RayDyLyo®!
CLOSURE SYSTEMS FOR STANDARD VIALS

Plastic push fit closure system
- For Lyophilization and serum applications
- Can be fitted manually
- Can be fitted automatically in an aseptic system
- Can be closed in the freeze-dryer
- Can be supplied in bulk or nested

SIMPLIFIED CAPPING PROCESS

Traditional closure method vs. RayDyLyo solution

- 2 Steps + crimping vs.
- 1 Step Stopper pre-assembled in RayDyLyo cap

NESTED VIAL CAPPING SOLUTION FOR RTU VIALS SYSTEMS

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A Seamless Fit

To meet the demands of modern sterile manufacturing, suppliers must constantly evolve. Given the pharmaceutical industry’s notorious 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.

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 gloved system, into which the tubs of vials and the tubes 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.

“Our 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.

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.

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.

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.

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