



# Container selection for a highly sensitive drug product: a success story





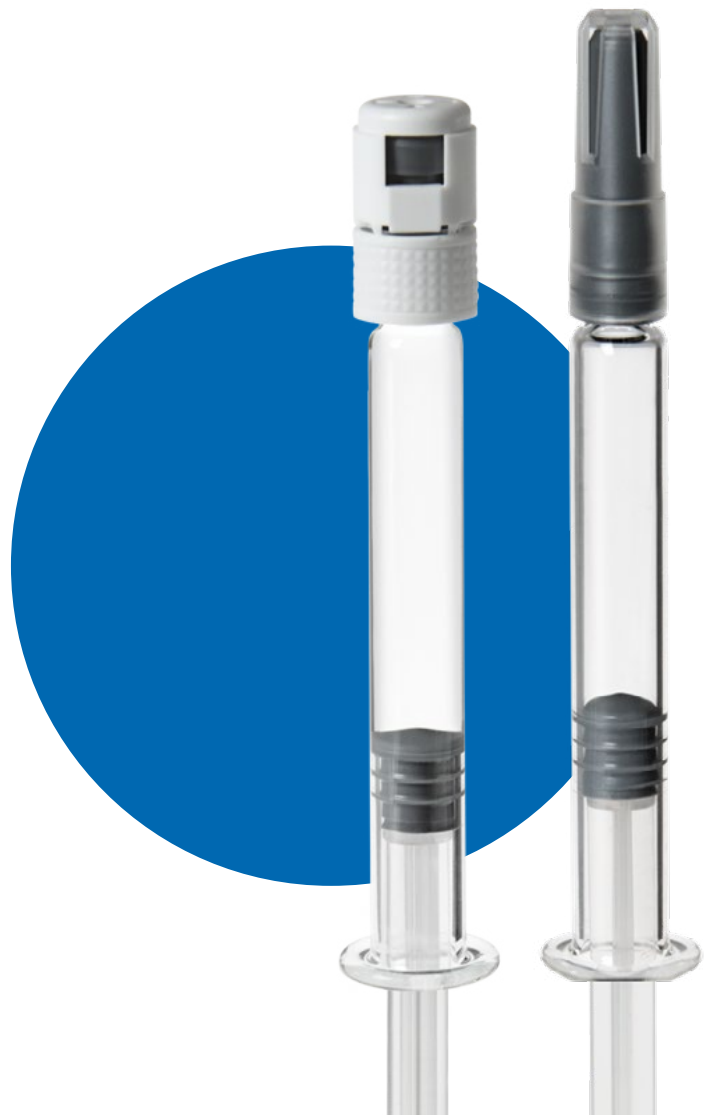
# Support from start to finish

For new drug products, it is essential that pharmaceutical companies utilize the experience of container suppliers as early as possible.

The supplier can enable a deep understanding of the primary packaging, and assist with the multifaceted, complex analysis required to select the appropriate primary container, especially if it is to be integrated into a device. Container suppliers are also able to demonstrate the performance of their product over time and in different conditions to prevent issues during stability testing which may cause

commercialization delays or safety risks to the patient.

Close collaboration between suppliers and clients is invaluable in overcoming initial issues and finding the right containment solutions for sensitive drugs. As this success story illustrates, Stevanato Group supports its clients every step of the way, forging successful long-term partnerships and finding the right solution for each unique situation.



