

# Medical Grade Material Definition Journey & Next Steps



**2025 Medical Grade Material Consortium Mini Conference**  
**Cincinnati, Ohio**  
**August 26<sup>th</sup>, 2025**

**Presented by:**  
**Jacqueline Anim**  
**Sr. Principal Materials Engineer /SME**  
**JNJ Medtech**

**Johnson & Johnson**  
**MedTech**

**R&D Materials**  
*OneMDSpecEngineering*

# What is the problem statement?



## Purchaser

Medical Device OEM  
expecting healthcare  
grade materials for  
device manufacturing

## Supplier

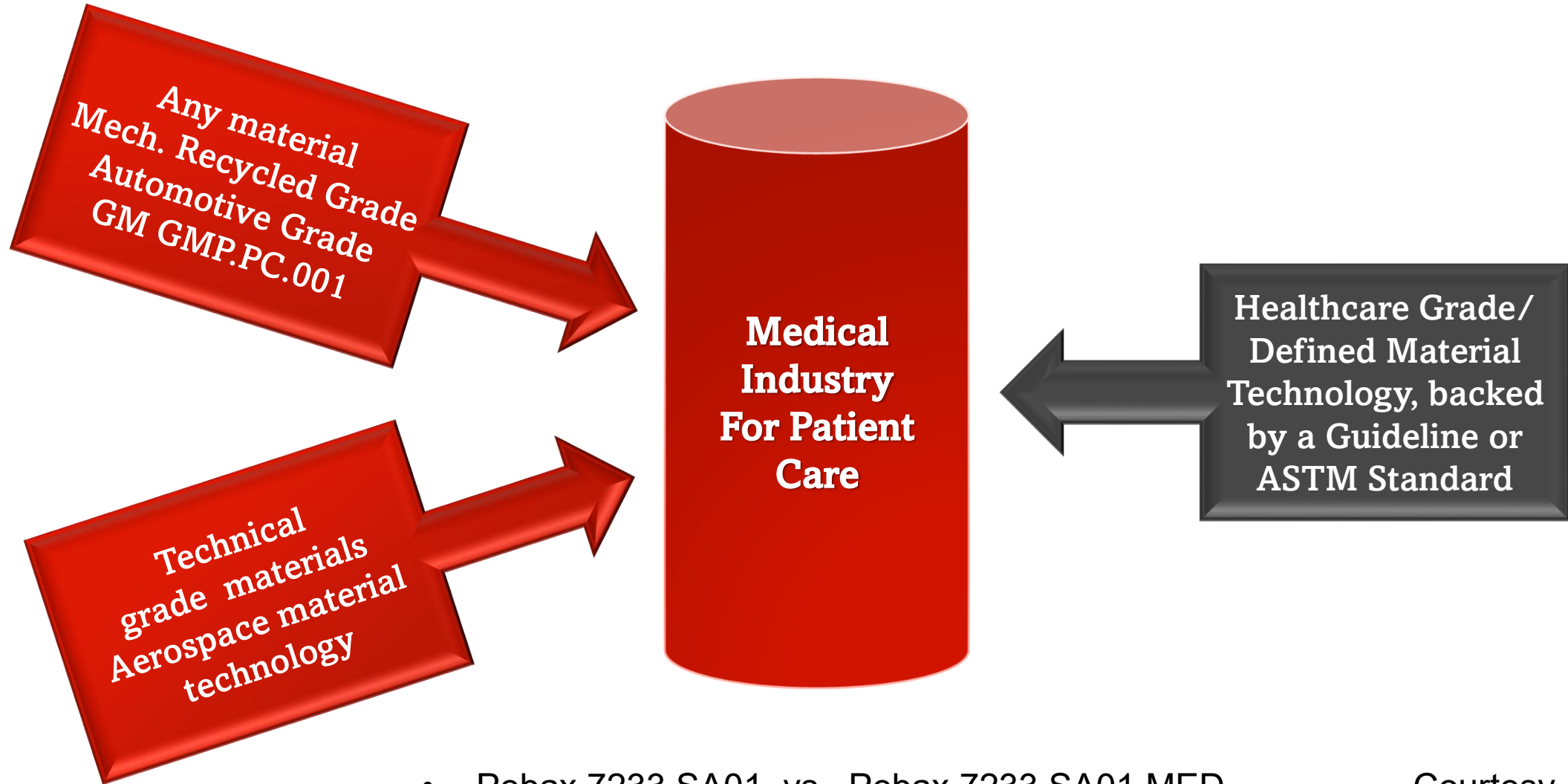
Material supplier  
asking for the  
meaning of  
healthcare grade and  
a standard to ship by?



## End User

Meanwhile the  
doctors & patients are  
waiting.

