POLY-MED, INC.

Standardizing 'Medical Grade' ASTM Work Item Update

August 26, 2025

M. Scott Taylor, PhD

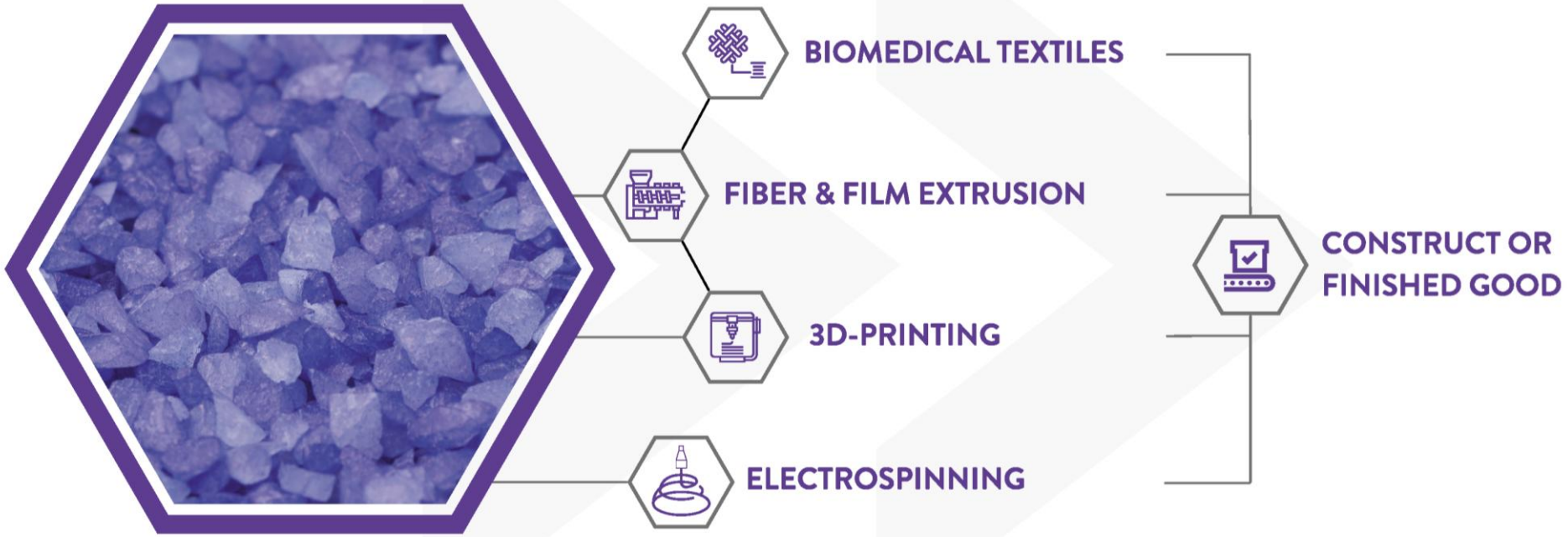
Chief Technology Officer

Adjunct Faculty, Clemson University

ASTM Member, F04 and F42

→ *Chair F04.11/.15 Joint Task Group for Absorbable Polymers*

Poly-Med's mission is to design, develop, and manufacture custom biotechnology materials to propel specialty product visions into tangible, highly competitive, & unique product offerings.



