A MODEL FOR TRANSFORMING BREAKTHROUGH INNOVATIONS IN SUCCESSFUL PRODUCTS

Here, Eric Dessertenne, Chief Operating Officer, Philippe Lesaulnier, Business Development Manager, and Arnaud Guillet, Business Development Manager, all of Biocorp, outline Biocorp's approach to device design and detail two products in the company's portfolio, Newguard and Easylog, which are anticipated for market launch next year.

A major concern for pharmaceutical companies is the comfort and safety of patients during the administration of their treatment. All too often, noticeable weaknesses in this area, including needlestick injuries or dosing errors, are observed.

Biocorp strives to offer reliable solutions to improve patients' lives. After a thorough research and development phase together with experimental collaborations with different partners, the company is now expecting its first market launches in 2019. In order to ensure it never loses sight of the patient, Biocorp works systematically to understand the needs of patients and propose the most suitable devices. To illustrate this approach, let's have a closer look at two key devices in Biocorp's portfolio: Newguard, the integrated safety system for prefilled syringes, and Easylog, the connected add-on device for pen injectors.

NEWGUARD – ANSWERING THE NEED FOR SECURITY

Enhancing safety for syringe use has been an increasing concern for pharmaceutical companies and healthcare providers, as handling prefilled syringes (PFS) all too often leads to needlestick injuries. The concept of needlestick protection is not new but, during the last decades, we have seen a significant modification of technical solutions available to reduce those risks. Early devices were manually activated, meaning that additional movements and manipulation of the device were required to activate the safety features.

A second generation of device was later developed, designed to be passive systems but still part of the overall concept of adding an additional element to the PFS. These systems do not require any additional action by the user, with the safety mechanism activated upon complete administration of the drug.

For many years, the "add-on safety principle" was the main answer to protect end-users against needlestick injuries when using PFS. These systems widely contributed to needlestick injury reduction in hospitals and during self-injection. However, they generated some burdens for pharma companies, such as additional costs, manufacturing complexities and increased product size.

Recently, a new trend in safety systems appeared: integrating the safety system at the syringe manufacturer site before the sterilisation cycle. Integrated safety systems are active or passive, pre-assembled on syringes by the glass suppliers and ready to use. The main benefit for pharmaceutical companies is that they receive a ready-to-fill system that comes already equipped with safety protection for the staked-needle PFS format.

That led Biocorp to develop Newguard, an integrated passive safety system for prefilled syringes. In doing so, Biocorp transformed a simple idea into a concrete innovation for the pharmaceutical industry.

Eric Dessertenne
Chief Operating Officer
T: +33 6 08 02 14 51
E: edessertenne@biocorp.fr

Philippe Lesaulnier
Business Development Manager
T: +33 7 87 60 50 76
E: plesaulnier@biocorp.fr

Arnaud Guillet
Business Development Manager
T: +33 6 48 28 51 16
E: aguillet@biocorp.fr

