Stevanato Group

MEETING QUALITY DEMANDS THROUGH INTEGRATED PRODUCTS AND SERVICES

In this article, Lars Keinicke Hansen, Business Line Manager for Pharma Inspection and Packaging & Assembly; Chiara Mussoi, Product Manager for the Cartridge Platform; and Odra Pinato, PhD, Head of SG Lab Analytics Laboratory; all of Stevanato Group, describe how the streamlining of processes and harmonisation of products and services can better serve pharmaceutical companies. A case study highlights how a unique combination of expertise in automation and glass primary packaging benefited pharmaceutical giant Merck Serono in a recent project.

Combination products are being launched for an increasing range of therapies, including low-volume orphan drugs, high-volume pharmaceuticals and highly competitive biologics and biosimilars. However, very few pharma companies are equipped to handle these complex drug-device integration projects alone.

In a traditional supply model, a pharma company would source primary packaging from one vendor and the drug delivery device from another. Performance of these two separate constituents would be analysed and characterised by external laboratories. Automation specialists would fabricate assembly and testing equipment and yet another company would perform commercial production. This effort required a tremendous amount of co-ordination between the pharma company and various suppliers.

Organising information and materials, and sequencing the movement of both, can be an imposing task. The risks are high, as a single wrong step along the way could cripple a project. Delays to a drug launch can impact the lives of millions of patients around the world, as well as creating devastating financial consequences for the pharma company itself.

To minimise the risks and ease the burden on the pharma company, some suppliers have been expanding their offering

> "At the heart of any combination product is the primary packaging."

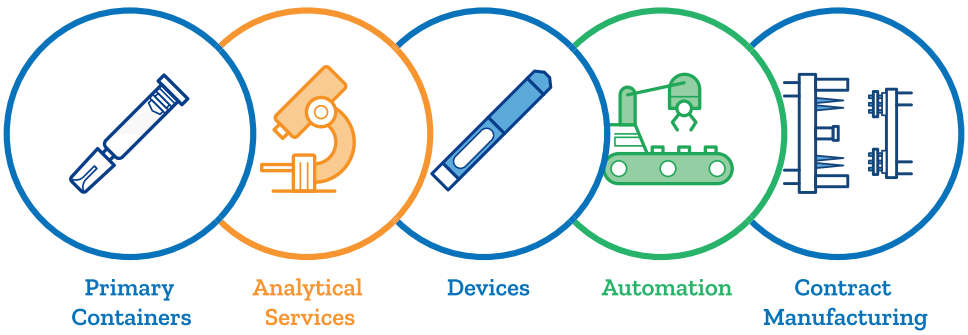


Figure 1: Working with integrated partners ensures smooth transitions of information and materials that streamline processes and harmonise products and services.

Lars Keinicke Hansen
Business Line Manager for Pharma Inspection and Packaging & Assembly
E: lars.keinickehansen@stevanatogroup.com

Chiara Mussoi
Product Manager for the Cartridge Platform
E: chiara.mussoi@stevanatogroup.com

Dr Odra Pinato
Head of SG Lab Analytics Laboratory
E: odra.pinato@stevanatogroup.com

Stevanato Group
Via Molinella 17
35017 Piombino Dese
Padova
Italy

www.stevanatogroup.com

by integrating one or more products or services to better serve pharma partners directly. The relationship between pharma companies and these suppliers has evolved into a collaborative partnership, with a joint desire and responsibility for project success.

HARMONISATION THROUGH INTEGRATION

As an integrated project partner, Stevanato Group supports pharma companies at all stages of the drug development journey through a comprehensive suite of products, technologies and services. Through continually expanding its capabilities, Stevanato Group can oversee a drug delivery device programme under a unified project management and quality system (Figure 1).

The experience gained from developing primary containers, integrating drug delivery devices and performing contract manufacturing services has enabled Stevanato Group to produce an intimate perspective of the critical path for any medical device project. This knowledge and experience are used to streamline processes and harmonise products and services. This includes expansion of the company's primary packaging offering through laboratory and analytical services, as well as streamlining its automation offering.

