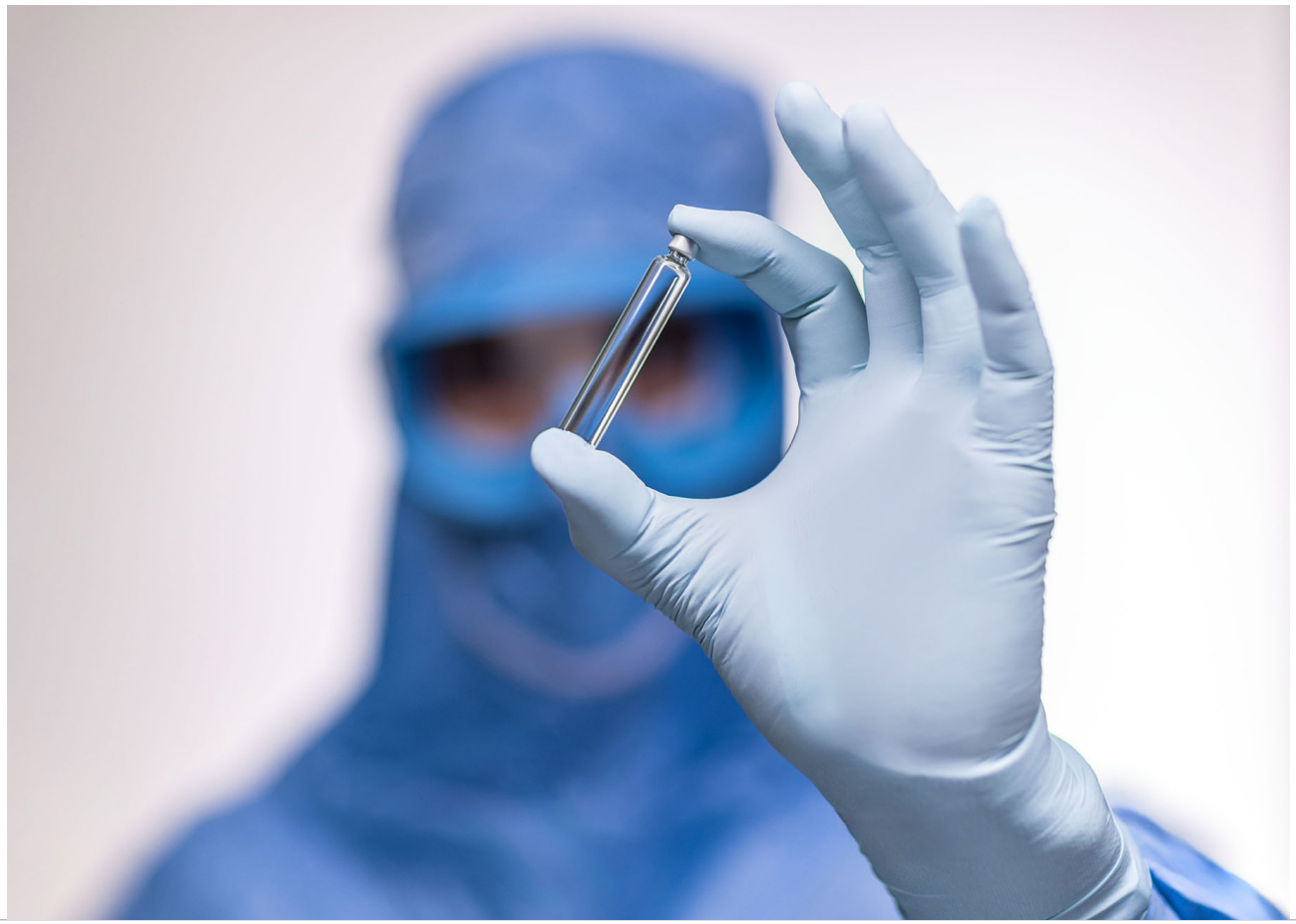
Advanced primary packaging for biologics: STEVANATO GROUP's integrated approach

BIOLOGIC DRUG MARKET EVOLVEMENT AND NEEDS

The biologic segment is widely recognized as the fastest growing within the pharmaceutical industry, consistently outpacing small molecule drugs in sales growth and market expansion.

