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Collaborate to Innovate

Working together is more important than ever before

Collaboration is increasingly prevalent in the pharma world. The blockbuster era is over, and companies are turning to outside sources to find 'the next big thing'. To boost innovation and populate pipelines, drug makers are forming partnerships with emerging biotechs, allying themselves with academic institutions or brokering mega-mergers. Some companies are even looking outside of the industry altogether, with GlaxoSmithKline seeking advice from Formula 1's McLaren to accelerate manufacturing.

In some areas, multiple companies are joining forces, forming precompetitive partnerships to undertake early-stage research. Although historically the pharma industry has been tentative about teamwork, the last decade has seen an increasing recognition of the benefits for companies and patients alike.

Sweeping changes in the industry are also having an impact on suppliers. As we explore in this supplement, the trend away from large-scale production towards smaller batches has put flexibility to the forefront of customer's minds. To be truly flexible, products must work seamlessly in systems up and down the supply chain.

Cooperation between equipment suppliers at different stages of the supply chain has been ongoing for decades – after all, some of the companies involved in this supplement have been working together since the 1970s. However, it is no longer enough to simply inform your partners of new products and specifications. Today, there is a need to consider – right from the earliest phases of design – how equipment will interact, especially as solutions become increasingly sophisticated.

The world of pharma manufacturing can be stubbornly opposed to innovation and fresh perspectives, which can make the introduction of new products challenging. By collaborating and offering universally considered solutions, suppliers can spread the risk – and gain increased customer confidence.

Charlotte Barker
Editor

Contents

Are You Ready?

Ready-to-use containers are the perfect fit for a growing specialty drugs market.

Ready-to-use (RTU) syringes have long been a staple of the pharmaceutical industry, and now make up the vast majority of the syringe market. Pre-sterilized and neatly packed in nests and tubs, pharmaceutical manufacturers do not need to perform the pre-treating steps of washing, depyrogenation and sterilization. Instead, the syringes are delivered in a sterile bag and can be stored until the customer needs them. "For pharmaceutical companies that means that they can open up the packaging inside their sterile filling suite and start processing the product right away," says Gregor Deutschle, Product Manager at pharmaceutical packaging manufacturer SCHOTT.

Now, the same concepts are being applied to other packaging categories, such as vials and cartridges. Based on proven nest-and-tub standards, RTU systems enable pharma companies to process different types of packaging on the same production lines without long set-up times. Consequently, even smaller batches can be filled very efficiently.

Different times

Broader trends in the pharmaceutical industry mean that the flexibility and low capital costs of RTU are becoming increasingly attractive (see Figure 1). Markus Hörsch, Sales and Marketing Director at Bausch + Stroebel – makers of filling line equipment – comments, "There aren't many blockbusters being produced these days, so the industry is moving away from high-speed, high-volume production lines."

Deutschle agrees, "When you are running a traditional syringe or vial line dedicated to producing one product at very large volumes, investing in a washing machine and tunnel makes sense. But with the high-value, low-volume drugs now on the market, it pays to be flexible with the capability to quickly change over from one product to the next. RTU containers are the ideal fit."

"Many companies are pinning their hopes on specialized medicines, such as highly potent cancer drugs and drugs for orphan diseases."

Many companies are pinning their hopes on specialized medicines, such as highly potent cancer drugs and drugs for orphan diseases. Indeed, market analysts at IMS Health last year predicted that specialty medicines could make up 50 percent of drug revenue in developed

