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NA-MGMC Newsletter

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The 5th Annual Mini Conference Update

The 5th Medical Grade Material Conference brought together 46 MedTech polymer manufacturers, marking a significant milestone in the industry. This event featured a two-day mini-conference and vendor fair that showcased medical-grade, Material quality/ impact of material obsolescence / medical polymers and material trend, highlighting the growing demand for safer and more sustainable materials within the medical sector.

One of the key accomplishments of the conference was the review of a draft ASTM Standard "Guide for Criteria and Classification of Medical Grade Polymers and Polymer Compounds for Non-implantable Applications" The target release for this standard is set for the second quarter of 2026, and the development committee led by Scott Taylor (Poly-Med, Inc.) comprises industry stakeholders such as medical device companies, polymer manufacturers, and the US FDA.

ASTM INTERNATIONAL

Johnson&Johnson MedTech

Sustainability Trajectory:

The burgeoning demand for sustainable healthcare solutions, driven by escalating regulatory mandates and consumer advocacy for transparency, has precipitated a paradigm shift towards innovation in materials and manufacturing processes.

A critical strategy to address this evolving imperative is the integration of alternative polymer solutions derived from renewable sources, mitigation of carbon footprint via rigorous Life Cycle Assessment (LCA), and adoption of bio-based materials. Notably, technological advancements have enabled the development of materials with bio-based carbon content ranging from 40% to 99% (ASTM D6866-12).

A promising approach, highlighted during the session, involves leveraging high content castor oil and robust annual plants, such as non-food crops, to create sustainable material solutions.

Leap frogging into the creation of ASTM Standard for MedTech:

Progress in our journey

The leader of the ASTM cohort provided a section-by-section update on the first draft and communicated the progress made to date. This is in readiness for the first voting session scheduled for Sep 19th, 2025.

Accelerating towards the establishment of an ASTM standard for the medical device industry, the 5th Medical Grade Materials Conference featured an invitation to participate in the development of this pivotal standard through membership in the Medical Grade Material Definition ASTM Cohort Working Group. This Working Group, comprised of industry stalwarts and subject matter experts, tasked with achieving key objectives, including the codification of a marketing term into a definitive standard, and the creation of a harmonized lexicon and framework to facilitate expectation management between suppliers and purchasers, thereby ensuring clarity and consistency in the medical technology sector.

The Influence of Change in Regulations and Our Environment

Environmental perspective on ETO sterilization techniques and a recent debate on medical material / device sustainability evolution and definition.

The predominant utilization of ethylene oxide (ETO) as a sterilization modality for medical devices, accounting for approximately 50% of all methods employed, is being reevaluated considering stringent Environmental Protection Agency (EPA) regulations.

To mitigate the environmental and health risks associated with ETO, alternative sterilization technologies, including steam, electron beam (E-Beam), hydrogen peroxide (H2O2), X-ray, chlorine dioxide (CD), and nitrogen dioxide (NO2), must be developed and implemented to ensure accessibility and affordability. The EPA's recent announcement of a final rule to significantly reduce toxic ETO emissions and associated human risks, coupled with shifting demand dynamics and concerns regarding cobalt supply chain resilience through 2030, underscores the imperative for diversification of sterilization methods. Consequently, the medical device industry is compelled to adopt a multifaceted approach to sterilization, driven by evolving regulatory requirements and environmental stewardship.