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Small Particles, Big Impact: Addressing the Dangerous Implications of Micro Material Contamination

Pharmaceutical drug products are carefully engineered, manufactured, and administered with patient safety, drug efficacy, and business success in mind. Drugs and the components they are packaged in are subject to strict regulations and requirements, including sterilization and comprehensive quality review and testing. While pharmaceutical manufacturers consistently work to mitigate any substances or processes that could hinder ultimate quality, small particles still pose a challenge to the industry. With this in mind, companies must take proactive steps to mitigate particle contamination's impact on the sensitive drugs that are critical to the health and safety of patients and company success.



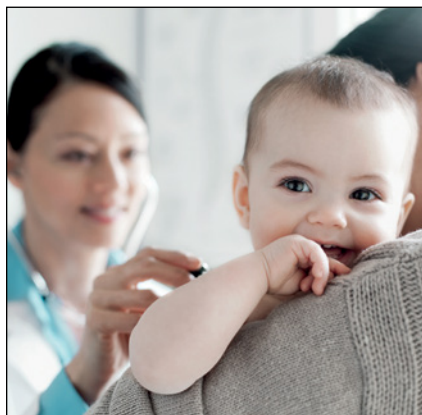
Katie Falcone, Datwyler

■ Particle Impact

Particles can be foreign substances inadvertently introduced to a pharmaceutical, which can then directly enter the human body through administering a pharmaceutical drug. The source of particles can include human skin and hair particles, cellulose fibers, or even metal fragments resulting from different stages of the manufacturing process. While many drugs may contain trace levels of particles that are not considered harmful to a patient, particles can have a drastic impact on the patient once a drug enters the bloodstream. To understand the impact of these particles, it is important to look at the pharmaceuticals to understand how small particles can have such a major impact.

Biologics are proteins carefully formulated from biological sources. When any foreign particles are introduced, those particles can interact with the proteins to denature them, rendering them ineffective. Through the denaturing process, the active pharmaceutical ingredient is lost, resulting in a patient not receiving the intended dose, directly affecting the desired therapeutic effect and treatment process.

In addition to the effects particles can have on patient safety and the sterility of drug products, particle contamination can have major business and financial implications for pharmaceutical manufacturers. If particles are found to have contaminated the entire batch, then the entire batch must be scrapped resulting in financial loss to the manufacturer. Digging even further, scrapping entire batches of products has an impact on a company's sustainability efforts. Throwing out batches of products results in a waste of energy it took to make the drug product, a waste of fuel it took to transport the product, and a pile up of scrapped vials, stoppers, expensive drug products that cannot be used. While there are currently regulations in place to mitigate these impacts, companies can still experience issues that impact patient safety and business success.



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■ Implications in Today's World

Regulations in the pharmaceutical industry are strict and ever-evolving, especially when it comes to patient safety. Over the years, companies have begun placing a heavier emphasis on testing for and reducing particles. Pharmaceutical manufacturers have been particularly challenged with producing high-quality products while fulfilling quick turnaround times for COVID-19 vaccines. With manufacturers working against high levels of demand, there is little room for batch contamination issues, which can be detrimental to companies and their customers, in terms of finances and the health of patients. Companies such as Datwyler implement rigorous

quality control processes to ensure preventative measures are in place to decrease potential contaminations, recalls, and costly issues for customers. The call for quality is always increasing — companies are constantly striving to do better, and even exceed the already tight regulatory standards. By implementing strict quality control measures, companies place even more of an emphasis on sterilization, safe shipping and storage, and proactive thinking to mitigate any opportunities for infiltration of foreign particles. By adopting a forward-thinking, innovative mindset, pharmaceutical manufacturers can focus on ways to reduce particle contamination, and always stay ahead of the regulations curve.

■ Innovation in the Industry

With the multitude of implications and concerns over particles, even after adhering to industry regulations, it may be overwhelming for pharmaceutical manufacturers to determine how to move forward. Fortunately, there are still measures companies can implement to mitigate particle contamination. Datwyler's DuraCoat™ combiseals incorporate a protective lacquer on the aluminum shells to reduce the opportunity for aluminum particles to form. Aluminum shells can easily rub together during transit, causing tiny aluminum particles to form. From there, the aluminum particles can then transfer to the elastomer, which has primary contact with drug products. Incorporating the protective lacquer reduces the opportunity for particles to form.

Our households, the air we breathe, and the food we consume all contain particles. However, one of the most dangerous places for unwanted particles to exist is in pharmaceutical drug products and items that help keep patients healthy. By auditing company processes and incorporating innovative thinking, pharmaceutical manufacturers can work to reduce particle contamination across the supply chain, resulting in positive impacts to companies, their customers, and patients around the world.

This editorial was written by Katie Falcone, Scientific Support Manager, Datwyler, Middletown, DE. Datwyler develops, designs, and manufactures solutions for injectable packaging and drug-delivery systems. For more information, visit www.datwyler.com.