Medical standards and support

for Eastman medical grade polymers

Access to high performance medical grade materials is critical for manufacturers of innovative medical devices and packaging. To provide lasting reliability and proven patient safety, manufacturers and OEMs require medical grade material suppliers to not only provide advanced, high quality raw materials but also to offer capabilities and systems that help comply with medical protocols and regulations.

Eastman can provide a high level of support throughout the regulatory journey to commercialization of a new product. From the early stages of material selection to premarket submissions to the U.S. Food and Drug Administration (FDA), Eastman is prepared to work with customers using any of its medical grade polymers.

Biocompatibility (ISO 10993)

Products positioned for use in medical device and medical packaging applications have met selected tests from the FDA-Modified ISO 10993, Part 1 "Biological Evaluation of Medical Devices."

Note: The final device manufacturer is responsible for the biological evaluation of the finished medical device and submission of these data to regulatory agencies. Summary certificates showing statements of test results from our contract laboratory are available to customers on request. Full test reports are only available with establishment of an appropriate confidentiality agreement and approval of the business manager.

Packaging for terminally sterilized medical devices (ISO 11607)

Eastman medical grade materials utilized in medical packaging applications also comply with applicable sections of ISO 11607 (including microbial barrier).

Quality systems and GMP

In most countries, there are no specific regulations for good manufacturing practices (GMP) for raw materials for devices. In the U.S., 21 CFR Part 820 contains the quality system regulations for finished medical devices.

Eastman operates using a system which complies with the requirements of ISO 9001 for the design, development, manufacture, and supply of polymers. Eastman has also developed an internal quality manual and implemented appropriate GMP applicable for raw materials used in medical devices and medical packaging. Eastman manufactures and handles several products subject to GMP. Global Quality (GQ) is responsible for the company policies and guidelines of these products.

Traceability

Traceability of raw materials is a critical component of ensuring safety and repeatability in the manufacturing of medical devices and medical packaging. By employing strict manufacturing and quality guidelines of the products through GMP, Eastman ensures the reliability and consistency of the materials that fulfill this requirement.

Dedicated regulatory support

Understanding regulatory requirements for the medical industry is critical to provide high quality products that meet the expectations set out by the regulatory bodies. Eastman has dedicated global regulatory support to ensure the compliance of our medical grade materials. Our regulatory experts, product stewards, and staff toxicologist are available to help. They will answer questions about our products, share relevant documentation necessary for filing for new device applications, and provide general support to our customers throughout the approval process.

Regulatory statements

Product regulatory information sheets (PRIS) with applicable product regulatory topics are available through the customer center or your local Eastman representative (CSR).

U.S. FDA Drug Master Files (DMF) (for select products)

DMFs for polymers are applicable for customers making applications for drug approvals to the U.S. FDA. There are no master file systems in other countries.

Supporting services*

- NOC (notification of change)
- Quality agreements
- Quality audits
- Business continuity plans
- Application development and technical service
  - Accommodation of unannounced audits by Notified Bodies and/or regulatory authorities as required under European Union Medical Device Regulation 2017/745, effective May 2020

If you have questions about Eastman materials and the regulatory process, contact your local CSR or call 1-800-EASTMAN.

**Some services may be limited to qualifying opportunities.*

USP General Chapter <661.1>, "PLASTIC MATERIALS OF CONSTRUCTION."

Eastman's select medical device and medical packaging materials also comply with specifications within USP General Chapter <661.1>, "PLASTIC MATERIALS OF CONSTRUCTION." This standard states: "A plastic material is deemed to be well-characterized for its intended use if the following characteristics have been adequately established: its identity, biocompatibility (biological reactivity), general physicochemical properties, and composition (i.e., additives and extractable metals likely to be present)." USP <661> is applicable to pharmaceutical applications and not applicable to all Eastman polymer products.

EASTMAN
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