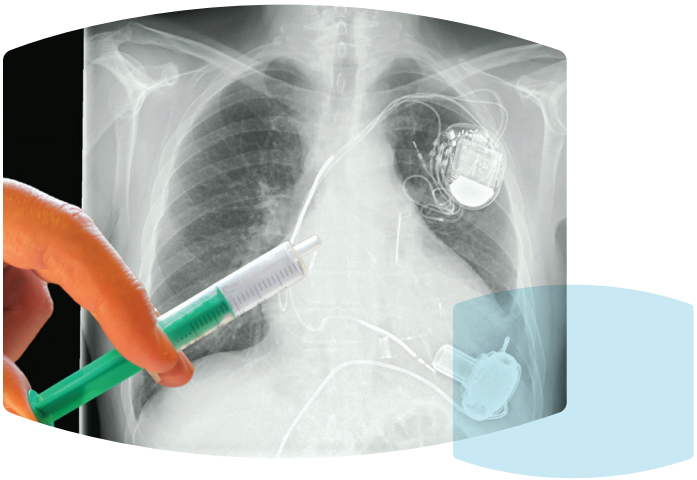
CASE STUDY

Quick action avoids a regulatory update delay

HEALTH

Receiving marketing approval for your device isn't the end of your need for regulatory support from your material supplier. Far from it. Whenever device makers change a material used in a medical device, they need to file an update. If the device was approved through a premarket notification pathway, the assessment will be made in comparison with the predicate device named in the original filing. This sometimes results in the regulatory body requesting additional information on the new material. That was the case with this customer:



CUSTOMER TYPE

OEM manufacturing a medical device in long-term contact with patient's blood.

CUSTOMER CHALLENGE

The customer was filing regulatory updates to the device to change the grade of thermoplastic polyurethane (TPU) material provided by Lubrizol. The regulatory body surprised the customer when it asked for additional clarification around the TPU manufacturing process and material formulation. Analysts wanted the information to help in comparing the modified device (with the new TPU grade) to the predicate device in the OEM's original filing. Demonstrating basic similarities between a new or modified device and the predicate device can require manufacturers to provide descriptive information such as a comparison of specifications, materials, and technology. In this case, the information requested was proprietary and confidential to Lubrizol.

SOLUTION

Lubrizol went above and beyond. Direct communication between a material supplier and a regulatory body on behalf of a customer is not the norm. However, we worked out a way to provide the sensitive information directly to the regulatory body within 48 hours of the original request without the need to set up additional time with the OEM.

OUTCOME

The OEM was able to continue their regulatory filing process with the agency with minimal delay and without the need for further follow-up questions regarding the new material.

"Our commitment during this process is to provide supporting medical grade material information through the OEM's entire device lifecycle, especially when it's needed quickly."

Jennifer Green, Technical Marketing Manager,
Medical Polymers, Lubrizol Life Science Health

Another area where many OEMs rely on their material supplier for ongoing support is in monitoring additions to chemical warning lists such as California Proposition 65 and the European Chemicals Agency's Substances of Very High Concern (SVHC). If we learn that a substance that is present in an ingredient used to manufacture one of our products is slated to be listed, we immediately advise customers that the change is coming and how we plan to mitigate the impact.

To discuss a specific inquiry or project need, please contact us to be connected with one of our regulatory experts.

LUBRIZOL LIFE SCIENCE