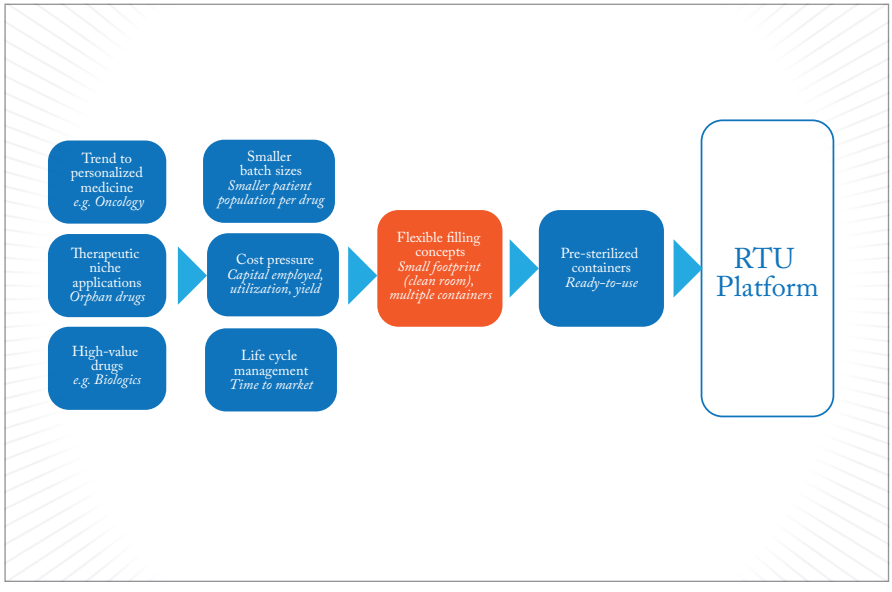

Figure 1: The advantages of ready-to-use containers.

markets by 2017. "In biotech, there is a lot of uncertainty over what the characteristics of future products will be. There is definitely a trend towards greater flexibility – systems and processes that can handle any type of product," says Hörsch.

Regulation is another issue driving the increasing popularity of RTU systems. In some countries, certain drugs can only be sold if they were manufactured inside that country, forcing pharmaceutical companies to set up their own local production facilities. No surprise then that pharma companies are looking to innovative processing concepts that help to keep the initial investment and footprint low.

Finally, with the rise in generic drug manufacturing and the emerging biosimilars market, pharma companies are usually under immense time pressure to develop and produce the medication before other manufacturers saturate the market. In this instance, reduced processing complexity accelerates the pharmaceutical line up.

These factors have put flexibility and low capital costs at the top of pharma's priority list, and demand for RTUs is growing. "I think it's still a niche application, but that niche is growing quickly," concludes Deutschle.

All aboard

So why isn't everyone making the switch

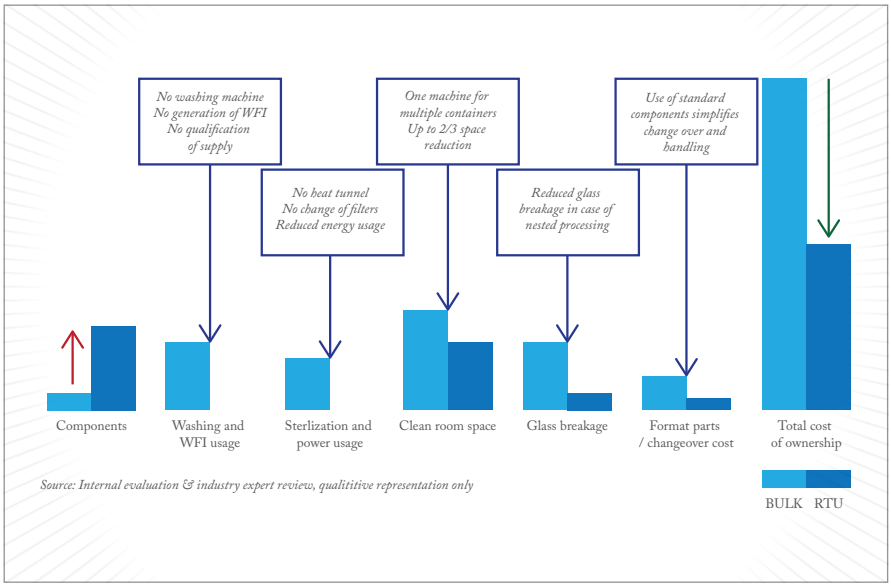

Figure 2: Total cost of ownership calculation.

Figure 3. The SCHOTT adaptiQ system.

to RTU containers? One answer is simple – RTU vials are more expensive than standard vials at first glance. However, in many applications, the additional costs are more than covered by the elimination of the washing/sterilization processes and the need for large clean rooms (see Figure 2). Moreover, says Hörsch,"RTU systems mean a smaller footprint for the production system, which really saves costs for the customer."

Another historical challenge was processing of the vials. Filling line machinery for vials is typically set up for bulk (un-nested) vials, meaning that the product would have to be de-nested several times during the process, increasing the risk of scratches or breakages. Notably, this has not been a problem for RTU syringes because they are supplied in a nest and remain in those nests for filling. To solve the problem, SCHOTT worked in close cooperation with filling line manufacturers to develop a new nested packaging system that trims costs and streamlines production (see Figure 3). Up to 100 sterile and pre-fillable vials can be fixed securely inside the nest of the new SCHOTT adaptiQ® system. Vials no longer come into contact with each other and are unlikely to be scratched, and this in turn reduces the reject rate. In fact, pharmaceutical companies can freeze dry, weigh, or close their filled vials inside the nest.

