



Aptar Pharma: Derisking the Development of Prefilled Syringe Delivery

Primary packaging plays a critical role in the development and delivery of every injectable drug and offers many opportunities to meet evolving market expectations. Thus, primary packaging manufacturers have been improving their processes and are working with material sciences to develop innovative solutions, such as rubber components laminated with fluorinated films (i.e. ETFE). “While Halobutyl formulations are specifically designed to limit their chemical interaction with therapeutics, ETFE films form an additional barrier that further reduces the transfer of extractables and leachables into the drug product,” says Claire Raynal-Olive, Vice President of Business Development for Aptar Pharma. “Coated components help drug developers meet the stringent requirements of regulatory agencies and reach the market faster.”



Additionally, as the demand for self-injection increases, primary packaging manufacturers must also guarantee that the functional performance of their components (such as the activation and gliding forces) is congruent with patients' capabilities or autoinjector integration. “Such functional requirements are further emphasized as drug developers work toward reducing the frequency of injection for improving patient compliance and comfort,” she says. “Functionality issues can be avoided by selecting premium components designed to deliver consistent performance, whether for manual injection or autoinjector integration.”

Finally, accelerating time to market while optimizing and derisking operations is of key importance for pharma companies that may also rely on contract manufacturing organizations for performing the final filling steps. Primary packaging's functionality can be a source of risk for compatibility with filling lines, and therefore a potential barrier to efficient industrialization. “Aptar Pharma's PremiumCoat® is compatible with both vent tube and vacuum technologies, enabling operational flexibility while facilitating the choice of primary packaging and CMO for pharma partners,” Ms. Raynal-Olive says. “PremiumCoat 1mL and 1-3mL plungers help derisk the primary packaging selection process so that our pharma partners can focus on their drug development.”

