POLY-MED, INC.

Standardizing 'Medical Grade' ASTM Work Item Update

August 13, 2024

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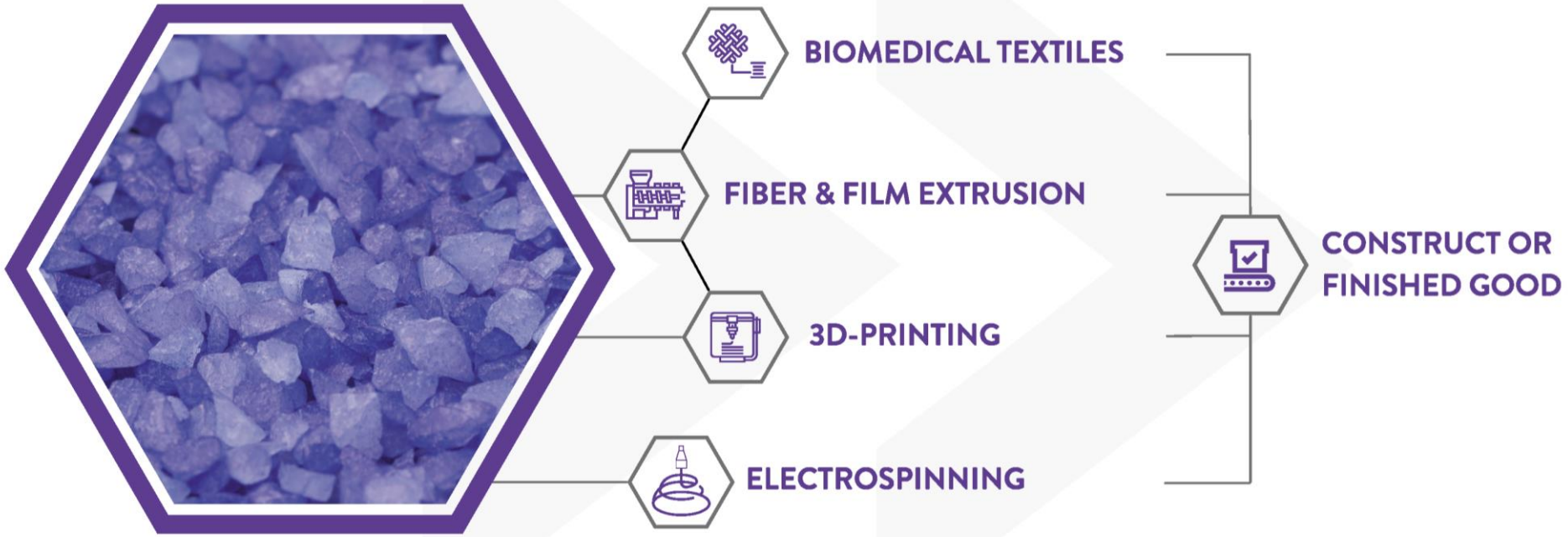
Poly-Med's mission is to design, develop, and manufacture custom biotechnology materials to propel specialty product visions into tangible, highly competitive, & unique product offerings.