"We decided to learn from the syringe experience and modify the concept to accommodate vials. So we're using a lot of standard components already in use for syringes, which are proven a billon-fold in the industry," says Deustchle. But simple doesn't always mean straightforward, "Creating a nest for vials took a lot of additional design compared with a syringe nest. We needed to ensure that they remain secure both during transport and processing."

By involving machine vendors like Bausch + Stroebel, BOSCH

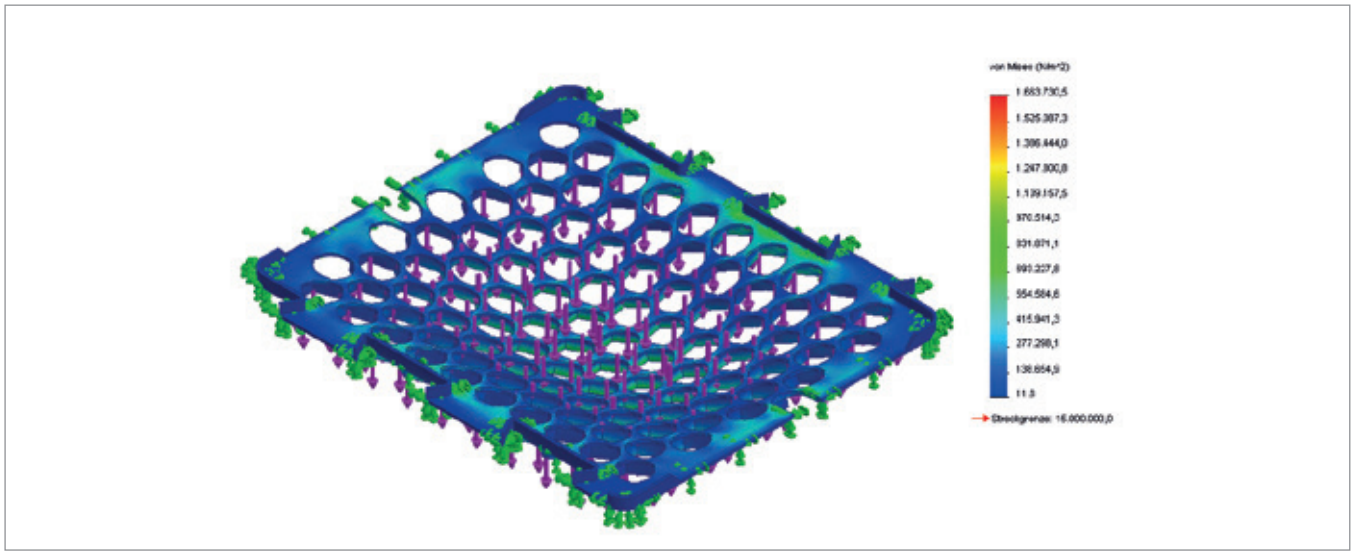

Figure 4. Finite elements method simulation.

Packaging Technology, Optima, GEA or VANRX from an early prototyping stage, the nested vials were designed to be compatible with existing filling lines. SCHOTT ran a number of finite elements method (FEM) tests to ensure accurate and efficient filling.

To ensure product integrity, the team of developers used simulations to ensure the nests' stability during the freeze-drying and sterilization processes. The team also tested that the nests would stand up to the weight pressure of all the vials when filled (see Figure 4).

The next task was to make sure vials could be easily and securely fixed into the nest and secured by their necks by three snap-in hooks.

"We did FEM testing and joint failure, mode and effect analysis on every critical design feature of the product – with experts from the processing side, and from the container side, to identify any potential problems and then put in place actions or design changes to reduce those risks. If you have multiple components, you really need to make sure that the customer gets a complete solution and not just a single product," says Deutschle.

Looking ahead

Hörsch has seen an increase in the number of customers looking into RTU systems and believes the area will see more growth in the near-term. "Right now and over the next couple of years, I see the biggest growth potential for the RTU market in clinical phase and small batch production. For high-speed (300–400/vials minute) applications, I believe RTU vials are still too expensive. But of course, 20 years ago the same could be said for RTU syringes, so who knows what the future will bring in the longer term?"

