CASE STUDY

Removing Regulatory Barriers Increases Speed to Market and Benefits Medical Device OEMs Worldwide

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For medical device OEMs, evolving global regulatory requirements can make it increasingly difficult to obtain product approvals, which can delay speed to market. Lubrizol has taken the initiative to offer non-animal derived medical grade polymers to help customers overcome regulatory roadblocks while still delivering the same quality and performance.

THE CHALLENGE

Medical device OEMs partner with Lubrizol utilizing their thermoplastic polyurethane (TPU) capabilities and expertise when developing medical devices for use in cardiology, urology, orthopedics, wound care, and many other applications. Medical polymers designed for extrusion or molding typically contain a small amount of lubricant. These amide-based lubricants are commonly used to impart processing benefits for a broad range of melting conditions and equipment. The lubricants are produced, in part, from fatty acids distilled from naturally occurring sources, the most common being tallow or fatty animal tissue.

The European Medical Device Regulation (EU MDR) has imposed risk assessment requirements on medical device OEMs that utilize animal derivatives in their medical devices. More recently, rule 18 of the EU MDR has changed from the prior medical device directive (MDD) to now include devices utilizing tissues of animal origin, or their derivatives, which are non-viable or rendered non-viable. Devices utilizing these substances are subject to a consultation process where the OEM is required to supply the Notified Body with documentation that demonstrates the benefits of the device outweigh the residual risks.

Medical device OEMs may need to compile extensive justifications, conduct testing, and incur expenses to obtain approval for their device which incorporates animal-derived materials.

THE SOLUTION

In a proactive approach to reduce the risk assessment burden from the updated MDR Rule 18 guidance, Lubrizol developed medical polymers which utilize non-animal derived lubricant additives for use in a wide range of products delivering the same performance characteristics as the legacy polymers. Lubrizol can provide OEMs with product samples and technical data to support their qualification activities.

THE OUTCOME

By formulating medical polymers which do not incorporate animal-derived ingredients, Lubrizol helps medical device OEMs navigate regulatory approvals with greater efficiency. Once the OEM meets the requirements of the EU MDR, approvals from other regulatory agencies are simplified. Improving speed to market not only benefits the OEM's bottom line; it helps put products in the hands of physicians faster, so they can treat patients with critical health issues.

To discuss a specific inquiry or project need, please contact us to be connected with our dedicated team of material experts. And to learn more about how Lubrizol delivers value beyond the device, visit our resource page.

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