3rd Annual Medical Grade Material Definition Mini Conference

Journey For MedTech Material Definition and Harmonization

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ETHICON
Johnson & Johnson SURGICAL TECHNOLOGIES

Interconnectivity of Purpose

Why?

No formal definition for medical materials exist – lacks guideline

For decades, the business case did not warrant the need to invest in MedTech materials until now with the introduction of digital and robotic surgery & changing regulations

Material selection made from external data bases designed specifically for automotive & aerospace e.g., Campus, Material Universe, prospector etc.

To meet FDA,MHRA and EUMDR requirements, you either hit or miss

Simulation analysis (mold flow/Moldex3D) was conducted with characterized data intended automotive /aerospace industry

Medical prototyping built with available automotive materials at the proto-shops/ proto-labs e.g., GMP.PC.002

Material selection focused on physical and functional properties only – biocompatibility was an after thought

APPROVED
ACCEPTED
PENDING
REJECTED

PASSED
UNDER REVIEW
DENIED
FAILED

Agenda

Overview of the Medical Grade definition journey and annual progression

Review summary report from last year's mini-conference

Unveil the New North America MGMC Website

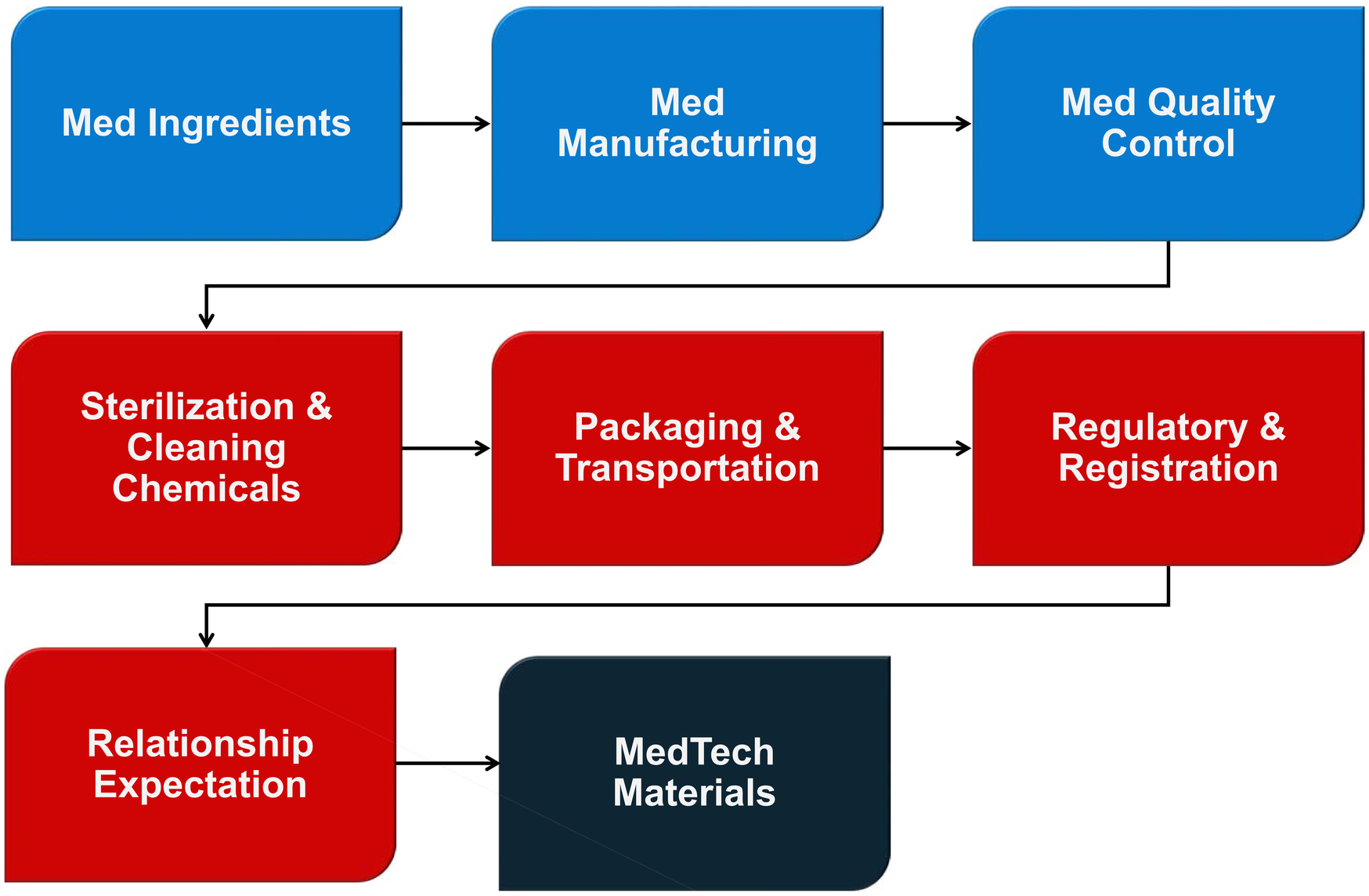
- Review white paper #2
- Review white paper #1
- Discuss OneMD e-Cert
- Review harmonized vendor material use questionnaire