LABORATORY AND ANALYTICAL SERVICES

At the heart of any combination product is the primary packaging. This component plays a crucial role in protecting the drug product and enabling the delivery of medicine to patients. Stevanato Group is a leading provider of glass primary packaging for pharma and biotech companies, offering a range of high-quality EZ-fill syringes, vials, cartridges (ready-to-use containers) and bulk packaging options. These devices are relied upon for delivering diabetes treatment, emergency medication, vaccines and high-value biologic drugs throughout the world.

With its history of processing glass for pharma applications, Stevanato Group has amassed a large amount of technical data and experience in primary packaging and related components of the container closure system. This important industry resource can be accessed through the group's analytical and testing services.

Partnering with Stevanato Group provides access to an accredited laboratory with teams of scientific experts that perform research projects and studies to help customers understand the potential interactions between pharma products, their containers and delivery devices. Operating in compliance with ISO/IEC 17025 2018, these experts use the latest technologies and methods to perform a wide array of tests and assessments, including chemical analysis, surface characterisation, container interaction, and physical and mechanical performance, including drug delivery systems testing.

The output of these studies can help customers navigate critical decisions related to container selection, device compatibility and process improvements, bringing value to any stage of a drug delivery device programme. To increase access to these resources, Stevanato Group has expanded this offering through a recently announced Technology Excellence Centre in Boston, MA, US.

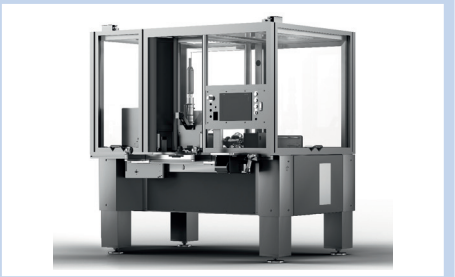
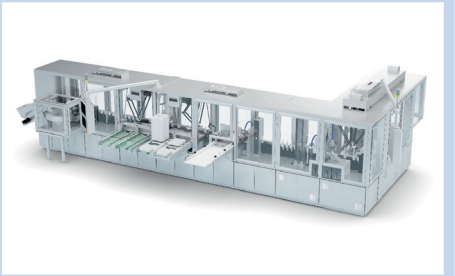
	Type	Description	Applications	Output Speed (parts per minute)	Flexibility
	**Benchtop or lab unit**	Low volume manual or semi-automatic assembly	Device & process development	1-6ppm	Fixtures are changeable to handle different products
	**Rotary**	Ideal for space saving assembly processes	Scale-up, clinical & low volume commercial production	6-40ppm	Machines can be linked together to reduce number of parts, processes and simplify reconfiguration
	**Linear (BasiQX XTV & XTH)**	Platforms based on linear transport system for complex assembly tasks	High-speed, large-scale commercial production	Up to 200ppm	Countless applications, accommodates different formats & future capacity needs at scale

Table 1: Stevanato Group has three customisable assembly platforms, bringing new levels of production flexibility and scalability for pharmaceutical partners.

SCALABLE AND FLEXIBLE AUTOMATION SOLUTIONS

In addition to this expansion, Stevanato Group has invested significant resources in how it delivers automated assembly solutions to clients. This streamlined approach centres on customisable platforms and modules that bring new levels of production flexibility and scalability for pharma partners, while reducing total cost of ownership.

Stevanato Group has applied its expertise and knowledge to develop three customisable platforms that form the foundation of its assembly solutions for autoinjector, pen injector, wearable and inhaler projects (Table 1).

Benchtop or laboratory units are available for device and process development purposes, including early proof of principle and assembly validation. Once the assembly process has been validated, it can be easily and rapidly scaled up to meet production demands, minimising risks through early debugging.