5,000+
Polymer Formulations

250+
Issued
Patents

FDA Registered

ISO 13485

11,000,000+
Implantations

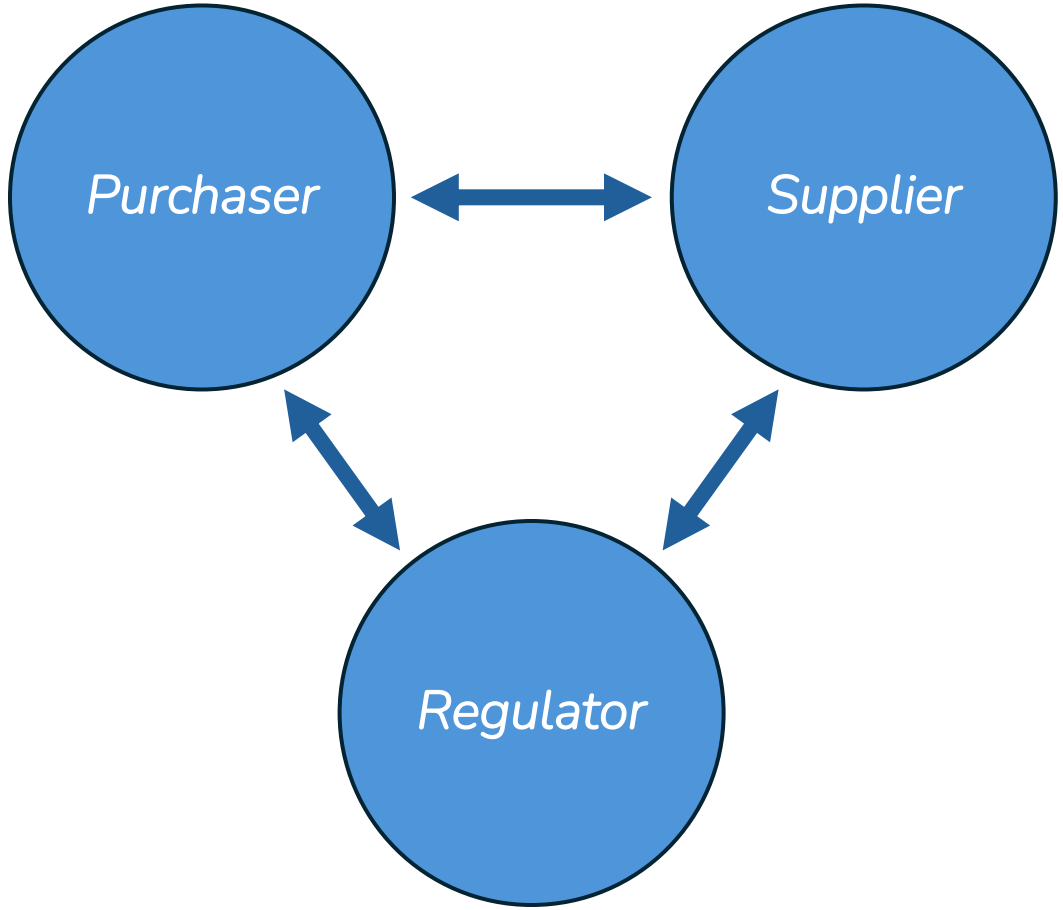
25%
Advanced
Degrees on staff

31 Years
In Business

200+
Employees

The call for standardization…

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

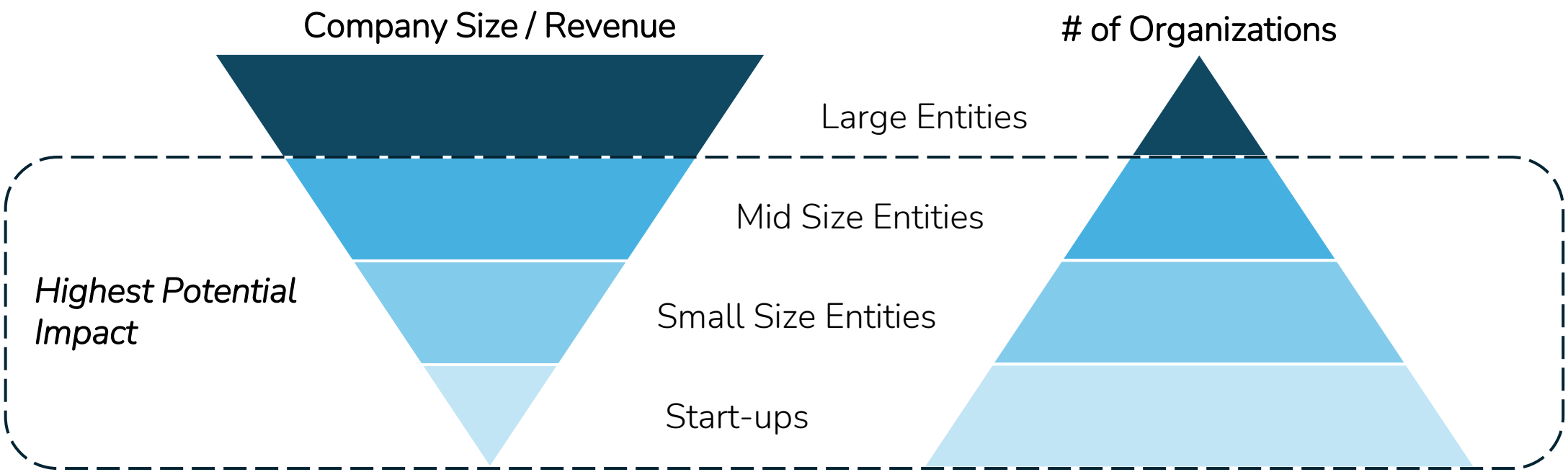


Who is this for?