# The challenge

## Sourcing the right container for a highly concentrated monoclonal antibody

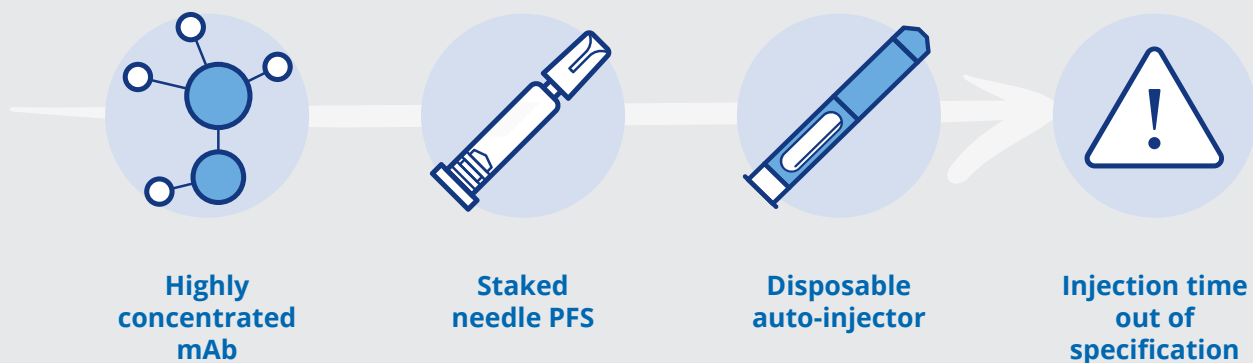
Our client, a leading pharmaceutical company, came to us for a solution to a very specific problem. They needed a staked needle prefilled syringe (PFS) in a disposable auto-injector for their high-concentration monoclonal antibody product. These products are among the most sensitive drugs on the market, and thus require advanced containment solutions and delivery systems. They are particularly sensitive to drug-container interactions and silicone particles, so maintaining drug stability and integrity is especially difficult.

The client had specifically encountered out-of-specification injection times during stability testing. Injection time is

a particular concern for pharmaceutical companies, as it is a major factor in the patient experience to receive the correct dose and therefore critical to the success of a drug delivery system. If left unremedied, these out-of-specification results could additionally lead to serious consequences for the client, including project delays, last minute firefighting and ultimately the need to change the primary container.

As a leading global provider of drug containment and delivery solutions to the pharmaceutical, biotechnology, and life sciences industries, Stevanato Group was able to work closely with the client to find an appropriate solution.

### Initial Challenges of the Case Study



# The solution

## Truly analyze the container selection

Our natural response to the customer's need to identify the appropriate primary container was to carry out a comprehensive analysis to:

- Understand all of the components involved in selecting a container closure system,
- Assess the interaction between drug and the above components using different surrogates,
- Investigate interactions between the primary packaging and drug delivery device assembly, and
- Verify overall performance by testing key performance attributes like injection force and injection time.

A thorough investigation of these

parameters is essential to then understand how interactions affect drug product delivery such as injection time and ultimately patient safety.

This helps to predict the best solution and, when the drug product formulation is defined, rapidly select the right primary packaging components.

This exhaustive analytical process, taking into account the fundamental container to the overall drug delivery system, revealed the outstanding performance of Alba® finally meets the specific requirements of our client.



