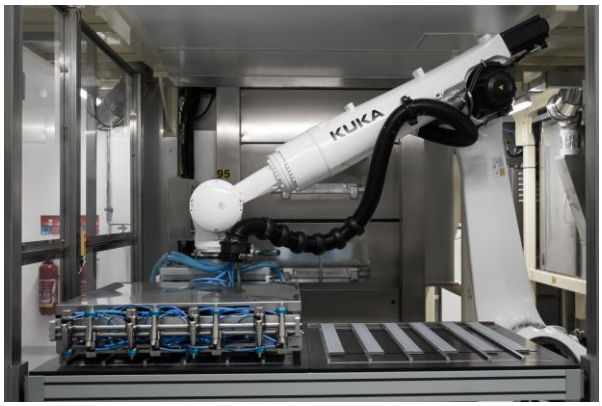
Aptar Pharma: Quality, Safety & Regulatory Compliance for Elastomeric Closures

In the pharmaceutical industry, the safety and efficacy of injectable drugs are paramount. One of the leading causes of recalls by the FDA for injectable drugs is particulate contamination, which can lead to adverse reactions. As the industry evolves and regulatory standards become more stringent, manufacturers are under increasing pressure to ensure the particulate cleanliness and safety of their products. Furthermore, with the prevalence of biologics and biosimilars in development pipelines, it is primordial for drug manufacturers to reduce their development risks and select a partner that will accelerate their access to the market, says Estelle Verger, Business Development Senior Manager, Aptar Pharma.

The recent revision of Annex 1 by the European Medicines Agency's Good Manufacturing Practices (EMA GMP) has further underscored the importance of contamination control. This revision mandates that manufacturers not only have a robust contamination control strategy in place for their operations, but also extends this requirement to their upstream supply chain.

As a leading manufacturer of closure components, Aptar Pharma developed PremiumFill® – a state-of-the-art solution in the realm of elastomeric closure components for injectable drugs, she says.

"Manufactured in ISO-classified cleanrooms and utilizing state-of-robotization, PremiumFill vial stoppers and syringe plungers offer improved specifications on particulate, fiber contamination, and overall product quality," she says. "This ensures that patients receive injectable drugs that are both safe and effective by minimizing the risk of contamination. This also supports pharma customers in demonstrating the implementation of a comprehensive Contamination Control Strategy in compliance with Annex 1 revision. Additionally, PremiumFill can significantly reduce scrap rate on fill-finish lines, leading to cost savings and increased production efficiency."



A recent case study, conducted by a leading injectables manufacturer, showcased the tangible operational benefits of PremiumFill. Upon integrating PremiumFill into their filling operations, the manufacturer reported a decrease in scrap rate by more than 20%, without requiring any process adaptation, explains Ms. Verger. "A deeper dive into the data revealed that the primary contributors to this reduction were related to fiber contamination and staining of the elastomer – both of which are comprised in PremiumFill's enhanced specification," she says.

To further improve their operation and fully leverage the advantages of PremiumFill, drug manufacturers can choose Aptar Pharma's Ready-to-Use (RTU) gamma-sterilized components. In addition to guaranteeing sterility at the point of use, thus meeting Annex 1 revision guideline for sterility assurance, Aptar Pharma RTU products are packaged in bags without Tyvek, which is a known source of fiber/particle contamination, Ms. Verger explains. Furthermore, PremiumFill product can be packaged in Rapid Transfer Portbags (RTP) that connect directly onto filling lines' isolators to limit the risk of particulate contamination and facilitate compliance to Annex 1 revision regarding contamination control.

She says: "As the pharmaceutical industry grapples with the dual challenges of ensuring patient safety and complying with evolving regulatory standards, Aptar Pharma's range of solutions help customers achieve operational efficiency and meet ever-increasing regulatory standards."