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Elastomer manufacturing: primary packaging for parenteral drugs

With the advent of biologics and highly sensitive drugs, primary packaging materials must meet the highest-level of functional, regulatory and cleanliness standards to ensure compatibility and ultimately, patient safety. Rahul Thakar, PhD, discusses **Datwyler**'s solution to these ever-stricter requirements is their highest-quality manufacturing standard, First Line.

The manufacturing concept of First Line adopts a quality-by-design (QbD) approach that begins with a fundamental question; if the common denominator is defined by the primary packaging material, should not the primary packaging environment be an extension of the drug manufacturing environment?

Before First Line's commercialisation in 2009, Datwyler collaborated with pharmaceutical and biotech clients to understand the needs of the market. To address the unmet market needs for the highest-quality components, it was important to redefine the manufacturing concept that was determined by Datwyler and challenged by industry experts. A decade later, it can be said with confidence that the concept is the new standard with the opening of the third First Line facility in Delaware, US.

Packaging challenges for complex and sensitive drugs

It is important to consider the QbD approach for the product first and extend it into the manufacturing environment. Highly sensitive drugs demand modern elastomer compounds with the cleanest extractable and leachables (E/L) profile, and are highly sensitive to foreign contamination. To meet these product challenges, Datwyler has developed best-in-class rubber compounds, such as FM457, which is widely recognised as the cleanest elastomer in the parenteral packaging space from an E/L standpoint.

Silicone, which is a necessary evil, is needed for machinability, functionality, and transportation of elastomeric products. Silicone also has a tendency to migrate into drug formulations. To mitigate risks against silicone sensitivity, Datwyler has developed the proprietary Omni Flex coating that eliminates the need for siliconisation. Omni Flex has been commercially successful with several drugs on the market that benefit from this fluoropolymer technology.

The First Line manufacturing concept starts with a 'zero defect philosophy' in mind. To achieve this, the smart facility design regulates personnel, material flow, and waste flow. The critical processes are automated to eliminate or minimise operator contact. Here, statistical process controls with continuous monitoring of products aim to minimise defects. Automation enables the entire production floor to be paperless, this is essential since cellulose is the largest contaminant in parenteral drugs. Finally, continuous improvement efforts are defined by process FMEAs and poke-yoke principles so as to build quality into the process. As a second line of defence, components can be vision inspected at a per-piece level for cosmetic and dimensional defects.

More stringent expectations of the regulatory authorities

Data suggests that authorities' expectations are becoming more stringent, pushing our industry to reach higher quality levels. It can be agreed that these trends on stricter expectations from the pharmaceutical companies, as mandated by the regulatory bodies, are here to stay, and will only get stricter. It is only a matter of time that this will be the 'new normal' within the industry. To meet these challenges, Datwyler pioneered the First Line manufacturing concept much ahead of its time. Strict specifications for particulate levels and continuous improvement efforts are in place to strive towards our goal of zero defects. This QbD approach is at the centre of the First Line concept.

Globalisation and supply chain optimisation

Pharmaceutical companies maintain a global manufacturing presence to provide drugs into several geographic regions and regulatory environments. It is expected that component manufacturers are able to match that global footprint, and have an understanding of the complex regulatory landscape.

For pharma and biotech clients to leverage a global manufacturing footprint, the First Line plants in Belgium, India and the US utilise the same raw materials, technologies, processes and produce pharmaceutical components with the same specifications. As a result, this risk mitigation strategy enables business continuity and supply chain, which is a key consideration in today's pharmaceutical manufacturing landscape.

By implementing a QbD approach when developing the First Line manufacturing standard, Datwyler has set the bar for high-quality parenteral packaging manufacturing. ●

For further information

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