

# 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: CPSIA, California Proposition 65, Conflict Minerals, Food Contact, EU MDR, Heavy Metals (CONEG), RoHS, and REACH SVHC.

**Early Material Change Notification** – We will provide customers with advanced notification of supplier material changes related to discontinuation, CAS composition changes, etc.

**Supplier Quality Audit Documentation** – We will assist with physical audit requests at the material manufacturing plants or at our PolyOne third party logistics warehouse locations, and review quality agreements & surveys.

**Pre-Approvals of Healthcare Materials for End-Use Applications** – We will review supplier-established medical policy guidelines and facilitate and/or assist to determine that the correct material has been selected based upon regulatory requirements for the customer-specific end-use device and also assist in any supplier indemnification agreements, as needed.

**Approval & Verification for Raw Material Product Specifications** – We will review customers' internal raw material product specifications to determine if they align with the suppliers' sales specifications as well as carefully review other provided specifications that may require additional services.

For more information, contact  
PolyOne at 1.866.POLYONE or visit  
[polyonedistribution.com](http://polyonedistribution.com)