The biologics market is projected to experience a double-digit (+15%) compound annual growth rate (CAGR) until 2027. [1]

In addition to market growth, biological drugs are increasingly complex and sensitive, while product quality requirements are becoming ever more stringent. Sensitivity to leachables, contaminants, and interaction with primary packaging materials poses risks for protein degradation and loss of therapeutic activity. Packaging materials used must ensure that there are



no interactions with the drug and, in addition, offer excellent compatibility with delivery devices.

The need to accommodate higher volumes, viscous fluids, an expansion of longer-acting injectables with weekly, monthly or even longer dosing intervals, smaller batches, and the omnipresent demand to reduce healthcare costs necessitates innovative and adaptable solutions.

To meet the increasingly demanding requirements of biologic drugs—such as sensitivity to packaging materials, precise dosing, and compatibility with complex delivery systems—primary packaging must evolve accordingly.

Stevanato Group's proprietary glass converting technology is specifically designed to address these challenges, ensuring that biologic formulations are safely contained and effectively delivered.

As a full solution provider, Stevanato Group is in the unique position of being able to offer both the process and the product to address the evolving needs of the market.

HIGHLY-ACCURATE GLASS CONVERTING TECHNOLOGY

Stevanato Group is the only company in the industry offering fully automated, high-speed and highest precision in-house converting technology. The production lines are equipped with a range of features designed to ensure the best product quality:

- Extended 100% forming temperature control by pyrometers
- Monitoring of forming speed (rotation and tool speed)
- 100% advanced inline dimensional control systems for the most critical and/or crucial dimensions and statistical in-process controls
- Optimized tool design and use of new materials for improved handling of the containers
- 100% online camera inspection for cosmetic defects

This proprietary technology ensures the production of glass containers that meet the stringent requirements of biologic drug packaging, offering both mechanical resistance and dimensional precision.

COMPLETE CONTROL AND IMPROVEMENTS

Full control over the forming process and continuous product improvements lead to an optimization of the internal shape, resulting in maximum dosing accuracy. In addition, this enables Stevanato Group to ensure high glass strength against external influences impacting the pri-

mary packaging, such as in drug delivery systems.

Stevanato Group develops its lines with an emphasis on all stages of forming, including the feeding of glass tubes, the glass forming process, transport, annealing, and packing, and manufactures primary containers that meet different market needs.

OUTSTANDING GLASS CONTAINER PLATFORMS

Fina®, Nexa®, Alba® are the Stevanato Group primary packaging product lines. All ensure improved mechanical strength, excellent cosmetic appearance, tight dimensional tolerances, consistent surface performance, and maximum compatibility with drug delivery devices.

These platforms are designed to meet the specific challenges of biologic drug containment, offering tailored solutions for different sensitivity levels and delivery requirements, including the delivery of higher-volume and viscous drugs.

Alba® represents a best-in-class solution for biologic drugs sensitive to silicone oil. Alba® platform comprises prefillable syringes, featured by a cross-linked coating technology based on standard silicone, significantly reducing potential interaction between drug product and container surface, thereby providing a superior packaging solution for sensitive ingredients.

Nexa® containers are superior to standard solutions on the market in terms of functionality and performance, featuring excellent mechanical resistance and superior cosmetic quality. They represent a state-of-the-art option when high quality and outstanding performance are required.

Fina® is the perfect solution when high cosmetic quality and strict dimensional controls are required. It also allows for a high degree of customization when a fully tailored solution is needed.

Alba®, Nexa®, Fina® platforms are all available in EZ-fill® configuration - ready-to-use solutions that reduce total cost of ownership and time to market, preserving quality and increasing flexibility.

CONCLUSION

In a rapidly evolving pharmaceutical landscape, biologic drugs demand packaging solutions that combine precision, safety, and scalability. Stevanato Group meets this challenge with an integrated offering—from advanced glass converting technology to high-performance container platforms and device compatibility. With end-to-end support and proven expertise, Stevanato Group is the trusted partner for delivering innovation and reliability in biologic drug delivery.

REFERENCES

1. Source: IQVIA and Stevanato Group internal analysis

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