Biocorp
Parc Technologique
Lavaur-La-Bèchade
63500 Issoire
France

www.biocorpsys.com

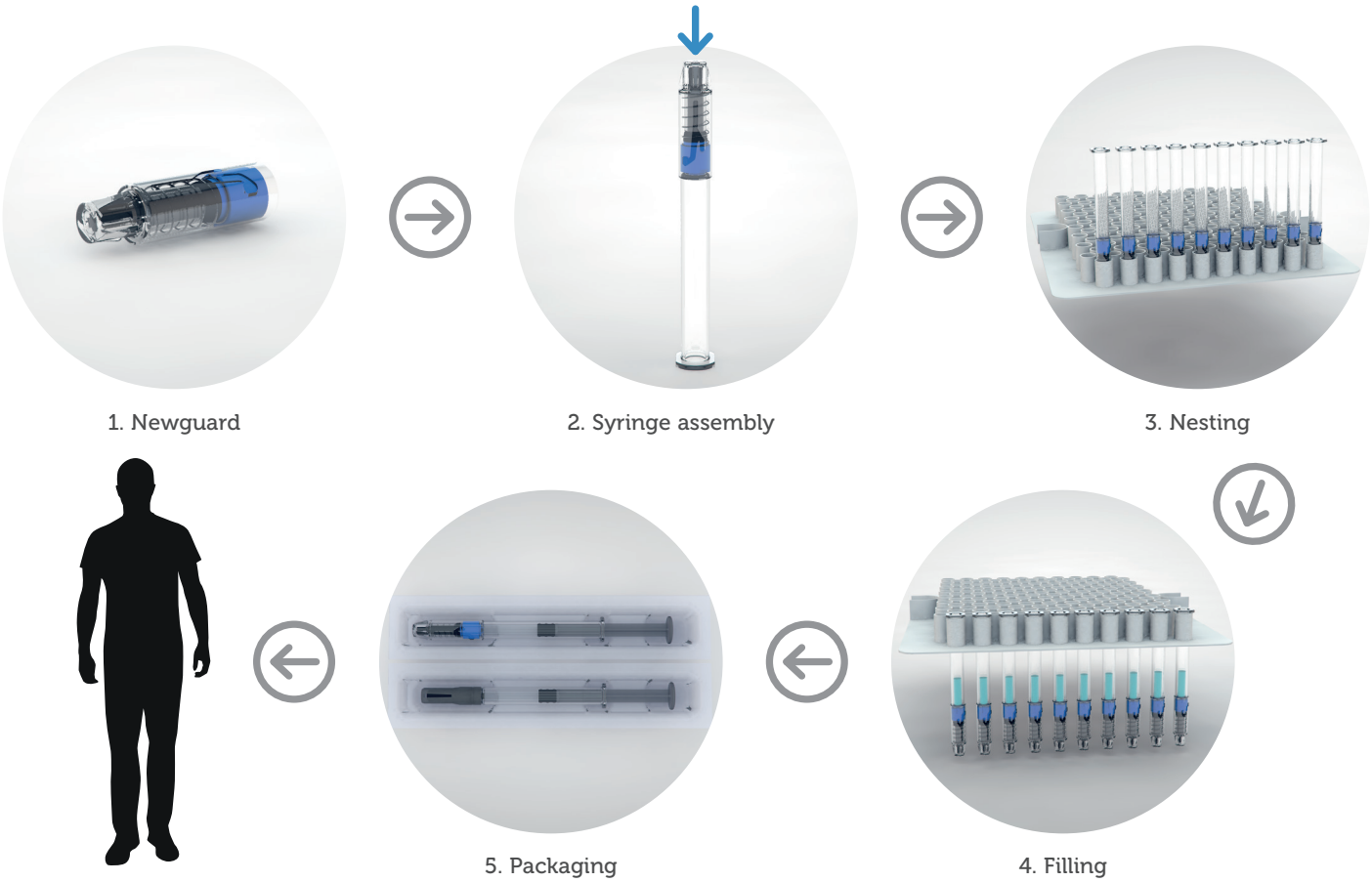


Figure 1: Newguard assembly process.

"After finalising several major steps of the development process, the Newguard design has been finalised and currently offers recognised technological advantages for optimal patient comfort."

There were numerous challenges to design a system that could both answer customers' requirements and that could be integrated into pharmaceutical processes with easy validation and limited impacts on regulatory aspects.

The user-friendly Newguard device is a system designed to be compatible with any standard PFS. It combines two functions in a single product: a rigid needle shield and a safety device. This all-in-one concept is highly appreciated by end-users, providing a reliable safety solution in a compact format.

The Up and Coming Standard Device On the PFS Market

Biocorp aims to work on innovative and cost-effective solutions. By adding Newguard to the syringe, every step of the PFS production process remains unchanged. Indeed, Newguard is produced and assembled at Biocorp's manufacturing site and then shipped to glass manufacturing partners for final assembly (Figure 1). The model is very similar to the existing model of assembling a rigid needle shield (RNS) to a standard syringe. After the nesting process of these assembled syringes, they will then go through the ethylene oxide (EtO) sterilisation process before being shipped to the end pharma customer. As Biocorp uses standard nest and tub formats, the filling process is also similar on the customer filling line, reducing the upfront conversion cost from a customer's previous safety system to Newguard.

After finalising several major steps of the development process, the Newguard design has been frozen and currently offers recognised technological advantages for optimal patient comfort. During this phase, Biocorp had extensive interaction with major technical partners to propose a ready-to-use product for pharma companies. Biocorp is now fully engaged with implementing an ambitious industrial model to serve a large market.

From Designing to Manufacturing

Biocorp's strength is not to deliver a mere concept, but specifically to take into consideration the design for manufacturing and industrialisation process from the very beginning of development. As a vertically integrated structure, Biocorp puts an emphasis on lean and effective collaboration between R&D and industrialisation teams to pave the way for an efficient manufacturing process.

