

newsflash

PHARMACEUTICAL SYSTEMS

SCHOTT
glass made of ideas

ISSUE 24 | March 2016

NEWS

Crystal Clear Insight



It's clear that as the market becomes more complex and challenging, the pharma industry and its suppliers must become better, faster and smarter than ever before. The "Insight Forum for Ready-To-Use Solutions in Aseptic Manufacturing", organized by SCHOTT in 2015, was designed exactly along that line.

The event brought together customers, vendors and suppliers for an open discussion of the challenges and benefits of ready-to-use (RTU) systems, and to show how a

coordinated effort can bring new packaging solutions to the rapidly changing pharmaceutical market. Partners in attendance included Bausch + Ströbel, GEA Lyophil, ARaymond Life, and West Pharmaceutical Services. The keynote address was delivered by the US biotech company Amgen, emphasizing the need for closer partnerships between the pharma industry and its suppliers in order to uphold patient safety, reduce particle contamination in packaging, and secure the supply chain.

Our flexible future

The Insight Forum brought to the fore several of the wider trends in the industry, and their impact on packaging suppliers. Andreas Reisse, Executive Vice President of SCHOTT Pharmaceutical Systems, opened the event by addressing the growth of the specialty medicines market, which is driving demand for smaller-volume manufacturing and greater flexibility. This was an ongoing theme throughout the event, along with the increasing cost pressure on manufacturers and the demand for a wide range of packaging options.

"The environment in which we operate is changing constantly," explained keynote speaker Ronald Forster, Executive Director Device Technology at Amgen. "As more patients around the world are gaining access to our medicines, supply chains are constantly growing and becoming more complex. Market demands continue to shift. The need for adaptive manufacturing is growing. In addition, regulatory agencies are constantly raising the bar of what they expect from us. It's a dynamic situation."

Together, these factors have led Amgen to reevaluate their manu-

facturing strategies, said Forster, moving towards adaptive manufacturing. Amgen has already built a next generation single-use systems (SUS) drug substance facility in Singapore. Without the traditionally huge overheads of traditional plants, it allows faster, more flexible production, with a significantly smaller footprint.

Suppliers team up

Packaging suppliers are well aware of the challenges facing their customers, and are working on solutions to fit these trends. Bausch + Ströbel's Markus Hoersch picked up the twin themes of flexibility and small footprint when discussing the rationale behind the VarioSys platform – a small standard isolator, which can accommodate various container types, while Gregor Deutsche, Product Manager at SCHOTT, described their new system of RTU vials called adaptiQ® as "a perfect fit" for the wider trends in the industry. "Smaller batch sizes and high-value drugs make a nested system particularly appealing to protect the vials and their contents from cosmetic defects and make switching between products easier."

Continued on page 2

EDITORIAL



Dear Reader,

To be truly flexible, drug products and their packaging must work seamlessly in systems up and down the supply chain. As we explore in this newsflash, there are already some examples for successful cooperation: our SCHOTT Cartridges HS, which were especially designed to meet the requirements of highspeed filling lines. Or the first large-sized delamination controlled vial we successfully developed and validated in a customer project. Last but not least the lead story of this issue – our SCHOTT Insight Forum, which brought together pharma companies and suppliers.

In short: It's time for all of us to team up. Therefore, we were all the more thankful that so many of you contributed to our recent customer survey. Your detailed feedback provides us with very valuable insights. It also clearly confirmed that we maintain close contact with our customers. We at SCHOTT believe that this is the way to truly add value.

I hope you enjoy reading our latest newsflash.

Andreas Reisse
Executive Vice President
Pharmaceutical Systems

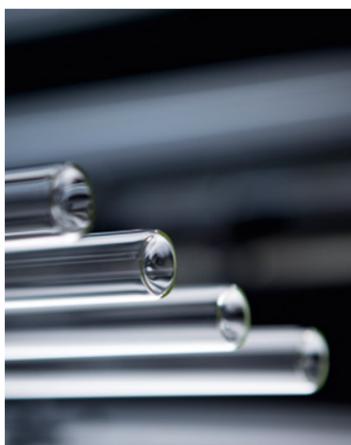
PREVIEW



PRODUCTS – SCHOTT Increases Production of Polymer Syringes by 50%.
Read more on page 2.



INNOVATION – SCHOTT Expands Delamination Control with new large-format Vial.
Read more on page 3.



TUBING – GMP Certification for all Pharmaceutical Tubing Sites.
Read more on page 4.



MARKETS – New Manufacturing Site for Pharmaceutical Packaging in China.
Read more on page 4.

NEWS

Crystal Clear Insight

Continued from page 1
True patient focus

As drug products become more complex, there is an increasing recognition that to offer truly innovative solutions, suppliers must have a complete understanding of the supply chain, including the end user – the patient. Forster set the tone in his presentation, stating that patients depend not only on Amgen but all of its suppliers.

“Suppliers need to appreciate that the end customer is not the pharmaceutical company – it’s the patient. Concentrating on our own processes is no longer enough – we need to understand the customer’s processes right through to the patient,” said Chris Sellards, co-Chair of the event and General Manager of SCHOTT’s Lebanon plant.

“One has to really understand the intended use, and put the patient at the center of the decision,” added Anil Busimi, Director Strategic Marketing and Innovation, for SCHOTT.

Putting patients first means that the quality of the end product has to be the number one priority for suppliers and pharma alike. Shifts in technology and markets have thrown up challenges for quality and supply chain management, reflected in a fourfold increase in drug shortages between 2005 and 2011. Forster said Amgen is proud to have never shorted the market. Preventing such shortages was a key tenet of their strategy and suppliers have an important role to play.