5,000+
Polymer Formulations

250+
Issued Patents

FDA Registered

ISO 13485

11,000,000+
Implantations

25%
Advanced Degrees on staff

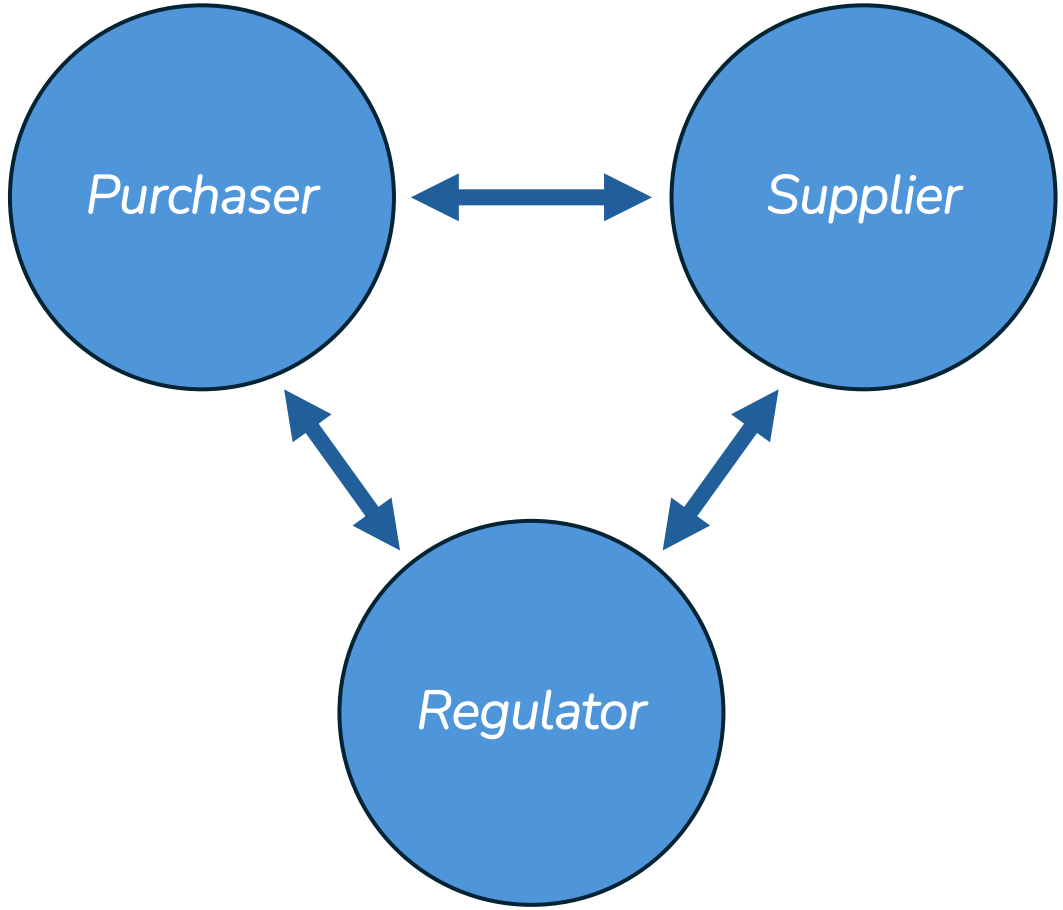
32 Years
In Business

220+
Employees

PMI POLY-MED, INC.

The call for standardization…

- *Common language*
- *Clear communication*
- *Manage expectations*
- *Understand risk*