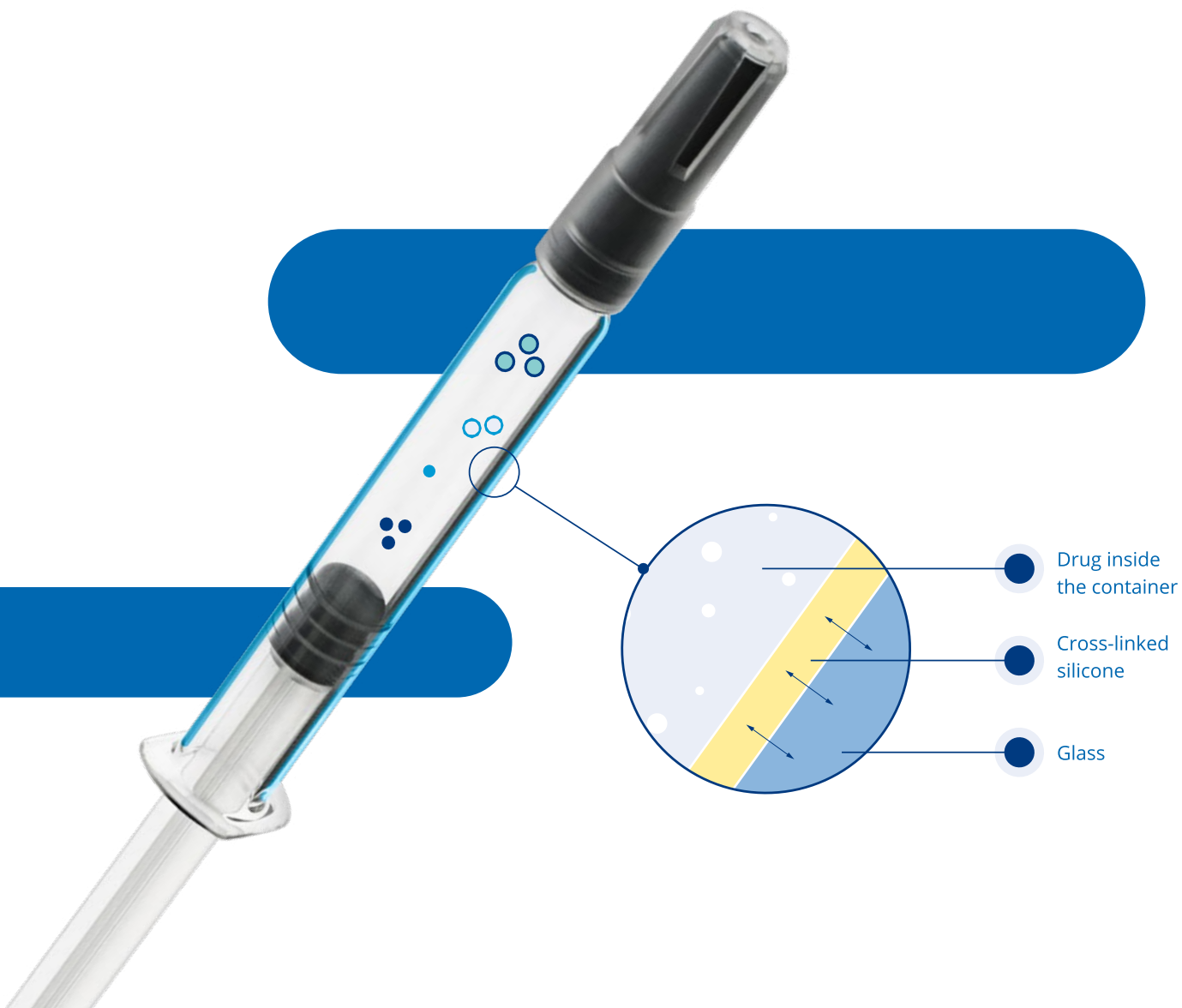
# Alba<sup>®</sup> Platform: Ticking every box

As Stevanato Group's breakthrough technology for biologics, Alba<sup>®</sup> syringes improves upon standard silicone by cross-linking it for exceptional stability and resistance to breakdown without introducing radically new compounds.

The coating provides consistent and predictable gliding force for the syringe, a critical factor in auto-injector performance.

The test data shows below that Alba<sup>®</sup> syringes perform consistently well and meet clients' difficult performance requirements even after storage.

Partners are also able to build on Stevanato Group data and conduct their own testing, to confirm suitability for their specific specifications – and this has resulted in positive outcomes as partners are increasingly confident in Alba<sup>®</sup> as their key solution.