By leveraging approaches across projects and predesigning common parts, Stevanato Group has developed flexible modules for operations that are often repeated in different projects. This includes in-feeds, assembly modules, in-process controls, robotics and other elements, such as labelling and packaging. These process modules are then customised according to project specifications and paired to the parent platform, creating a cohesive, fully tailored system.

This approach enables the company to engineer tailor-made solutions that deliver consistent performance and high-quality standards, and opens up the opportunity for greater flexibility to adjust to new device configurations, different device formats or production requirements.

Its modular system architecture streamlines production scale-up, lowers risk and accommodates future expansion, providing long-term value to clients by reducing total cost of ownership and future-proofing their investment.

"Once the assembly process has been validated, it can be easily and rapidly scaled up to meet production demands, minimising risks through early debugging."

CASE STUDY

A recent case study demonstrates many of the key benefits that a proven, integrated partner such as Stevanato Group can bring to a project by taking a holistic view.

As a long-term supplier of primary packaging to Merck Serono, Stevanato Group was engaged to provide highly resistant glass cartridges that could be easily integrated with a pen injector used in different treatments. To help the customer select the appropriate container for their device and processing equipment, Stevanato Group combined its glass expertise with proven testing methods and statistical analysis to establish a viable solution.

By developing a custom testing protocol that focused on mechanical characterisation methods, a comprehensive series of controlled data points was generated for two cartridge products. Performance evaluations and testing of both containers on processing equipment at Merck Serono's site followed. After analysing the results, Merck Serono could confidently select Nexa – a glass product with high break resistance, enhanced cosmetic appearance and tight tolerances that maximise device performance (Figure 2). Furthermore, the analytical team provided recommendations on how to adjust the processing parameters in order to increase the filling line yield.

In addition to these services, Stevanato Group's automation division was commissioned to develop a final assembly solution capable of manufacturing the three different configurations of pen injector. There were high expectations for precision, product quality and throughput.

With its proven linear motion system, Stevanato Group's BasiQX XTV provided

Figure 2: Nexa glass cartridges have an increased mechanical resistance, enhanced cosmetic appearance and tight geometric tolerances.

Figure 3: Linear motion assembly platform customised to Merck Serono pen injector needs.

a reliable and flexible platform for quickly developing a tailored system. Inspection, assembly and labelling modules were configured for the unique processes involved in the project. The result was a cohesive machine with very high precision that was tuned to assemble the different device configurations required. An intelligent layout ensured a compact footprint, a safe working environment for operators and system modularity for future scalability (Figure 3).

> "The result is a state-of-the-art, integrated automation solution that has been supported by the group's expertise in primary containers and analytical services."

Following Good Automated Manufacturing Practice (GAMP) guidance, all incoming materials are checked within the in-feed modules. Rejects are ejected locally to ensure they do not progress further down the line. Labels are verified before application to the final device, which reduces waste by removing the risk of rejecting a fully functional pen due to a misprinted label.

With an emphasis on product quality, the line performs numerous inspection and verification steps, with eight key parameters controlled throughout the process. A combination of cameras, sensors and force position controls are used to detect, verify and pre-orientate components. The dosing mechanism on each pen is tested and, by detecting the exact position of the plunger disc in relation to the cartridge stopper within tenths of a millimetre, each pen can be individually predialled for priming.

Three different pen configurations are handled on the same final assembly machine through a fully automatic format changeover, with the machine changeover time taking less than 10 minutes. No parts need to be physically changed, allowing operators to focus on executing a full line clearance. Equipment highlights include:

- 100% quality control – pens are individually primed to ensure proper dosing
- Highly efficient design – allows three pens with different dose settings to be assembled on one line
- Reduced waste – local reject stations reject only defective components
- Fully automatic changeover – supports flexible production requirements
- Scalable – opportunities to expand equipment to meet future capacity needs.

The result is a state-of-the-art, integrated automation platform that has been supported by the group's expertise in primary containers and analytical services – the combination of which has provided tangible value to an established pharma client.

