## Drug Development & Delivery

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## Credence MedSystems, Inc.: Solving Problems with Needle Clogging & Steel Incompatibility

As injectable therapies become more complex, greater challenges arise in delivering these injectables to provide patients and healthcare providers a user-friendly experience. "A syringe with a pre-attached needle ("staked needle") is the gold standard in our industry, vastly preferred compared to the alternative of requiring the user to attach the needle at the time of use," says Laxman M. Halleppanavar, Head of Portfolio Strategy and Management, Credence MedSystems, Inc. "There are significant usability benefits resulting from the use of a pre-attached needle, including reduced likelihood of user error in attaching the needle, fewer user steps and shorter preparation time, and compatibility with autoinjectors for device-assisted injections."

However, there are circumstances that have traditionally prevented use of a pre-attached needle. Drug formulations that either include suspensions and viscous solutions with the propensity to clog a needle or demonstrate incompatibility with steel or tungsten have prevented use of a pre-attached needle because the needle is in contact with the drug during storage. Without the use of a staked-needle syringe, compatibility with autoinjectors becomes limited. The end-user's experience is therefore negatively affected, which is especially problematic with the ongoing trend wherein delivery of medications moves from formal healthcare settings to administration at home.

Credence MedSystems focuses on identifying problems and bringing innovative design and development to solve these problems and enhance the end-user experience. "The Credence Isolation Valve<sup>™</sup> technology solution enables all the end-user benefits of a pre-attached needle to be realized even with drug formulations that pose needle-clogging risk," he says. The Credence Isolation Valve prevents the drug from migrating into the needle lumen during storage, therefore eliminating the needleclogging risk. When the user or autoinjector applies appropriate pressure, the valve opens, allowing the drug to travel through the needle into the injection site. The Credence Isolation Valve is pre-mounted into a standard staked-needle syringe prior to filling and the syringe arrives to the filling suite pre-sterilized and ready for filling. Because of the valve's low profile, typical fill volumes can be achieved for any specific syringe barrel size.

For drugs where compatibility with steel or tungsten is the problem, Credence offers the Stainless Steel-Free Companion syringe. The Credence (SSF) Companion Syringe<sup>™</sup> is a derivative of Credence's Dual Chamber Syringe<sup>™</sup> platform, utilizing a front stopper to completely isolate the drug product from any exposure to the needle during storage. "Therefore, despite the formulation challenges, the user still benefits from a pre-attached needle as well as all of the demonstrated usability enhancements that come

along with Credence's Companion<sup>®</sup> needle-retraction technology," says Mr. Halleppanavar. At the end of the injection, the user feels and hears an end-of-dose cue in the form of a click, and then the needle retracts into the syringe, preventing accidental needlestick and syringe reuse.

He concludes: "With the end-user in mind and an openness to implementing new approaches, Credence is enabling the gold standard of a pre-attached needle to be employed even with challenging drug formulations. This, combined with autoinjector-assisted injections and Credence's needle-retraction technology, provides user enhancements to healthcare professionals and self-injecting patients."



The Credence Isolation Valve Prefilled Syringe enables all the end-user benefits of a pre-attached needle to be realized even with drug formulations that pose needle-clogging risk.