A quality by design approach is crucial when making decisions about all aspects of packaging. Legacy equipment may not be the best fit for innovative new drug products, and it’s important that pharma customers weigh up all the options when choosing pack-

aging components. Speaking about the choice of container closure systems, West’s Peggy Frandolig said, “One of the most common mistakes customers make is to stick to what they know.”

Busimi, discussing the choice between polymer and glass, also urged careful consideration. “There are a lot of misconceptions about both glass and polymer products. Companies need to carry out an in-depth analysis of the pros and cons of both materials, rather than jumping to conclusions.”

Innovation in packaging may not be as dramatic as a new drug product, but it can have a real impact on quality and cost, which in turn can determine whether a patient even receives the drug. And suppliers once again have a serious role to play in cost. “Some will say, what’s so innovative about adaptiQ®? Pharma companies have been doing RTU for 100 years already,” said Michael Vollgold, VP Global Sales & Marketing, SCHOTT. “But the innovation lies in the nest, which allows you to carry out operations more efficiently and protect the container. That is crucial for today’s high-value biotech drugs, where each vial can cost \$500.”

In it together

Forster concluded his presentation by saying, “We need to change the way we work. In order to meet the needs of our customers we have to move much faster – and have more confidence.” As emphasized by speakers and attendees throughout the day, partnership is the only way to achieve that change, and cooperation was the overriding theme of the event.

Nigel Ware, Business Development Manager at ARaymond, agreed: “As demonstrated in today’s event, collaboration across

the whole network is crucial. As a part of the pharmaceutical industry, our expectation and obligation is to create the best product, and we can only do that by working together with our partners.”

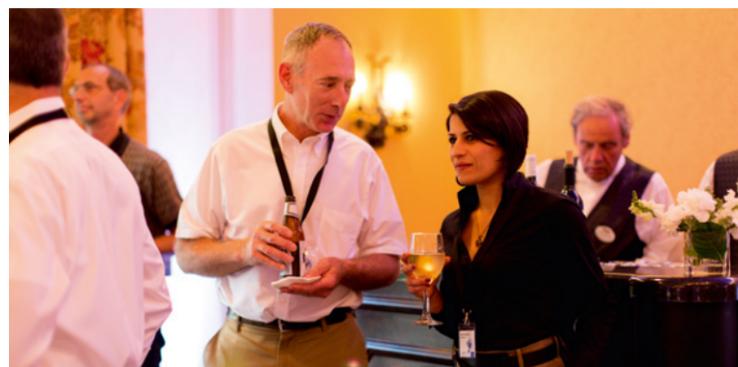
Hoersch noted that adaptiQ® is a good example of cooperation between suppliers. SCHOTT approached machine builders, customers, and other partners from an early stage to work together on the design of the system, and the depth of collaboration was apparent from the two panel sessions, with contributions from five of those partners, making everything from filling line machinery to closure systems to freeze dryers.

A matter of trust

RTU systems, by definition, require a level of trust; customers are relying on the supplier to carry out steps that are critical to quality. Responding to a question from the audience on this point, Deutsche said, “It highlights the importance of transparency and partnership with our customers – allowing them to view all our processes to show them how we make sure they get a good product, every time.”

If the era of transactional relationships is really over, as Forster contends, pharmaceutical industry suppliers need to find a new path. What will that look like? The key themes from the Forum suggest that successful suppliers will need to be focused on the patient, committed to quality, and willing to partner up to provide the best solutions.

“Ron Forster put it perfectly when he said that if we want to improve patient’s lives, we have to find new ways of working. One company can only contribute. We need a collaborative effort to truly change the game,” concluded Vollgold.



This article appeared originally in „The Medicine Maker“

PRODUCTS

SCHOTT Increases Production of Polymer Syringes by 50%



SCHOTT is currently expanding the manufacturing capacity for its SCHOTT TopPac® prefillable polymer syringes to address increasing customer demand. The new production line will be installed at the company’s center of excellence for pre-fillable syringes in St. Gallen, Switzerland. This move will offer a greater degree of flexibility for customers and further strengthen the importance of the Swiss site which focuses on both, glass and polymer syringes.

“The demand for our polymer syringes has increased since customers appreciate the versatile advantages of the material: It’s break resistant and lightweight, yet has

a glass-like transparency. And the excellent barrier properties of the SCHOTT TopPac® syringe system keep the drug stable over shelf life”, says Anil-Kumar Busimi, Director Strategic Marketing and Innovation, SCHOTT AG.

The new production line will seamlessly be integrated in SCHOTT’s existing setup which uses advanced technologies. SCHOTT TopPac® syringes are manufactured in clean rooms with a fully automated process starting from injection-molding to the final packaging in nest and tub. The syringes are sterilized and ready for aseptic filling operations.

Complete Syringe Portfolio

SCHOTT has been manufacturing glass and polymer syringes in Europe since 1996. Today, the production is concentrated in Switzerland and is supported by an R&D team based at the site.

From here SCHOTT has developed a complete portfolio of both glass and polymer syringes. This offers pharma companies a broad range of solutions, suitable for a variety of applications like heparin, vaccines, biotech, and special applications such as intensive care.

In the field of glass syringes, the offerings range from 0.5 to 3 milliliter (ml) products marketed under

the brand name syriQ®. All glass syringes are available with luer lock, luer cone or with staked needle.

SCHOTT TopPac® polymer syringes, in turn, are available in the range from 1ml to 50ml with cross linked silicone for optimal functionality. In addition, the company has recently introduced an innovative polymer syringe designed to improve the safety of sensitive drugs: the new product named SCHOTT TopPac® SD offers new features for a significantly reduced E&L (Extractables and Leachables) profile and ensures high drug stability.