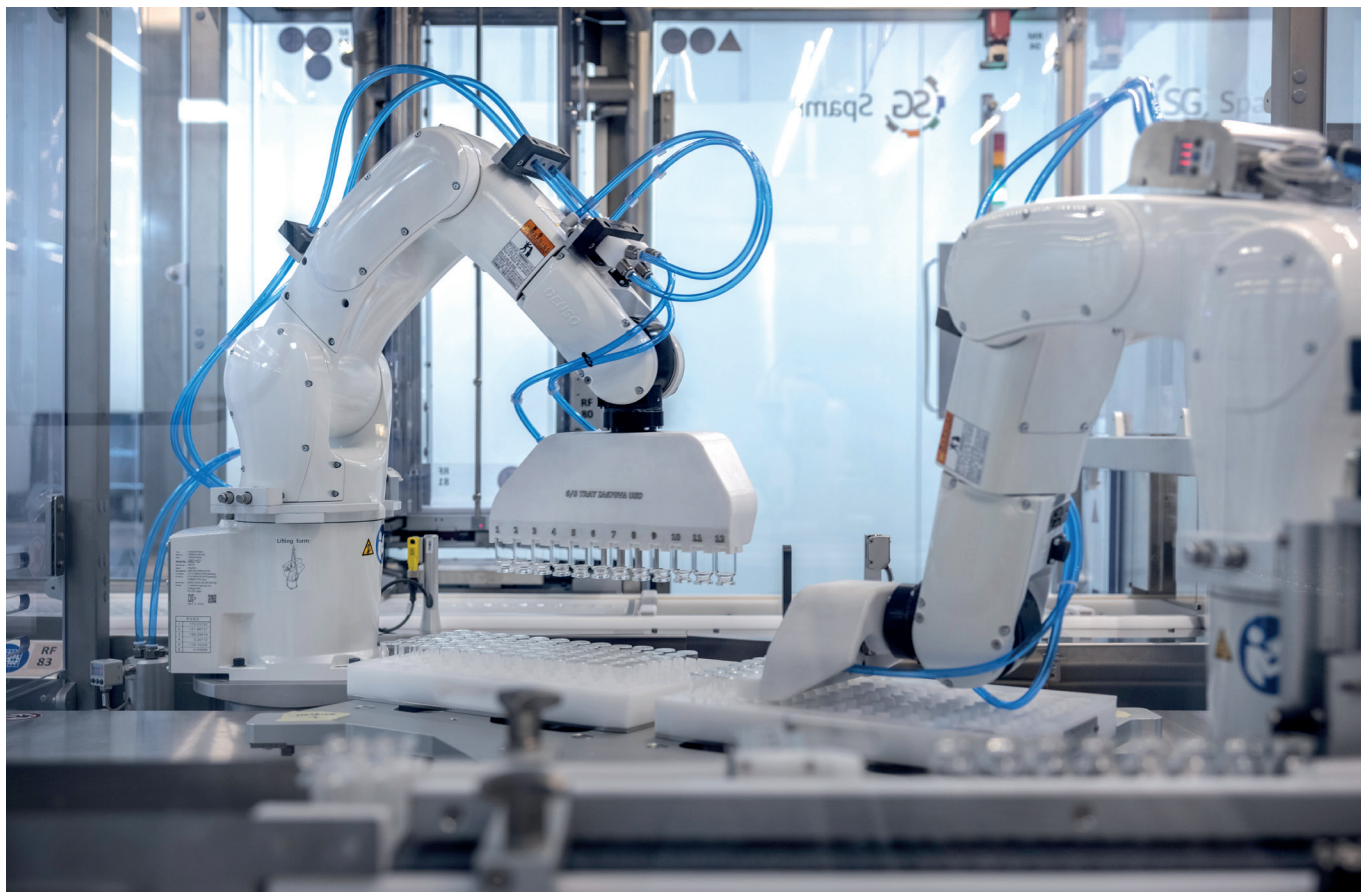




ANSWERING PHARMA'S CALL FOR SMARTER SOLUTIONS TO ASEPTIC MANUFACTURING CHALLENGES WITH READY-TO-USE VIALS

Innovation and continuous improvement have always been cornerstones of the pharmaceutical industry. Supply chain partners who are invested in the research and delivery of innovative solutions, those that never stand still and are committed to support the success of their customers, tend to witness long term, sustainable growth.