This vertical integration is in Biocorp's DNA and offers a very specific positioning of the company within the drug delivery technology landscape.

Biocorp's Easylog has also been developed and moved along via the same methodology.

EASYLOG – IMPROVING PATIENTS' COMPLIANCE

Easylog is a smart cap compatible with all pen injectors that captures the exact dose dialled and delivered to the patient, together with time and date, and transfers that data automatically to a mobile app, utilising Bluetooth technology (Figure 2). Easylog is representative of Biocorp's "from design to production" approach.

Figure 2: Easylog, the connected add-on device for pen injectors.

"Easylog will be ready for distribution in the coming months. CE Mark and US FDA applications will be filed for the first ones before the end of the year."

The final assembly process relies on Biocorp's internal capacities together with the support of leading electronics integrators. Biocorp sees great benefits in manufacturing the first series of devices itself: it allows the industrial team to validate the production equipment, identify and correct any production incident and master the process, before potentially relying on external providers once the production volume increases.

Focus On What Really Matters for Patients and All Healthcare Stakeholders

Across the different therapeutic areas Biocorp is working in, diabetes and insulin injection is the first where the value of Easylog has been widely recognised, being integrated in a global ecosystem where diagnosis, insulin delivery and coaching advice will form a revolutionary offer to the patient.

Based on strong market knowledge and evidence collected from patients and healthcare providers (HCPs), the team mainly focuses on the most valuable and relevant functionalities for patients. For instance, right from the early stage of development, the team focused on the most critical factor for pen injector monitoring: capturing the exact dose delivered by the patient together with the time and date. The design of the device also allows for proper differentiation between priming doses and injection doses – delivering the patient or the HCP the injection data only.

"Easylog is of huge benefit, as it circumvents the danger of a patient forgetting their logbook and relieves the burden of constantly keeping track and reporting their doses, knowing that this effort is taken care of automatically and accurately by the Easylog connected device."

This data is key information for the patients, therefore Easylog is of huge benefit, as it circumvents the danger of a patient forgetting their logbook and relieves the burden of constantly keeping track and reporting their doses, knowing that this effort is taken care of automatically and accurately by the Easylog connected device. It's also crucial for HCPs, who can get reliable information thanks to Easylog's accurate recordings, improving the precision of the data on which they can base their diagnosis, for instance the measurement of the impact of the evolution of insulin dosages among their diabetic patients. The quality of their diagnosis and support of the patient depends on this key factor.

But beyond the traditional duo of patients and HCPs, many actors, such as blood glucose monitoring (BGM) and continuous glucose monitoring (CGM) actors, pharma companies, drug delivery networks and probably payers as well in the near future, are increasingly involved in the diabetes management space and propose a revolutionary approach: the "closed-loop system" or "semi-closed-loop system". The principle is to pull all the information and data from key devices and solutions involved in the management of diabetes (glucometers, titration solutions, coaching, activity trackers, dietary solutions, pen injectors and/or pumps) and gather them in a single platform for analysis, support and real time decisions. It goes without saying that the value of the entire service relies on the accuracy of the information reported; analytics and algorithms are only as good as the input data they utilise. Biocorp intends to be part of this effort and has already built strong connections with some of these players to bring Easylog on board. The 100% accuracy of the system is the key selling point for Biocorp's partners, who want to feed their systems with input data to provide the most relevant analysis and the best level of services.

Device to be Launched in 2019

Easylog will be ready for distribution in the coming months. First CE Mark and US FDA applications will be filed for the first before the end of the year. Easylog will cover all the major insulin pen platforms on the market. After Easylog gets approval from the regulatory authorities, Biocorp will commercialise the solution with partners, and connect to any diabetes support platforms, fulfilling its purpose of facilitating treatment management for the patient.

Nonetheless, whereas the Easylog device will be marketed first as an accessory to insulin pen platforms for diabetes, the add-on will be adapted to other indications. Biocorp has already engaged in developing tailored-made adaptations of Easylog for use in other therapeutic areas.

CONCLUSION

Over the years, Biocorp has been developing a firm idea of bringing innovative products to the market with a continuous mindset of making these devices simple. Newguard and Easylog reflect this philosophy and our long-term commitment for making patients' lives easier.

ABOUT THE COMPANY

For 20 years, Biocorp has been designing, developing and manufacturing medical devices for the pharmaceutical industry, enhancing drug reconstitution, safety, packaging and delivery. Today, Biocorp continues to innovate in medical plastics, bringing new solutions to the market such as the Newguard™, an integrated passive safety system for PFS compatible with nest, and Biopass, a reconstitution system with an integrated needle ready to inject.

