

SCHOTT
glass made of ideas

CREATING PREFILLABLE SYRINGES FOR THE BIOLOGICS MARKET

As pharmaceutical companies increasingly shift their focus towards biopharmaceuticals and large-molecule drugs, the need for syringes that can handle these sensitive and complex substances becomes more pressing. One such product, syriQ BioPure® is made of high-end materials and integrates seamlessly with autoinjectors to ensure patient convenience. In addition, the syringes link with an innovative filling platform that enables small batches and/or different containers to be filled on one line. Nicolas Eon, Global Product Manager, and Fabian Stöcker, Head of Global Strategy & Innovation, both of Schott Pharmaceutical Systems, explain more.

Over the last several years, the number of blockbuster drugs in the development pipeline has decreased. Drug companies have largely shifted their research interests towards biopharmaceuticals, protein-based therapies and other large-molecule drugs.

As sensitive and complex drugs are often highly viscous, it makes them more difficult to administer. Furthermore, biologic therapies face some constraints when it comes to drug storage, being prone to interactions with the packaging material. Those interactions can

limit efficacy and purity, consequently requiring extensive risk analyses and staking tests before regulatory approval.



Figure 1:
The new syriQ BioPure® syringe for biologics.

To tackle these constraints, Schott recently introduced prefillable glass syringes for the biologics market known as syriQ BioPure® (Figure 1). The syringes are designed to keep sensitive drugs stable during their shelf life and shorten time to market while making administration more convenient for patients. To do this, syriQ BioPure® syringes are manufactured under improved processes to lower tungsten and adhesive levels and to ensure a uniform silicone layer – all validated and documented under US FDA regulations.

USE OF HIGH-END MATERIALS

The syringes are made of highly inert Type I FIOLAX® borosilicate glass – the gold standard for packaging complex drug products. The suitability of this glass type for sensitive drugs is well researched and it has a strong track record.

In addition, the rubber plunger stoppers used in syriQ BioPure® syringes are made of the newest polymers to limit interaction with elastomer-coating compounds. The plungers and various closure systems, such as Aptar 4800, Aptar 4900, West 7025 and West 7028, are tailored for sensitive applications. More than 48 combinations have been validated. The use of high-end materials also gives syriQ BioPure® a



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superior extractables and leachables (E&L) profile. Lastly, the syringes are manufactured using a particularly thorough production method to limit the risk of adhesive residuals in the luer.

SEAMLESS AUTOINJECTOR INTEGRATION

The new glass syringes work with leading safety and autoinjector devices, thus meeting market demand for products that can be administered at home for patients' convenience. Seamless integration into these devices is achieved thanks to the syringe's high dimensional accuracy. Each single glass tube used for the manufacture of the syringes is closely inspected by lasers, cameras and infrared systems – a process which is known as Schott's big data perfeXion™. By collecting roughly 100,000 data tags per minute, the integrated IT system picks up imperfections with such precision that it can later identify the corresponding individual tubes, which can then be discarded.

ADDITIONAL DIMENSIONS

The syringes also have additional dimensions beyond ISO requirements, as well as new geometrical tolerances, which are achieved by cutting-edge forming technology and online inspection systems. This gives the device optimum compatibility, and leads to superior functionality for patients.

The syringes are documented according to the latest design-controlled guidelines (according to FDA 21CFR Part 820) to support the requirements for combination products. As all required documentation is fully available, this means there is a short time-to-market for the pharmaceutical industry.

THE IQ™ PLATFORM CONCEPT

The syringes are delivered in a standard sterilised nest and tub and can be filled on a wide variety of standard, ready-to-use (RTU) filling lines. They are part of Schott's new iQ™ platform, which is based on the proven nest-and-tub format of RTU syringes that has been used by the pharmaceutical industry for decades. The new platform builds on the advantages of RTU filling concepts by enabling pharma companies to fill small batches and/or different containers on one line (Figure 2).

Currently available solutions from packaging suppliers require drug manufacturers to fit the filling machines to



Figure 2: The iQ™ platform standardises the tub format for cartridges, vials and syringes.

the specific tub format, which means the machine needs to be optimised each time to fit the individual products and the same work has to be done multiple times.