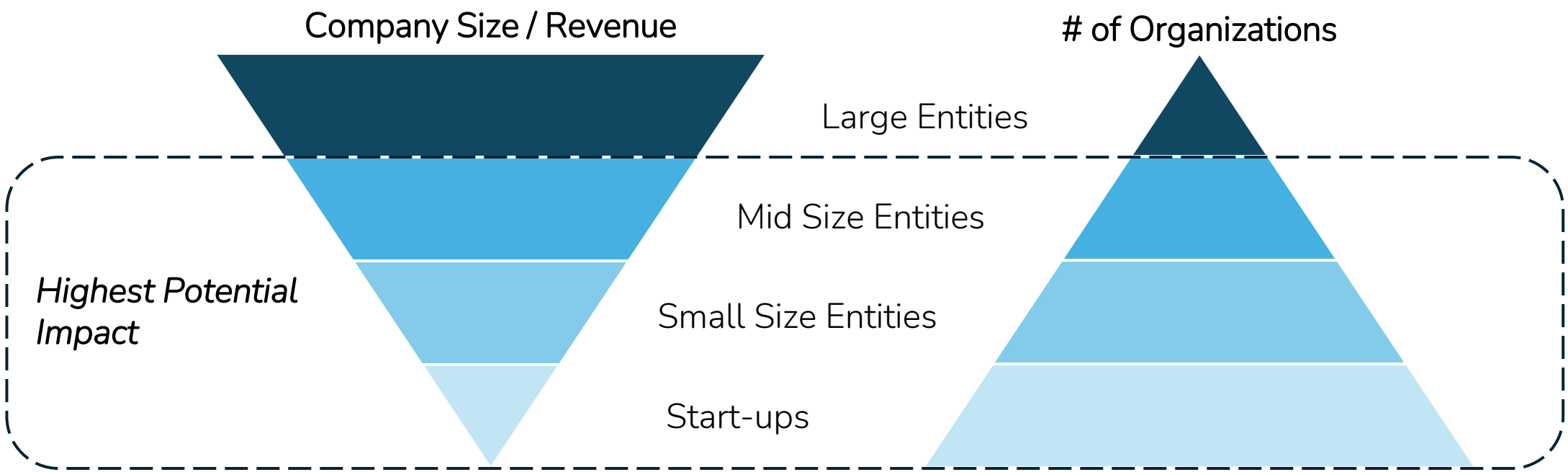


Who is this for?

- *Purchasers, Suppliers*
- *Regulators*

What is this for?

- *Evaluating and specifying materials*
- *Evaluating and managing change*



Key Aspects of ASTM Standards

- Voluntary (not a requirement)
- Global
- Consensus
- 6 Types - Test method, Specification, Classification, Practice, **Guide**, Terminology
- The Standardization Process
  - ✓ New Standard Proposal
  - ✓ Approval of Work Item
  - ✓ Task Group is formed
  - ✓ Draft is created
  - Draft is balloted
  - Any Negative Votes are discussed, Draft is revised
  - Revised Draft is balloted, repeat until Negative Votes are resolved
  - Work Item published as a New Standard

Our Task Group has members from

Goals of this Standard

- Transition a ***Marketing Term*** into a ***Meaningful Term***
- Create ***Common Language***
- Framework to ***Manage Expectations*** between Supplier and Purchaser

Rational (*As provided to ASTM F04 Committee*): There is no standard definition, or even industry norms, for the application of 'medical grade' or related terminology. This proposed guide will support purchasers (e.g. medical device component manufacturers, OEMs, etc.) and suppliers by creating a guide to support uniform application of terminology and expectations between these groups. Suppliers will be able to establish a clear value proposition and purchasers will be able to communicate requirements and compare available suppliers more effectively. This guide may include recommendations to help establish the supplier / purchaser relationship. Application of this standard guide is intended to improve the safety, quality, and consistency of medical devices, with the patient being the ultimate benefactor.

Goals of this Standard

Possible Material Identification?

- *Medical grade polymer according to ASTM Fxxxx-26*
- *Conforms to ASTM Fxxxx-26*
- *This material was assessed and tested according to the guidance of ASTM Fxxx-26*

Section Outline

- Scope
- Referenced Documents
- Terminology
- Significance and Use
- Material and Manufacturing Characteristics
- Safety Considerations
- Regulatory and Compliance Test Status
- Supply and Quality Considerations

Title and Scope – DRAFT LANGUAGE

Guide for the Criteria and Classification of Medical Grade Polymers and Polymer Compounds for Non-Implantable Applications

Scope

- This Guide provides information for purchasers (e.g. Medical Device OEMs) and suppliers (e.g. medical polymer manufacturers) to **align expectations** of the essential requirements for **polymers** used in the manufacture of **non-implantable** medical devices, in vitro diagnostics, and packaging and to create a harmonized understanding of the application of 'medical grade' terminology.

- This Guide addresses polymeric materials for a wide range of applications within the medical device and technology ecosystem but **excludes implantable applications** due to additional safety and regulatory requirements therefrom. This includes stratifying materials by classification for risk associated with the final application.