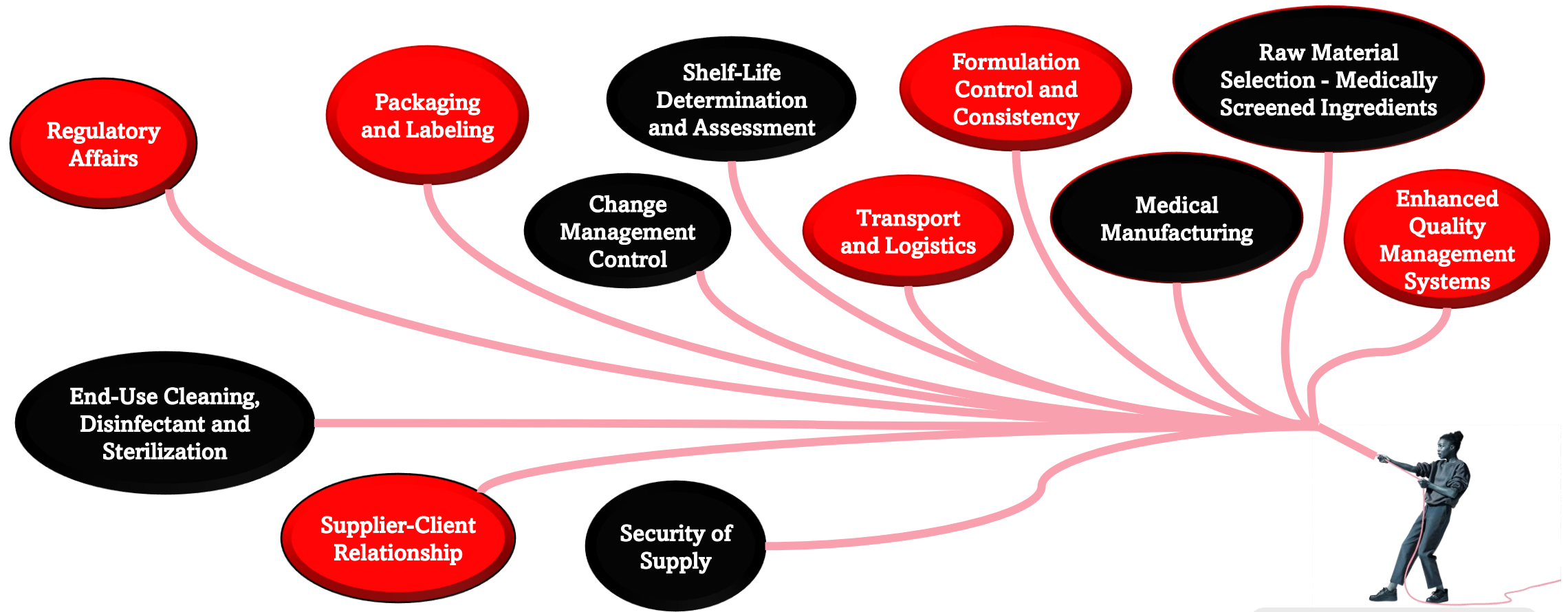
# Our collective mission statement



- Pebax 7233 SA01 vs. Pebax 7233 SA01 MED

Courtesy Arkema

# Basis of our soft guideline medical grade material definition



# Medical grade material designation guide

ASTM F Grade = Medical Grade Metals	Implant Grade
Care Grade	MED = Medical Grade
ChemMed = Medical Compounds	Mevopur = Medical Masterbatch
ColorRx	MT = Medical Technology
Dental Grade	NS = No Substitute Grade
Excipient Grade	ORG = Operating Room Grade
FC = Food Grade	PC = Premium Control
H = Health Care Grade	PC = Pharmaceutical Contact Grade
HC = Health Care	PCG = Pharmacopeia Compliance Grade
HC = Health Care Grade	PG = Premium Grade
Health Care Grade	Premium Grade
Health Care Plus	Pure = Pure Grade
Health Care Unit Grade	RG = Regulated Grade
HMG = Health Management Grade	Rx = Medical or Pharmaceutical Grade
HP = Health Care Policy	SC = Special Control
HP = Health Care Policy Grade	SC = Specialty Grade
HX = Health Care	SC = Sustainable Grade



# The overall context - standardization

## Why



- Provide information for purchasers and suppliers of medical materials to align expectation
- To agree on the essential requirements
- Create a harmonized understanding
- Surprises avoidance

## Who



- Medical polymer manufacturers, toll compounders & purchasers
- Closing the gap in expectation and terminology

## When



- Collective decision after the ASTM standard is released
- Compliance and adaptation strategy
- Reference format on technical data sheets e.g. material conforms to ASTM F4444
- Non-Implantable polymer ASTM F4444 standard compliance

# 2025 MGMC Updates

- Invitation to the upcoming 2026 MGMC Mini-Conference.
  - Additional information to be located on the Consortium website: <https://namgmc.org>

Q&A

Thank you