## Silicone particle test results

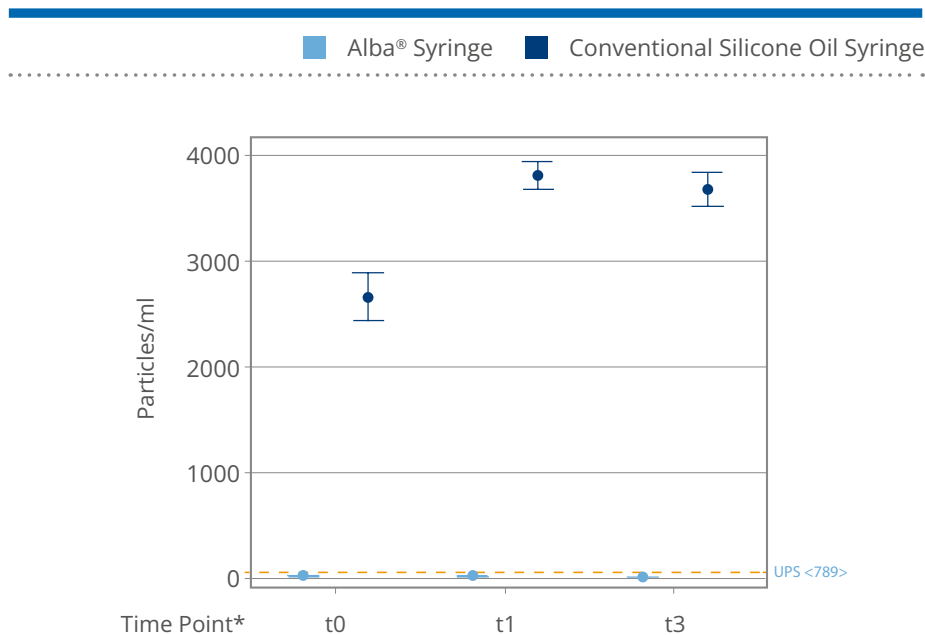
Syringes often must be siliconized in order to allow consistent mechanical performance with the plunger but the drug product may interact adversely with silicone particles. Thanks to the cross-linked silicone oil layer on the inside of the syringe barrel, silicone migration is significantly reduced.

Figure 1 shows how Alba® pre-filled syringes have significantly lower particle levels in comparison to standard siliconized syringes, proving that Alba® provides measurable benefits to silicone oil-based products while minimizing

the risks associated with traditional technologies.

Samples were filled with representative placebo solution containing polysorbate 20 and stored up to 3 months at accelerated conditions (40°C/75% RH), to best simulate the performance of a drug filled syringe along its shelf life.

**FIGURE 1  
INDIVIDUAL VALUE PLOT OF TOTAL PARTICLE CONCENTRATION ≥10 µm (LIGHT OBSCURATION) - STORAGE 40°C/75% RH**



\*t1 and t3 represent the number of months that filled syringes were at an accelerated storage condition (40°C/75%RH per ICH Q1A). These time points were chosen to evaluate potential product performance over its shelf life

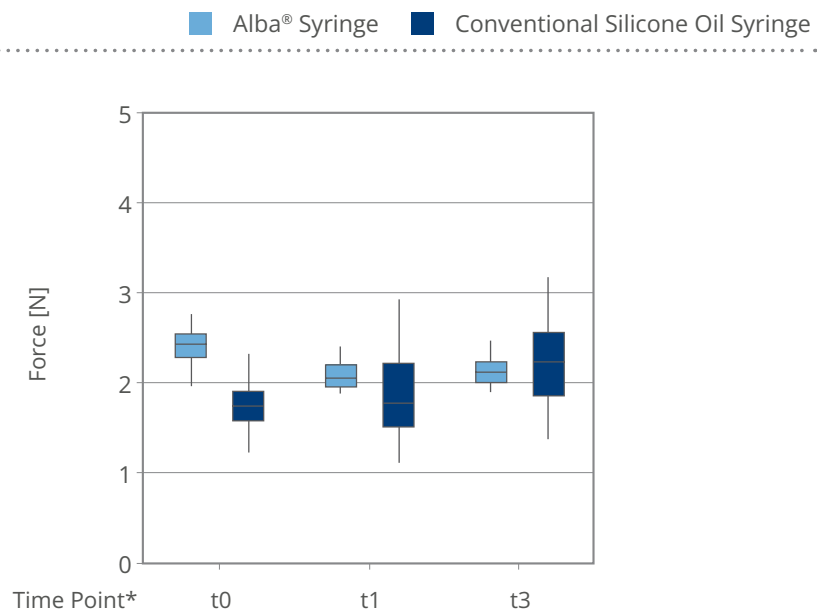
## Gliding force test results

Alba® coating also ensures increased stability of functional performances, notably gliding force. It provides a consistent and predictable gliding force for the syringe over time (Figure 2). This makes it an optimal solution for drug delivery devices like auto-injectors, since it enables adherence to injection time specifications – which was the client's key

concern in this case.