- *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

RJ Lee Group

Johnson&Johnson

FDA

stryker

GORE

Medtronic

PMI Poly-Med, Inc.

Cambridge Polymer Group

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.

Title and Scope – DRAFT LANGUAGE

Guide for the Criteria and Classification of Medical Grade Polymers 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 and USP <88> classifications.

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.

Outline

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

Material Characteristics

- All materials in a polymer or polymer composition, as well as materials contacting the materials of composition, should be of a quality suitable to allow use of the polymer composition in the manufacture of a medical product.
- The polymer composition may include fillers, stabilizers, plasticizers, colorants, and/or other additives to achieve the desired end use performance. All materials of composition, including any additives, should be identified. **The sum of composition should equal 100%.**

Material Characteristics

- Three optional forms of disclosure include (may require NDA):
  - **Positive Disclosure** – Highest level of transparency
  - **Negative Disclosure** – Inclusion or exclusion of any known materials of concern
  - **No Disclosure** – The Purchaser performs chemical assessment to establish safety and appropriateness of a polymer

Material Characteristics

- Purity and Potential Impurities
- Product Form
- Stability
- Packaging Format

Safety Considerations

- Biocompatibility
  - Not a requirement
  - USP Class IV, V, VI
  - ISO 10993
  - USP <661.1>, <661.2>, <665>
  - **How else do we mitigate biocompatibility risks with polymers?**
- Contamination and Cross-Contamination Risks
- Packaging and Storage Risks

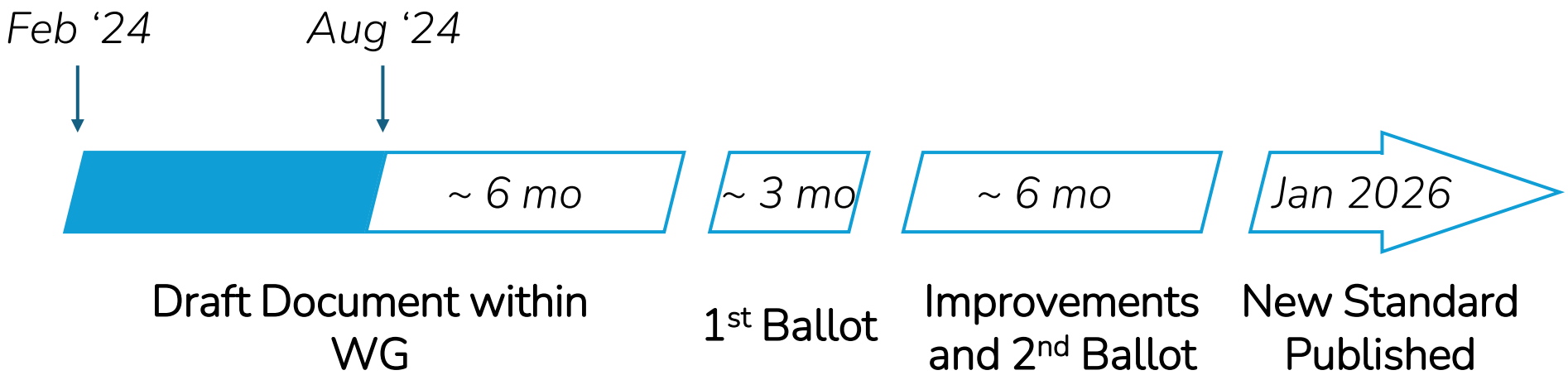
Regulatory and Compliance Test Status

- May depend on the disclosure status of the relationship
- Prior approval in medical products, and the presence of any drug or master files
- Compliance with materials of concern
  - RoHS
  - REACH
  - PFAS
  - **Any others?**

Supply, Quality, and Regulatory Recommendations

- **Change Management** will be addressed in this section
- **Quality System** should be in place
  - ISO 13485 is good to have, but not necessary
  - ISO 9001 is also not necessary, but may be broadly applicable
- **Quality Assurance** will be addressed in this section

Timeline


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

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

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