Though it's hard to predict what technology will be ascendant in 20 years' time, it seems safe to assume that one trend is here to stay – that of close collaboration between suppliers. Like many suppliers, SCHOTT and Bausch + Stroebel have a long history of working together, with the first B + S machine delivered to SCHOTT in the early 1970s. The difference now, says Deutschle, is that cooperation starts at the early design stages, with suppliers invited to comment on the first prototypes.

Hörsch agrees that relationships between suppliers are becoming closer as customer needs become more complex, "Cooperation makes perfect sense in order to come up with innovative and proven products for our common customers."

"Cooperation makes perfect sense in order to come up with innovative and proven products for our common customers."

To facilitate this collaboration, SCHOTT hosted their first Insight Forum in September 2015 – bringing together market leading suppliers and customers to discuss the future of RTU solutions in aseptic manufacturing (page 14).

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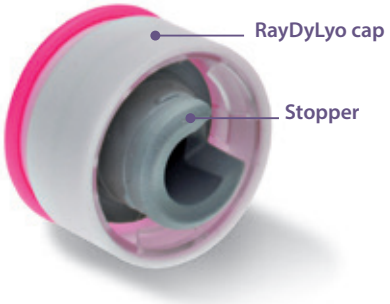

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To meet the demands of modern sterile manufacturing, suppliers must constantly evolve. Given the pharmaceutical industry's notoriously conservative nature, it can be a difficult market for innovation. And yet, to stay a step ahead of competitors – and meet our customers' future needs – innovation is essential.

With so many interlinked elements involved in the sterile production supply chain, innovation is not simply a case of having a great idea for a new product. It's no good designing and manufacturing a spectacular new type of vial if customers can't buy matching stoppers.

It is already common practice for suppliers to work together; for example, by providing specifications to ensure a good fit between the various components of a system. But sometimes, cooperation is taken a step further, by involving a number of partners from the early design stages of a new product, to ensure a seamless fit from end to end. Here, we speak with two leading pharma suppliers to find out how collaboration is driving innovation in the RTU space.

Achieving Closure

Nigel Ware, Business Development Manager at ARaymond, offers first-hand experience of how his company used expertise in closure systems to develop a nested solution for RTU vials.

ARaymond are relatively new to the pharma market – could you introduce the company?

ARaymond designs, develops and manufactures targeted fastening solutions. Our biggest market is the automotive industry – our parts are present in pretty much every vehicle being built around the world. In more recent years, we have been diversifying into other markets, including a new subsidiary – ARaymond Life – which focuses on medical devices, drug delivery systems and pharmaceutical packaging. In the pharma industry, aluminum capping has been around for more than 100 years. We thought we could come up with something better – a novel, all-plastic capping solution: RayDyLyo.

How did the collaboration on RTU nested vials come about?

We were showing our plastic vial closure system in 2012 at InnoPack in Madrid. SCHOTT were working on a RTU nested vial solution, and looking for a suitable closure system. SCHOTT were working with a machine equipment provider, to produce fully enclosed filling machines – essentially a gloveless system, into which the tubs of vials and the tubs of caps would be fed, and the completed product would come out the other end.

Closing the vials in the machine was proving problematic; traditional aluminum crimp seals would have demanded de-nesting of the vials, slowing the process, and increasing the risk of spillage or breakage. We were asked if we could develop a nested solution that would complement their system. We said "of course" – plastic injection molding is one of our core competencies.

And was it a challenge?

The closure itself was already suitable for ISO vials, so no problems there. But there were plenty of technical issues to consider in terms of the nests. For the smallest vial size, there are 100 caps in an area not much larger than a sheet of A5 paper. As the nest is mainly thin air – but still needing to support 100 caps – it could have become very delicate, so making it robust enough for the machines was quite a challenge. In fact, we brought in another partner – a toolmaker – who was able to refine the design to come up with a workable solution.

"The project was particularly challenging as we had to design our nest to fit the vial nest, but also to function correctly in the machine."

Is it difficult working on a project with so many partners?

The project was particularly challenging as we had to design our nest to fit the vial nest, but also to function correctly in the machine. The very limited space meant there was little room for handling or for the stiffening ribs and other necessary features of the nest. The project required a very rich four-way correspondence between the four parties (ARaymond, the machinery manufacturer, the toolmaker and SCHOTT) – and it required compromise; it's very friendly but we were all coming from a slightly different angle – what was good for us was not necessarily good for the

machinery maker and vice versa. It is a complex process, but ultimately it results in a product that is very simple for customers to use.