Schott addresses this particular issue by standardising ready-to-use syringes, vials and cartridges within a single tub format to run on the same filling line. By standardising this part of the process, less changing of machine parts is necessary when switching from one container to another as the vials, syringes and cartridges all come in the same tub. Consequently, pharma manufacturers can fill various drug and container configurations on the same line with as little as 10–20 minutes of changeover time. They can also switch from one container to another, or one dosage to another, or to new drugs.

AIMS OF THE IQ™ PLATFORM

Maximise Flexibility

The platform was developed with the world's largest filling line and elastomer component suppliers to simplify the entire filling process and ensure pre-validated and flexible container/elastomer systems can be offered. This further reduces testing efforts, improves quality and accelerates time to market. It comes with a versatile container portfolio including Schott's syriQ® prefillable syringes and adaptiQ® ready-to-use vials, as well as the new cartriQ™ ready-to-use cartridges, which will be available soon. Moreover, iQ™ is compatible with over 30 machine platforms of all leading and also upcoming machine vendors.

Reduce Complexity

The platform enables pharma companies to reduce the total cost of ownership (TCO). A case study has shown that iQ™ decreases the need for format parts. Companies can thus reduce investments by up to 40%, clean room space by up to 60% and running costs by up to 40%. Additionally, when considering that nowadays drugs need to be manufactured in ever-smaller

batches in shorter periods while adhering to higher quality standards, the iQ™ standardised tub format increases filling flexibility and greatly reduces complexity. Consequently, pharma companies can accelerate time-to-market and accommodate new drug development.

Enhance Patient Safety

With the highest industry-quality type I glass, FIOLAX®, and the nested configurations, the iQ™ platform eliminates glass-to-glass contact during filling, transport and storage. Thus, the risk of scratches and defects is decreased significantly, which ensures and improves patient safety. Moreover, the particle load is minimised in all of Schott's RTU containers. Therefore, the platform also provides a solution to various industry concerns, such as glass breakage and particle reduction.

CONCLUSION

By combining the advantages of Schott's new iQ™ platform and using the highest quality materials in the manufacturing process, syriQ BioPure® syringes are ideally positioned to handle the growing market in sensitive and complex pharmaceutical drugs. In addition, the syringes integrate seamlessly with autoinjectors through the use of Schott's big data perfeXion™, and time-to-market is reduced through documentation and use of the platform.

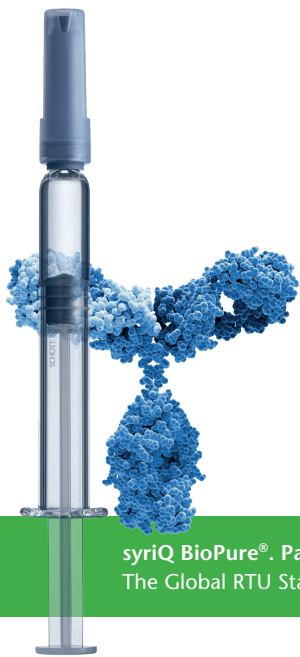
ABOUT THE COMPANY

Schott Pharmaceutical Systems is one of the world's leading suppliers of parenteral packaging for the pharmaceutical industry. More than 600 production lines in 13 countries worldwide produce more than 10 billion syringes, vials, ampoules, cartridges and special articles of tubing glass or polymer. The company has more than 130 years of outstanding materials and technology expertise.

SCHOTT Pharmaceutical Systems

He depends on the reliability
of his highly sensitive
biotech drug.

Increase drug stability with syriQ BioPure®.



syriQ BioPure®. Part of iQ™.
The Global RTU Standard.

The new glass syringe syriQ BioPure® is designed for highly sensitive biopharmaceutical drugs. Ultra low tungsten, low glue residuals and less particles reduce the risk of interaction with your drug. Your benefit: greatly increased drug stability during shelf life. **What's your next milestone?**

SCHOTT AG, Pharmaceutical Systems, www.schott.com/pharmaceutical_packaging

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