Right now, much innovation comes in the form of smarter solutions for aseptic manufacturing. The evolution in regulatory

requirements is always constant in our sector, with increased regulation creating ever greater demands in quality; specifically in terms of protecting the integrity of medication and reducing contamination via particulates.

The market growth in more complex, and therefore more expensive, biologics and biosimilars is placing a real focus on high performance primary packaging and process performance to mitigate against waste. There is also an emphasis

on enabling small batch production with rapid changeover to support low volume and personalised medicines. Indeed, according to recent market intelligence data, the growth in premium Ready-to-Use (RTU) vials is significant, with a Compound Annual Growth rate (CAGR) of 14.5% in the period 2021–2030¹.

Alongside the trends in quality, come requirements in terms of reduced time to market, reduced complexity of operations and rationalised space

and resources available for pharma companies and CMOs to achieve lower total costs of ownership. This is manifested in several ways, but most notably the push is on investment optimisation, flexible cost configurations, scalable processes and a refocus on core pipeline activities.

As usual, the supply chain has responded; developing technologies in Ready-to-Use (RTU) vials that deliver increased quality, reduced complexity, and higher levels of sustainability in equal

measure.

Despite RTU vials meeting all the requirements mentioned above, it can still be argued that there are some hurdles in their adoption, mainly related to costs. But when looking into detail, the advantages of adopting this option become crystal clear.

When it comes to the impact on customer's TCO, there are de-facto real savings to be realised in every aspect of the aseptic manufacturing process. RTU components enable total cost savings of up to 45% versus the conventional packaging containers² over a period of 8-10 years.

One such example is EZ-fill: a fully integrated pre-sterilised containment solution from Stevanato Group. An easy, flexible and streamlined production process means pharmaceutical and biotech companies can immediately fill their pre-sterilised vials containment solution, consistently shortening their time-to-market. But there is more to this, leveraging this technology, Stevanato Group recently developed EZ-fill Smart: a further enhanced version of its pre-sterilised platform, focusing initially on vials.

EZ-fill Smart grants the same top-notch features as EZ-fill in terms of flexibility and streamlined pharma operations whilst providing extra benefits. The platform commits to improving pharmaceutical manufacturing quality standards while reducing the Total Cost of Ownership (TCO) by mitigating the cost of upstream operations such as utilities and equipment as well as reducing the costs and issues associated with lower quality solutions. These



gamechanger savings can be realised, thanks largely to improvements in product quality, and by process optimisation.

Because the platform features no-glass-to-glass and no-glass-to-metal end to end, the integrity of pre-sterilised containers can be maximised throughout the manufacturing process, while reducing costly rejects and breakages which have serious impacts on productivity. In addition, the Tyvek lid has been replaced by a transparent polymer film featuring a reduction of >90%³ in particles by comparison to older technologies. Moreover, it can grant a clean peeling without residuals of adhesive due to a different sealing material than Tyvek.

Improving operational efficiency via high levels of automation is another key feature of the platform. As well as increasing productivity, a reduction in production risks and human error can be realised. From a sustainability perspective, the sterilisation method integrates a safer and more environmentally friendly



method in the process, with the use of biopolymers, re-usable materials and weight reduction also leading to improved sustainability standards.

Critically, the EZ-fill Smart platform was developed in close collaboration with major machine vendors, testing the processability, and can be seamlessly configured with current fill and finish processes and production

lines.

It is often said that there must always be a compromise in the cost, time, quality triangle. In an industry with innovation at its core and safety/efficacy guiding principles, there can be little room for compromise. The EZ-fill Smart pre-sterilised platform has been realised through innovation but is deeply rooted in quality and efficiency.

1. <https://www.psmarketresearch.com/market-analysis/rtf-rtu-vials-market-trends>.
2. 2018 Roots Analysis Research Report.
3. Reduction verified by external certified laboratory.