Aptar Pharma: Helping Pharma Manufacturers Meet New Annex 1 Requirements

In the pharmaceutical sector, ensuring the safety and effectiveness of injectable medications is of utmost importance. Particulate and microbial contaminations are among the main cause for FDA recalls as they can put patients at risk. The increasing quality expectations of the industry are accompanied by a tightening of regulatory requirements, which intensifies the pressure for manufacturers to guarantee the purity and safety of their drugs. Additionally, the growing focus on biologics and biosimilars within research and development is accompanied by a need to minimize development risk. “Choosing the right partners throughout drug development journeys is crucial to accelerate market access and ensure patient safety,” says Estelle Verger, Business Development Senior Manager at Aptar Pharma.

These observations align with the latest update of Annex 1 by the European Medicines Agency’s Good Manufacturing Practices (EMA GMP), which emphasizes the criticality of contamination risk mitigation. This update requires manufacturers of sterile products to implement a comprehensive contamination control strategy, not just within their own operations, but also throughout their upstream supply chain.

Aptar Pharma, a leading manufacturer of primary packaging solutions, offers solutions that can help pharma manufacturers meet new Annex 1 requirements and take their contamination control strategy to the next level, she says. “When working with primary packaging components, microbial and particulate contamination could come from the components themselves, their packaging or be accidentally introduced on the filling line during aseptic transfer,” Ms. Verger says.

To address the first situation, Aptar Pharma developed PremiumFill®, an improved manufacturing process for elastomeric closure components that leverages robotization and clean rooms to reduce the risk of contamination during production. She explains: “This improved process enables improved specifications on key contamination criteria (i.e., fibers, embedded particles, loose particles, biological contamination) as listed in the Annex 1 revision. PremiumFill components use the same rubber formulations and designs as standard products, allowing manufacturers to easily upgrade their operations, without requiring regulatory reapproval.”

As of Annex 1 revision, sterile drug manufacturers must be able to demonstrate and check the sterility of their primary packaging. To answer this need, Aptar Pharma offers Ready-To-Use gamma sterilized vial stoppers and syringe plungers, a validated and market-proven sterilization method offering all the required guarantees and certificates.

“The proprietary process for RTU components demonstrates integrity at the point of use, as required by Annex 1, and avoid the use of Tyvek material, which is a potential source of fiber contamination,” she says.

To further minimize risks of introducing extrinsic contaminants during the transfer of components on aseptic filling lines, Annex 1 highly recommends using isolators or RABS. Aptar Pharma aligned with this recommendation by offering components packaged in a large variety of Rapid Transfer Port bags to connect directly to the manufacturers’ filling lines, therefore, helping to limit the risk of accidental contamination.
Ms. Verger adds: “Though the Annex 1 revision imposes stricter guidelines to manufacturers, solutions are already commercially available on the market to help them implement their contamination control strategies, while improving their operational efficiency.”