How do you see the market evolving?
Many in the industry see the future lying with biotech and personalized medicines. There will be an increasing need for small to medium sized batches, and traditional filling and capping systems are not most efficient at those scales. We are already seeing a great deal of interest not only from smaller companies doing small runs, but larger companies that do medium-sized runs of valuable products. They are potentially losing thousands of dollars' worth of drug due to glass damages and crimping defects on a traditional line. We're talking to customers who are very seriously looking at nested solutions to overcome some of those issues.

Supporting Excellence

Mike Schaefers, Vice President, Global Marketing, Pharmaceutical Packaging Systems, West Pharmaceutical Services, Inc., believes earlier collaboration between suppliers and drug makers can move the field forward.

What products do West offer customers in the pharma industry?
From concept to patient, West creates products that promote the efficiency, reliability and safety of the world's pharmaceutical drug supply. We support our customers with 30 manufacturing sites worldwide, covering packaging, drug delivery and contract manufacturing operations.

How has the ready-to-use market developed in recent years?
As outsourcing of container/component processing and sterilization becomes more important, we see more customers transitioning to RTU components and containers. This is especially true as industry focus on sterility for injectable drug products increases. Keeping injectable drugs safe from contamination is crucial, as any bioburden could present a significant risk to patients. However, achieving the sterility required by regulatory standards while increasing operational efficiency can be a challenge for any drug manufacturer. The transition to RTU is not just in the world of prefilled syringes – more and more customers are demanding RTU stoppers, seals and vials. The trend is supported by the emergence of flexible fillers – to fill clinical and small-scale commercial volumes as a result of lower unit volumes – which preferentially operate on the basis of sterile container, closure and caps.

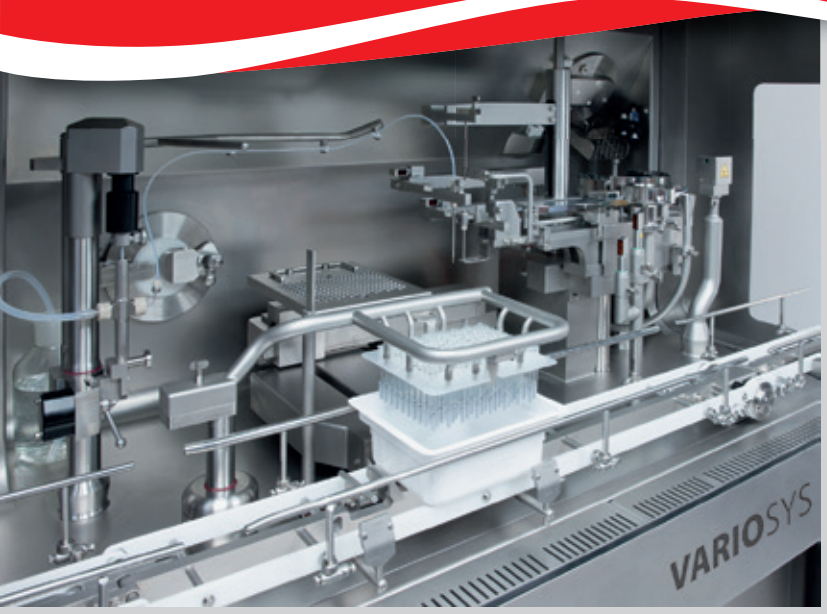
What are the biggest challenges when moving to RTU vials?
No matter if we are considering sterile glass or polymer vials, sterile stoppers, plungers or caps, customers are outsourcing a very critical process step to their vendor. Sterilization processes and validation must meet global regulatory standards, and processes and offerings must meet customer expectations for format, cleanliness and quality. In addition, supply chain and risk mitigation solutions for such a critical processing step must be in place to ensure continuity of supplies in case of unforeseen events or demand peaks.

How have you collaborated with other vendors?
With products like prefilled syringes, it is common to collaborate with multiple vendors to ensure that the syringe system is functioning well, can be filled easily and works perfectly in combination with an injection device. The prime focus here is less on functionality, and more on machinability and quality. Therefore the vial, component and machine manufacturer need to work collaboratively to ensure that all aspects of the vial system work well together. For example, filling line speeds can be optimized while quality of the final product remains excellent. Another key approach is the trend toward barrier isolators and RABS systems, which demand deliveries of stoppers and seals in rapid transfer port bags. The emergence of flexible fillers triggers an even bigger need for cooperation between these parties as stoppers and seals supplies need to be tailored around small unit volume fills as well as nested vials.

