a very significant impact on development and regulatory time, expense and risk. The 'simple' act of changing a drug's primary package can result in millions of dollars and multiple years of development related to revalidation of container closure integrity, biocompatibility, stability, extractables/leachables, reformulation, and other requirements. That choice generally results in a lengthier, more stringent clinical and regulatory approval process and necessitates dramatic changes to the filling line. Further, the industry and its consumers have benefitted from continued advances in the critical primary package components by leading companies with specific core expertise and the ability to provide consistent supply. Changing the primary package can introduce unanticipated and undesired risk associated with both the product and the supply chain.



Challenging the Status Quo

Due to these challenges, drug companies have historically been forced to choose from a series of less-than-ideal options related to pursuing delivery system improvements. First, they can simply do nothing, potentially jeopardizing the safety of users, forgoing the potential of delivery device advances, and incurring both commercial and litigation risk. Second, they can proceed with dramatic changes to the primary package and/or delivery system in an effort to maximize the end-user experience and drive market differentiation. Finally, they can fall back to a more conservative ground where the level of change is less severe but concessions are made on the performance and novelty of the delivery system.

Why the need to compromise? Where is the solution that mates the needs of the manufacturer with those of the user? Where is the approach that values the journey alongside the destination, offering a simplified path to commercialization that fits within well-established fill/finish methods and avoids unnecessary risk to the trusted supply chain, but still leads to a delivery device with the best end-user benefits and safety features?

A New Option

A new approach now exists. Recently a pharmaceutical manufacturer asked Credence MedSystems to assist with a challenging project. One of their injectable products, already commercially available in a prefilled syringe, needed passive needlestick safety for a long needle. The Companion Safety Syringe System offered a logical fit because it is a platform solution that produces an advanced anti-needlestick drug delivery device by 'snapping on' modules to any conventional prefilled syringe primary drug container. The pharmaceutical manufacturer would therefore not need to change the existing syringe, plunger or tip cap, nor would it need to alter its

primary package sourcing strategy. The syringe filling would not change at all. In a secondary procedure after filling, the Companion plunger rod and flange would be assembled as is conventionally done for plunger rods and backstops. Because the primary drug container and vendor would remain unchanged, and because there would be no contact between the Companion components and the drug product prior to use, the development, regulatory and sourcing impact and risk could be mitigated.

The delivery system that results from this modular approach will combine passive needlestick safety with other critical end-user features. The user will be able to freely maneuver the plunger rod as is done with conventional syringes without concern for premature activation of the safety mechanism. This will allow standard air bubble removal and aspiration techniques, as well as the ability to use the Companion in reconstitution applications where a diluent is first injected into the vial and then drawn up into the syringe. The passive safety features will be maintained intact for the injection into the patient. At the completion of the injection, the user will be provided visual, audible and tactile cues as the needle automatically retracts into the barrel of the syringe. This passive safety will be possible even with the use of long intramuscular needle and the syringe will then be automatically disabled from future use.



Credence could also address another important performance feature communicated by the pharmaceutical manufacturer: promoting a proper connection between the needle and the syringe. The Companion Guide-On Needle Cover will address this by requiring a proper needle connection before allowing the cover to be removed from the needle, and by providing visual, audible and tactile cues of a successfully connected needle.

Change is hard. Sometimes the benefits that result make the effort worthwhile, but other times the hurdle is too high and cannot be justified. The application of a fresh perspective to an old problem and the understanding of what not to change have lowered the hurdle and yielded a new option. Pharmaceutical manufacturers can now address their needs and those of the end-user by following a simplified path to differentiating their products while delivering the best technology available for the wellbeing of their providers and patients.



For more information, please visit www.CredenceMed.com or email info@CredenceMed.com.

This product has not yet been evaluated by FDA.