Title and Scope – DRAFT LANGUAGE

Scope (*continued*)

- This Guide addresses the need for polymeric materials that are **safe for their ultimate intended application** and **consistent in their manufacture and supply**.

- This Guide is **limited to virgin grade resins**, which may include **polymeric materials that have been compounded with additives**, and does not include additional considerations for the use of recycled material(s) in part or whole. Any modification to materials performed by the user, including use of recycled content, and associated risks therefrom is the responsibility of the user.

- **Biocompatibility** is addressed as one risk-stratified aspect of safety, including references to existing standards, for example the ISO 10993 standard series.

Title and Scope – DRAFT LANGUAGE

Scope (*continued*)

- The following aspects are addressed to support the purchaser / supplier relationship:
  - Material characteristics (e.g. shelf life and stability),
  - Biocompatibility test status,
  - Regulatory and other compliance status (e.g. FDA Master File, RoHS compliance),
  - Supply, quality, and regulatory recommendations.

Shall versus Should

'Shall' denotes a provision that is mandatory

'Should' is used to indicate that a provision is not mandatory but is recommended as good practice

'May' is used to indicate that a provision is optional

'Will' is used to express futurity, but never to indicate any degree of requirement

- Form and Style Guide for ASTM Standards

Shall Statements in Draft

Section 5 – Material and Manufacturing Characteristics

5.1 – All constituent materials in a polymer or polymer composition as supplied by the manufacturer shall be of a quality suitable to allow use of the polymer composition in the manufacture of a medical product. Such quality includes adequate control of particles and other potential contaminants that may affect the suitability for use in non-implant applications.

5.2 - The properties listed below shall be considered adhered to in selecting material(s) in accordance with the specific end-use requirements and concomitant risks associated with the application.

5.3 – The polymer composition shall be fully lot-traceable to raw materials.

5.3.1 - For most applications, polymer shall be virgin grade and shall not include regrind, re-used polymer, or mechanically recycled content.

Shall Statements in Draft

5.4.1.3.4 - The inclusion of nanoparticle-based fillers, defined as having a diameter between 1 – 100 nm, shall be disclosed by the supplier for safety evaluation by the purchaser. Considerations for identifying nanoparticles, may include guidance by US-FDA and EU MDR, for example.

5.8 - All materials contacting the materials of composition shall be of a quality suitable to allow use of the polymer composition in the manufacture of a medical product.

5.8.1.1.3 - Packaging material(s) shall be of such composition that it protects the polymer within.

5.8.1.1.4 - Packaging material(s) shall provide an effective barrier to prevent contamination of the product.

5.9 - The purchaser shall make the determination for the suitability of a polymer or polymer compound for their particular application for compatibility with sterilization or sanitization processes and requirements, including whether it is a single-use device or requires some form of reprocessing. The supplier may have information related to prior use of a polymer or polymer compound, and should provide relevant information as available.

Shall Statements in Draft

Section 6 – Safety Considerations

6.1 – The supplier of the polymer or polymer compound shall make available on request an SDS (Safety Data Sheet). The format and content requirements may vary across regions and countries, but at minimum it is recommended to use the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) format.

6.2 - The purchaser shall make the determination for the suitability of a polymer or polymer compound for their particular application. While implantable applications are not within the scope of this standard, polymers and polymer compounds may have applications that interact with the patient through other contact categories, including those designated in ISO 10993 standard series, but not limited to:

- 6.2.1 Surface devices
- 6.2.2 External communicating devices
- 6.2.3 Breached or compromised surface
- 6.2.4 Non-patient contacting, inside sterile surgical field
- 6.2.5 Non-patient contacting, outside sterile surgical field

Shall Statements in Draft

Section 7 – Regulatory and Compliance Test Status

7.1 – The supplier shall provide available biocompatibility information pertaining to the polymer and polymer compound on request

Shall Statements in Draft

Section 8 – Supply and Quality Considerations

8.1 – The supplier shall maintain a quality management system suitable for assuring traceability and reproducibility of the virgin grade polymers and polymer compounds. The quality management system shall involve all aspects of manufacturing and distribution, from raw material management through chemical synthesis, quality control, material handling, product release, and ultimate packaging and shipping to the purchaser.