"The biggest challenges are the protection of intellectual property and a lack of clear standards."

What are the common roadblocks to this type of collaboration?
The biggest challenges are the protection of intellectual property and a lack of clear standards. Often, customers request specific solutions that result in new developments for all parties. One solution is to start creative collaboration among drug manufacturers, packaging and delivery systems manufacturers, and machine manufacturers much earlier in the drug development process.

PRECISION TO THE HIGHEST STANDARD



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A Study in Collaboration

In the pharmaceutical industry, freeze drying or lyophilization plays a key role in the production of parenteral drugs. GEA's Johannes Selch, Product Manager, ALUS™, examines how sterile, nested vials can contribute to the efficiency of the process, particularly regarding loading and unloading in a manufacturing environment.

Sterile pharmaceutical manufacturing is an ever-changing environment and, as such, the critical production criteria for our customers have changed dramatically during the past 20 years. When we first introduced the GEA Automatic Loading and Unloading Systems (ALUS™), functionality was key. Now, with our sixth generation available, more stringent regulations have put an increased emphasis on good manufacturing practice (GMP) and ease of cleaning.

In addition, as manufacturers switch from the large-scale production of a single product to a more extensive portfolio, multi-purpose freeze dryer lines have become more popular. For example, a manufacturer may be producing a non-toxic product in a variety of vial sizes at rates of up to 400 vials/min, but wishes to introduce a highly potent product line in the future, which requires a slow vial speed of 200 vials/min. The challenge is identifying and implementing a solution that offers both enhanced productivity and the right level of containment, whether it's an isolator or an open/closed restricted access barrier system (RABS).

Another factor is cost. Even when producing small batches of very expensive medicines, every vial counts. Even a rejection rate of one percent — the accepted industry standard 20 years ago — could represent a significant loss with some of today's high-value cytotoxic and hormone-based drugs.

Owing to newly developed products, smaller and smaller batches, more highly potent product and the need for flexible and efficient vial and syringe filling solutions, there are constant demands on the pharmaceutical and biotechnology industry to make the freeze drying process faster, safer and more cost-effective, particularly regarding changeovers.

One such product, a new development from SCHOTT, is the adaptiQ™ nested vial system. It can be used with existing nest filling systems and allows pharmaceutical companies to freeze dry and handle filled vials inside the nest. In collaboration with GEA, the system has been tested to ascertain its suitability for the freeze drying process in both a standard pilot plant and a production-scale lyophilizer, specifically to assess its handling capabilities with a standard loading and unloading system.

The development of ready-to-use nested vials was driven by the need to minimize vial rejection rates while maintaining high productivity levels. Although more expensive, compared with conventional vials, the idea is that compensatory savings can be made in terms of capital investment, energy use and utility consumption, enabled by the elimination of washing machines, water for injection systems and sterilization tunnels. Moreover, as the vials never come into contact with each other, scratches and breakages will be significantly reduced.

Testing nesting

In particular, we worked with SCHOTT to find out how the nests would work in our standard ALUS™ systems and whether they would influence the speed and efficiency of the freeze drying process. Our priority was to use a proven design that both manufacturers and regulators would be comfortable with. We found that the nests performed perfectly well using our standard tray loading and unloading systems, regardless of whether the nests were fixed or not, and that nesting and de-nesting could be easily automated. Furthermore, the nests were fully compatible with a range of containment systems.

In a comparative drying test with nested and non-nested vials, we processed a three percent mannitol solution in a standard freeze dryer. Any concerns that the plastic

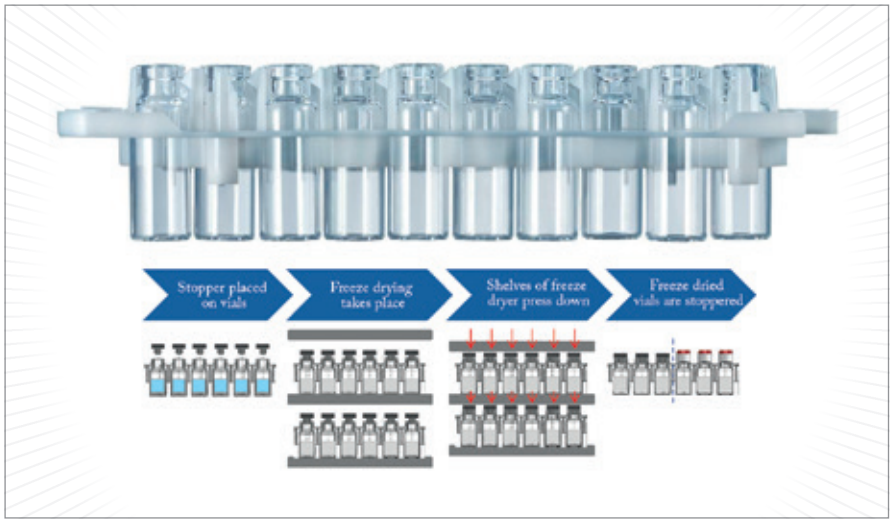

Figure 1. Freeze drying process.