Recognised for its expertise in device R&D, Biocorp has incorporated software development capacities to develop connected drug delivery systems, including the DataPen®, a reusable smart pen injector that automatically transmits data to a treatment mobile app, helping patients to manage their treatment, and a range of add-ons, smart sensors for existing drug delivery devices (pen injectors, MDIs).

In addition to its R&D activities, Biocorp also provides manufacturing services for plastic injection, process assembly and blister packaging.

ABOUT THE AUTHORS

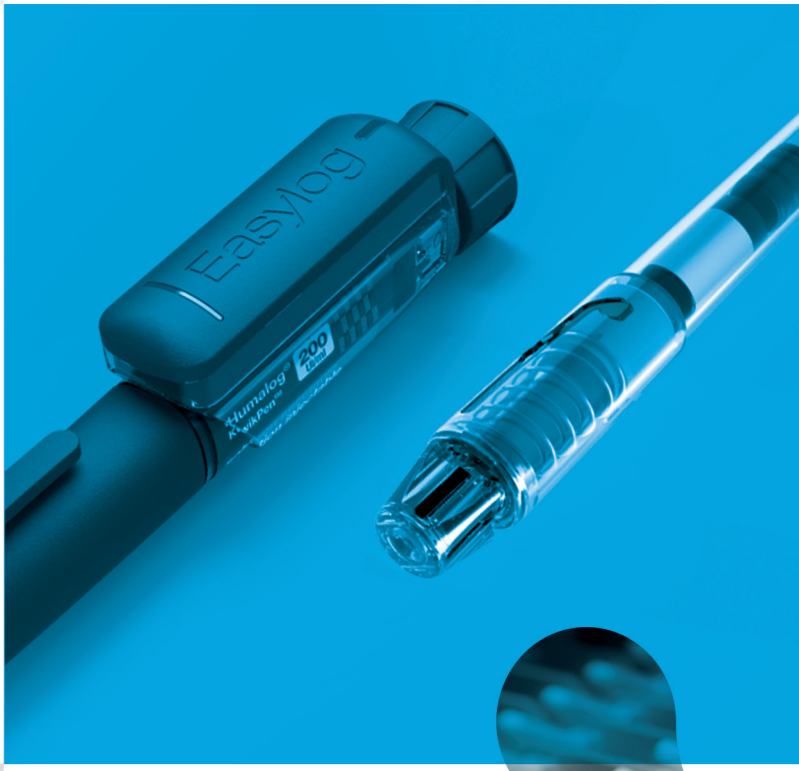
Eric Dessertenne, Biocorp's Chief Operating Officer, holds a pharmaceutical degree from the University of Clermont-Ferrand (France), an MBA from ESSEC Business School (Paris, France) and is a graduate of the Therapeutic Chair of Innovation at ESSEC Business School. He began his career in the pharmaceutical industry working for Servier in France in the Corporate Strategy department and then moved to the Chinese subsidiary in Beijing, where he handled positions in the marketing and sales force department. Mr Dessertenne then joined LEK Consulting where he worked as a consultant in the Life Sciences and Private Equity practices. In 2014, he brought his experience and insights on market opportunities to Biocorp as Head of Business Development & Commercial Operations.

Philippe Lesaulnier is Business Development Manager at Biocorp, in charge of finding opportunities for non-connected devices from Biocorp's range and customised solutions for pharmaceutical companies. Operating in the pharmaceutical packaging sector for 25 years, Philippe has worked for companies like West, Rexam and Gerresheimer, in charge of major pharmaceutical accounts on a worldwide basis. Specialised in primary packaging for parenteral products, he has a combined technical background (electronics and mechanics) and numerous business experiences.

Arnaud Guillet is Business Development Manager at Biocorp, in charge of finding partnerships and license opportunities for Biocorp's range of connected devices. Previously, Guillet worked for a healthcare consulting firm with a strong focus on connected health strategies for pharma and insurance companies and has additional past experience in the pharmaceutical industry (with Sanofi) and the insurance industry (with AXA). He graduated from HEC Paris, a major European business school.

BIOCORP

Upgrade your life!



COME AND VISIT US:
PDA, Orlando, FL: Booth #516
PODD, Boston, MA: Booth #40

WWW.BIOCORPSYS.COM