Glass handling in drug-delivery device development and commercialisation

Recent device launches in hypercholesterolemia therapy and for biosimilars have highlighted the increasing importance of auto-injectors as a drug delivery method. **SHL Group**'s Dr Thomas Schönknecht offers insight into prefillable syringes, glass handling and final assembly challenges.

Tension and stress-free handling is crucial for the successful final assembly of a combination product.

When prefillable glass syringes with staked-in needles were introduced in the mid-1970s, only manual injection was considered in the specification. The rise of biological drugs however, meant that combining primary containers with injection devices became the norm for development teams in the biopharmaceutical industry. It rapidly became evident that existing designs had to be updated in order to guarantee drug quality and ensure full-dose delivery.

Auto-injectors normally consist of two subassemblies. The front one carries the prefilled container, while the rear one – the powerhouse of the device – is where the force required to empty the container in one continuous motion is created. Syringes for auto-injection systems are typically made of glass and require specific handling by the container manufacturer to become 'device compatible'. Critical geometrical dimensions and performance parameters, such as glide forces, need to be carefully considered to ensure perfect fit and performance of the combination product.

Fully in control

Reliability in drug delivery is a major concern for regulatory agencies, who request substantial data sets demonstrating that the entire mechanism is under full control by the drug-licence holder. Following container-issue-related product recalls in the last few years, regulatory agencies now require documentation of the primary container's interface with the device within the filing dossier.

To address this, industry expectations and requirements for auto-injector-compatible syringes were defined in the PDA technical report number 73: 'Prefilled Syringe User Requirements for Biotechnology Applications'. The container-producing industry has been involved in the definition of these requirements and, as a result, new products are now successfully being introduced to the market.

In addition to syringe performance optimisation, the mindset about handling glass containers has also changed. In the past, speed and throughput on filling and assembly lines were the main industry drivers. However, since the costs of handling glass-breakage-related losses have become a real threat, other issues have come to the fore. Smooth handling of containers during production, including avoiding glass-to-metal contact or jamming of glass containers during transportation, is becoming standard. ■

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