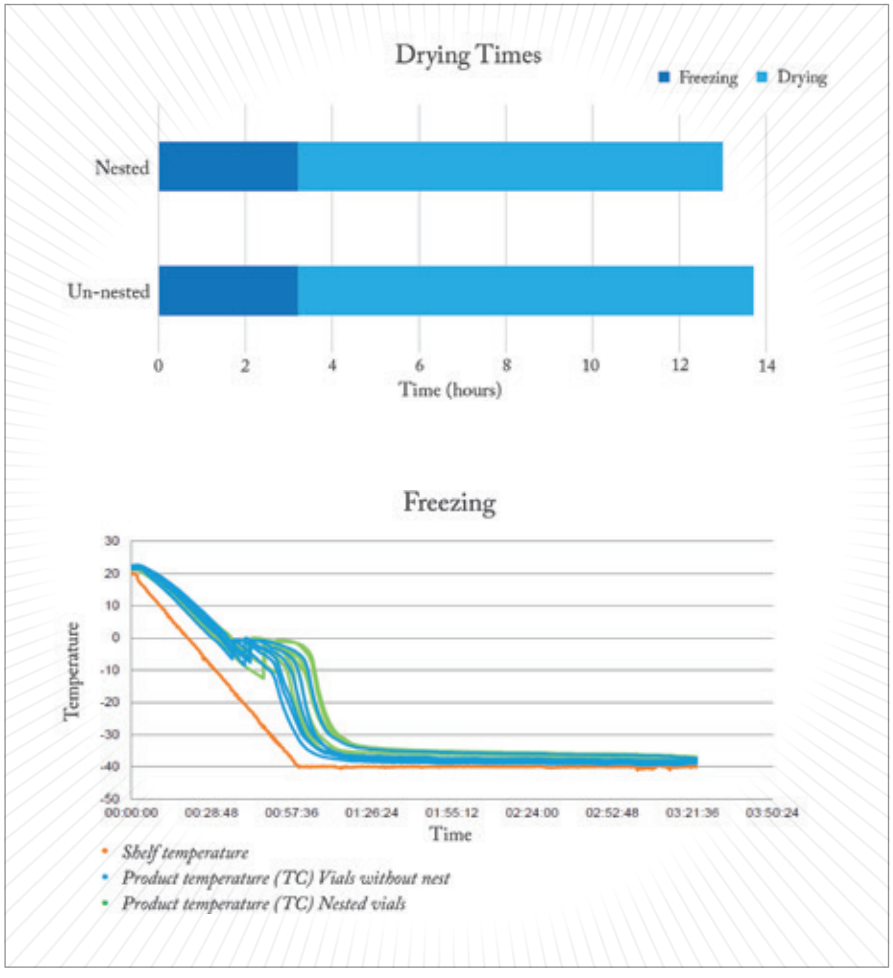

Figure 2. Results of the testing.

surrounding the nests might act as an insulator and prevent drying were quickly quashed. The results showed that the nested vials dried 10 percent faster than non-nested vials, even at full production scale. The nests also had advantages when it came to stoppering, preventing stoppers from sticking to the freeze dryer shelves and keeping the vials upright.

When looking at residual moisture values, we noted that the nested vials results delivered a slightly better result than the bulk vials, especially at the edges of the containers. The additional space between the vials enhances the sublimation flow and reduces the total level of residual moisture. All in all, we were satisfied that the nested vials were entirely compatible with freeze drying.

There is, however, a trade off. Up to 40 percent fewer nested vials can fit into a standard freeze dryer compared with non-nested vials. Although this is partly offset by faster drying times, to fully utilise nested vials and to compensate for this loss in the future, it will be necessary to address the issue at the design stage and produce tailor made freeze dryers.