**Figure 2:** Alba® coating provides consistent and predictable gliding force for the syringe, a critical factor in auto-injector performance. This boxplot demonstrates how Alba® performs consistently over an accelerated aging period of 3 months at 40°C/75% RH.

**FIGURE 2**  
**BOXPLOT OF EXTRUSION FORCE [N] - STORAGE 40° C/75% RH**



\*t1 and t3 represent the number of months that filled syringes were at an accelerated storage condition (40°C/75%RH per ICH Q1A). These time points were chosen to evaluate potential product performance over its shelf life

## A win-win partnership

When Stevanato Group is involved from the early stages, before the container is even chosen, we can support the client with a comprehensive data-driven analysis so the client can make an informed choice and select the optimal solution for their drug product.

For this client's high concentration monoclonal antibody, Alba® syringes are the most suitable choice as demonstrated by its outstanding test results in terms of both particle release and gliding force.

Stevanato Group has the expertise required to help partners select the right solution, offering:

- In-depth understanding of how drug interacts and impacts primary packaging/ medical devices
- Close collaboration with clients from face-to-face visits to facilitating new connections with our global network of internal capabilities and external CDMOs
- Support on complaints, technical issues, and characterization of samples in

root-cause investigations

- Support on processing of primary packaging components, inspection equipment and assembly lines.

For new drug products in particular, early-stage support from container suppliers like Stevanato Group is vital to ensure that all salient criteria are taken into account when selecting primary packaging – avoiding the costly repercussions of delays later in the regulatory and commercialization process. A strong supplier-client relationship, founded on collaboration and transparency, and driven by empirical data achieves a win-win outcome.



# Authors



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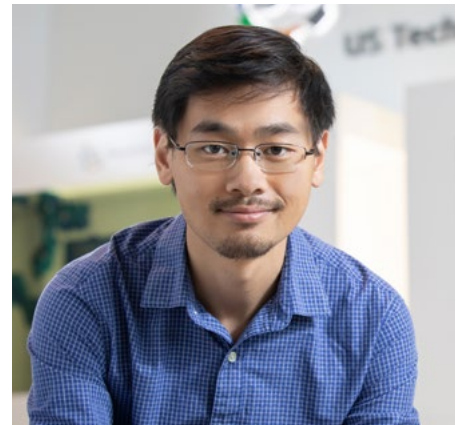
With a background in Industrial Engineering and a Master's in Management at the University of Padua, Enrico Barichello acquired broad-spectrum skills in technical concepts and complex processes.

He joined Stevanato Group in 2017 as a Product Management Specialist for the Syringe platform.

He defined and coordinated all the activities required to bring the products to market, bridging gaps between different company functions and aligning the involved teams.

He has been responsible for the roadmap and execution of the innovative platform Alba®.

Since 2023 he is Product Manager for the Glass Syringe Platform.



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**Alan Xu**  
Product Manager for Analytical  
Services, Stevanato Group's  
Technology Excellence Centers

Alan Xu is a primary contact for pharmaceutical and contract organizations around the world who are interested in leveraging TEC's expertise to de-risk and optimize their combination products. Alan also investigates new analytical opportunities like low temperature CCIT and promotes awareness on ways to improve product quality and patient safety using data-driven methods.

Prior to Stevanato Group, he was an Engineering Manager leading the development and pilot production of a novel primary container to be used with a novel auto-injector specializing in biologics. He holds a degree in Mechanical Engineering from the Massachusetts Institute of Technology (MIT).

# About Stevanato Group

Founded in 1949, Stevanato Group is a leading global provider of drug containment, drug delivery and diagnostic solutions to the pharmaceutical, biotechnology and life sciences industries. The Group delivers an integrated, end-to-end portfolio of products, processes and services that address customer needs across the entire drug lifecycle at each of the development, clinical and commercial stages. Stevanato Group's core capabilities in scientific research and development, its commitment to technical innovation and its engineering excellence are central to its ability to offer value-added solutions to clients.

To learn more, visit [stevanatogroup.com](https://www.stevanatogroup.com)



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