8.3 - The supplier shall retain a sampling of each lot or batch of polymer or polymer compound for a time period of at least the stated expiration date.

8.4 - The supplier shall establish change notification requirements and timelines for products and/or processes.

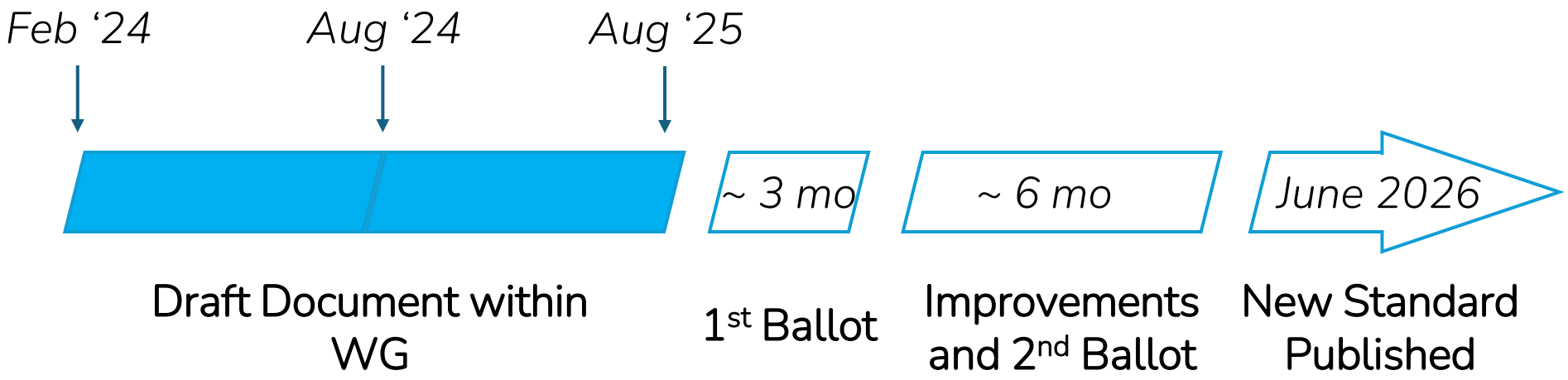
8.4.1 - The supplier shall establish definitions of what constitutes a change. This may involve delineation of levels of change, for example major and minor changes. As a non-limiting example, a vendor name change may constitute a minor change, while a change in specification or product CAS number is a major change.

Shall Statements in Draft

8.5.3 – Labels shall include, at a minimum

- Product name
- Catalogue and Version information, if applicable
- Lot number

Timeline


Feb '24
Aug '24
Aug '25
~ 3 mo
~ 6 mo
June 2026
Draft Document within WG
1st Ballot
Improvements and 2nd Ballot
New Standard Published

Summary

A raw material evaluation cannot possibly determine if a device is safe and effective, and is not sufficient to eliminate level risk, but high-quality raw materials and suppliers give a better chance to yield high quality devices.

We want to provide a guide for evaluating a polymer to be used for non-implantable medical devices.

There is no requirement that a raw material is ‘medical grade’ to be used in the manufacture of a medical device – we don’t want to change that, …

but suppliers and purchasers could benefit from a standard framework to identify materials intended and controlled for medical devices.

How you can help…

- *Become an ASTM Member - $115 annual membership*
  Committee F04 – 'Medical and Surgical Materials and Devices'
- *Get involved with developing this standard*
  *(*ASTM membership not required)*

Thank You

For questions, comments or to join the ASTM standardization effort, please email me at…

Scott.Taylor@Poly-Med.com