The benefits of collaboration

Given the pharmaceutical industry's (sometimes frustratingly) slow uptake of new technology, the main applications for nested vials are likely to be in pilot plants and low-volume, high-cost manufacturing. There are, however, opportunities to apply the system in both R&D and full-scale production. Indeed, a facility has already been set up in Asia, incorporating nested vials in a GEA freeze dryer, with full-scale production due to start this year.

For us, the project has been a great example of how collaboration can benefit both the companies involved in the project and the customers we serve. We at GEA firmly believe that co-operation with other like-minded suppliers is the best way to stay at the cutting edge of pharmaceutical technology and continue to deliver innovative solutions to our global clients.


SCHOTT

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 with exactly that goal in mind.

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, and emphasized 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.

"As more patients around the world are gaining access to our medicines, supply chains are constantly growing and becoming more complex."

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 manufacturing strategies, Forster added, moving towards adaptive manufacturing. Amgen has already built a next generation single-use systems (SUS) drug substance facility in Singapore. Without the 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 Deutschle, 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," said Deutschle.

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 packaging 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."

"A quality by design approach is crucial when making decisions about all aspects of packaging."

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, Deutschle 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 patients' 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.

The Road Less Traveled

Sitting Down With… Andreas Reisse,
Executive Vice President of Pharmaceutical Systems at SCHOTT AG

You've been with SCHOTT for over 25 years…
Yes, I studied industrial engineering at the University of Karlsruhe, and joined SCHOTT right after graduating in 1987. But there has been plenty of variety in my roles – I even worked in Spain for a few years.

How did you find moving countries?
I was in Spain with my family for a little over three years. Living where there is a different culture and language always poses challenges – even within Europe. But in our case, it was a wonderful challenge. I love traveling.

What does your current role entail?
For the past five years, I have been working within our pharmaceutical packaging group. What I find rewarding is the fact that primary packaging is perceived as an integral part of a pharmaceutical product. If we do our job well, the important drugs that are delivered to patients will be safe.

What role does packaging play in the industry?
It is absolutely necessary to store products, transport them safely from A to B and to supply information. It influences how the product is used, makes it easier to use, and can even rule out certain dangers for the user.

"I would like to see stronger and more open cooperation between suppliers – it's good for pharma companies and good for the patient."

What advances in packaging do you find most interesting?
Those that appear unspectacular at first glance, but have permanently changed how goods are transported and stored: ISO cargo containers or the euro pallet, for example. Similarly, transferring the proven ready-to-use (RTU) standard from syringes to vials may not seem very exciting, but helps companies integrate processes, reduce total cost of ownership and increase patient safety.

How does ready-to-use technology help pharma companies, doctors and patients?
It speeds up the process of turning research into health. If pharma companies can use the same production line for various lot sizes and different types of containers like syringes, vials and cartridges, this gives them much greater freedom to react to new market demands and launch new, promising treatments more quickly – to the ultimate benefit of their patients.

What would you like to see more in the industry?
I would like to see stronger and more open cooperation between suppliers – it's good for pharma companies and good for the patient. For example, with adaptiQ, we worked with filling line manufacturers and component suppliers from the earliest design stages, creating an integrated, highly efficient filling process in which the primary packaging and filling lines are perfectly tuned to each other.

What is SCHOTT doing to promote cooperation and innovation?
Among others, we are hosting an Insight Forum on RTU in September. We want to facilitate open discussion between suppliers, so we can take full advantage of the potential of the technology. The adaptiQ concept is not limited to vials, but offers flexibility to fill different formulation/container combinations on one filling line with short setup times in between. In the past, RTU was only suitable for syringes; we've now evolved to vials, and cartridges are on the horizon.

"What I find rewarding is the fact that primary packaging is perceived as an integral part of a pharmaceutical product."

What's next for SCHOTT?
We want to continue to expand our worldwide presence to support our customers' growth plans. Pharma companies expect their packaging suppliers to show regional presence at least in the most important markets. At the same time, we are expected to apply globally standardized processes. If a packaging supplier has only four or five plants, implementing global standards is not so much of a challenge, but it means that supplier can't offer proximity, which is absolutely essential for the best customer service. With a global production network of 600 lines in 13 countries, SCHOTT is certainly taking the more sophisticated route.

And what's next for you – more traveling?
Absolutely! I have a BMW 1200 GS motorcycle and like to ride around the borders of Italy and France. I'm planning my own sophisticated route: the Panamericana from Alaska to Tierra del Fuego. Traveling helps free the mind.


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