Commenting on the collaboration, Marcorosario Cusmano, Technical Services Director, Merck Serono Bari Site (Italy), said: "We set the bar very high in terms of both quality and flexibility for this production

Figure 4: Stevanato Group's proprietary and licensed devices portfolio.

line. We partnered with Stevanato Group due to their approach, technology and track record. Now that the line has been commissioned and is starting to operate commercially, I can say that we are very satisfied with the technical implementation and resulting quality that Stevanato Group's integrated approach provided.

CONCLUSION

As combination products continue to grow in both popularity and complexity, the risk placed on these development projects is similarly increasing. To best support project success, Stevanato Group has built upon its foundation as a trusted supplier of primary packaging to add analytical services, automation development, device development and manufacturing services (Figure 4). The integration of these products, knowledge, technologies and services reduces the burden on the pharma partner and de-risks the project, allowing insights and ideas to flow and value to be added at each step.

By providing end-to-end solutions, based on its broad knowledge base and extensive capabilities, Stevanato Group can help customers with the most complex projects. Partnering with a fully integrated supplier such as Stevanato Group provides a platform for deeper dialogue, improved efficiencies, shorter time to market and a single, fixed point of accountability.

"We set the bar very high in terms of both quality and flexibility for this production line. We partnered with Stevanato Group due to their approach, technology and track record. Now that the line has been commissioned and is starting to operate commercially, I can say that we are very satisfied with the technical implementation and resulting quality that Stevanato Group's integrated approach provided."

Marcorosario Cusmano, Technical Services Director, Merck Serono Bari Site (Italy)

ABOUT THE COMPANY

Established in 1949, Stevanato Group is the world's largest privately owned designer and producer of glass primary packaging for the pharma industry. From its outset, the group has developed its own glass converting technology to ensure high standards of quality. The group comprises a wide set of capabilities dedicated to serving the biopharmaceutical and diagnostic industries: from glass containers with its brand Ompi; to high-precision plastic diagnostic and medical components; to contract manufacturing for drug delivery devices; to vision inspection systems, assembly and packaging equipment. Stevanato Group also provides analytical and testing services to study container closure integrity and integration into drug delivery devices, streamlining the drug development process. The company is able to offer a range of solutions to biopharma companies for a faster time to market and a reduced total cost of ownership.

ABOUT THE AUTHORS

Lars Keinicke Hansen is Business Line Manager for the Pharma Inspection and Packaging & Assembly at Stevanato Group. He boasts extensive technical experience and management skills to deliver assembly and packaging solutions for the pharma industry. Mr Hansen has a BSc in mechanical sciences from VIA University College in Horsens (Denmark). Before joining the company, he worked as a mechanical engineer and project manager in charge of assembly equipment for insulin pen injectors, assembly lines for plastic syringes and packaging lines for vials, syringes, cartridges and process equipment for catheter production.

Chiara Mussoi is the Product Manager for the Cartridge Platform at Stevanato Group. She is responsible for the development and definition of the go-to-market strategy of glass cartridges (ready-to-use and bulk). After her studies in economics and business administration at the University of Udine (Italy) and Copenhagen Business School (Denmark), she built extensive knowledge working as Product Manager for medical devices for injectable products. Since 2016 – when she joined Stevanato Group – Ms Mussoi has been in charge of evaluating and promoting new products that meet customers' needs and expectations.

Dr Odra Pinato is the Head of the SG Lab Analytics Laboratory at Stevanato Group. She joined the company in 2014 as a protein chemistry expert. Dr Pinato is a pharmaceutical biotechnologist with a PhD in biochemistry and biotechnology. Her academic background is mainly focused on protein chemistry, with two years of post-doctoral experience in nucleic acid biophysics and pharmaceutical chemistry. Since May 2016, she has been leading SG Lab Analytics – Stevanato Group's advanced laboratory focused on analytical chemistry, material properties, and physical and mechanical performance testing of pharma packaging.