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Polymer-based prefilled syringes designed to minimize the aggregation risk of sensitive biodrugs

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Aggregation of therapeutic proteins is one of critical risk factors since it may impact negatively on the drug efficacy and safety due to the protein deactivation and immune responses in patients. In 2014, US FDA published a guidance entitled “Immunogenicity assessment for therapeutic protein products” recommending industry to minimize protein aggregation to the extent possible. Silicone oil has been widely used as a lubricant for prefilled syringes to achieve smooth plunger gliding functionality. However, for biopharmaceuticals, silicone oil can have a serious impact because it can induce protein aggregation. This became one of the topics frequently discussed, particularly for developers of highly sensitive biopharmaceuticals. To mitigate the risks related to silicone oil, the demand for a silicone oil free system is surging, and various technologies are now proposed. i-coatingTM developed by Terumo is a coating on the stopper surface having a strong and flexible layer of silicone resin and is applied through a chemical process, including polymerization of the layer. In this poster, the functionality of a newly developed silicone oil free prefilled syringe system using a cyclo-olefin polymer (COP) based barrel and i-coatingTM plunger stopper is presented and compared to silicone lubricated PFS systems. Silicone oil related particles and particles related to protein aggregation are significantly lower in the silicone oil free syringe system. Furthermore, in contrast to a silicone oil lubricated COP syringe system, the silicone oil free system shows no remarkable changes in break loose peak force and it remains stable over time; tests were conducted under various storage temperatures. These findings suggest that silicone oil free syringe system offer favorable performances for silicone oil sensitive drugs, leading to less risk of immunogenicity as pointed out by the FDA guidance.

Biography

Katsuyuki Takeuchi is a Manager of Business Development in Pharmaceutical Solutions, Terumo Corporation, Japan. With extensive knowledge in Pharmaceutical Science, he has worked in research and development of injectable drug products such as IV bags and prefilled syringes, and contributed to launch several products into the market. Utilizing his experience, he is now working on introducing polymer based prefilled syringes to the pharmaceutical industry.

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