HEALTH

5 KEY CONSIDERATIONS WHEN SELECTING POLYMERS FOR MEDICAL DEVICE DEVELOPMENT

Medical device development is often a long-term endeavor, requiring rigorous testing, quality control systems, and compliance to an ever-evolving set of regional and global regulatory requirements. For many implantable or invasive devices, the selection of a polymer is a major decision.

The choice of polymers for a specific device application is based on many factors. Functional factors are obviously the first consideration – biological performance, application performance, chemical resistance, and processability. But regulatory and compliance requirements also deserve attention. Here are five recommendations for device makers:

CHOOSE MEDICAL GRADE POLYMERS

While formulation, manufacturing, and testing of materials for biocompatibility are distinct and important characteristics of a medical grade polymer, other services such as regulatory support, change management and security of supply are of utmost importance. They may sometimes be overlooked during initial material selection activities.

REVIEW THE BASIC INFORMATION

Does the recommended polymer contain REACH or RoHS substances or other substances of concern? Are there other red flags? Lubrizol maintains Medical Information Packages on each of its medical grade thermoplastic polymers that detail relevant regulatory and compliance information like this.

LOOK FOR A PREDICATE

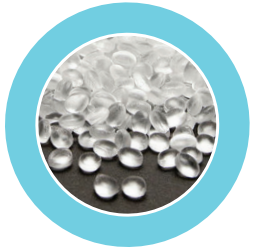
An FDA 510(k) premarketing submission must demonstrate the safety and effectiveness of the device to be marketed by proving substantial equivalence to a legally marketed "predicate" device. The selection of your predicate can be consequential. It determines what kinds of testing you will need to do and can ease the path to approval.

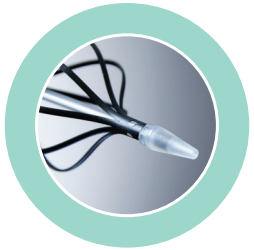
CHECK YOUR TESTING LAB

You want a lab that is familiar with the materials you are planning to use in your device. For example, a lab not experienced in testing devices that include polyurethanes might not understand how to differentiate a polyurethane-related extractable substance from extractable substances coming from other adhesives or thermoplastics in the device.

GET STARTED ON YOUR RISK ASSESSMENT

Don't put off planning the chemical characterization and toxicological risk assessment your regulatory agency may require. Consult with your material supplier about your chemical and toxicology assessment needs and they may be able to provide you with supporting material-level information.





LUBRIZOL LIFE SCIENCE

For more information and to view additional resources to help you understand and navigate the complex regulatory process, visit our Regulatory Page. To discuss a specific inquiry or project need, please contact us to be connected with one of our regulatory experts.

21-1592