POLYONE DISTRIBUTION

Navigating the healthcare regulatory process for polymer materials

Meeting quality and regulatory requirements is a critical step toward developing new device technology and ultimately, providing patient comfort and safety. This includes validating materials that meet composition, regulatory, quality and performance requirements.

PolyOne Distribution can help you navigate the regulatory process more efficiently. We offer help with material selection based on regulatory guidelines, required regulatory documentation, application approvals from material suppliers, and raw material product specifications. Our support services include:

Regulatory Verification of Medical Grades – We will review polymer approval status against ISO 10993 and/or USP Class VI requirements, and provide biocompatibility testing results or Letters of Authorization into the FDA Drug Master Files, upon request.

Material Composition Documentation – We will coordinate responses from material manufacturers to address concerns with product composition and provide assistance should a regulatory NDA be needed. Also, we will provide compliance documentation for various EU/US directives including, but not limited to: Animal/Plant/Human Origin, BPA, California Proposition 65, Conflict Minerals, FDA Food Contact, Heavy Metals (CONEG), Latex/Rubber, Phthalates, RoHS, and REACH SVHC.

Early Material Change Notification – We can provide customers with advanced notice of material discontinuation, or composition or manufacturing changes.

Supplier Quality Audit Documentation – We will assist with audit requests at the material supplier manufacturing plants or PolyOne third party logistics warehouse locations, facilitate Supplier Quality Questionnaires, and provide ISO/A2LA certification for our suppliers.

Pre-Approvals of Healthcare Materials for End-Use Applications – We will review supplier-established medical policy guidelines and facilitate and/or ensure the correct material has been selected based upon regulatory requirements for the specific FDA/EC MDD device classes.

Approval & Verification for Raw Material Product Specifications – We will review customer internal raw material product specifications related to property tolerances, packaging, labeling and certificate of analysis requirements.

For more information, contact PolyOne at 1.866.POLYONE or visit polyonedistribution.com

PolyOne Corporation, 33587 Walker Road, Avon Lake, Ohio USA 44012