Review breakout session topics

Visit VDI @ K-Show 2022

Conclusion

Medical Grade Material Definition Road Map



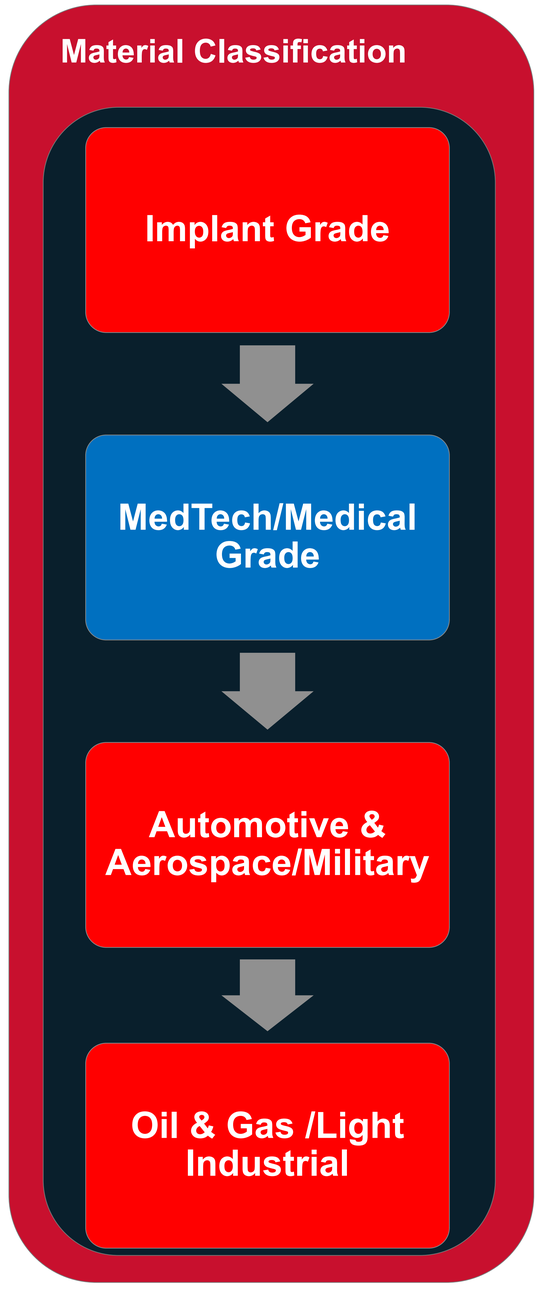
Part I of the conference focused on items in blue boxes
Part II of the conference focused on items in red boxes

Overview of Medical Grade Definition Journey

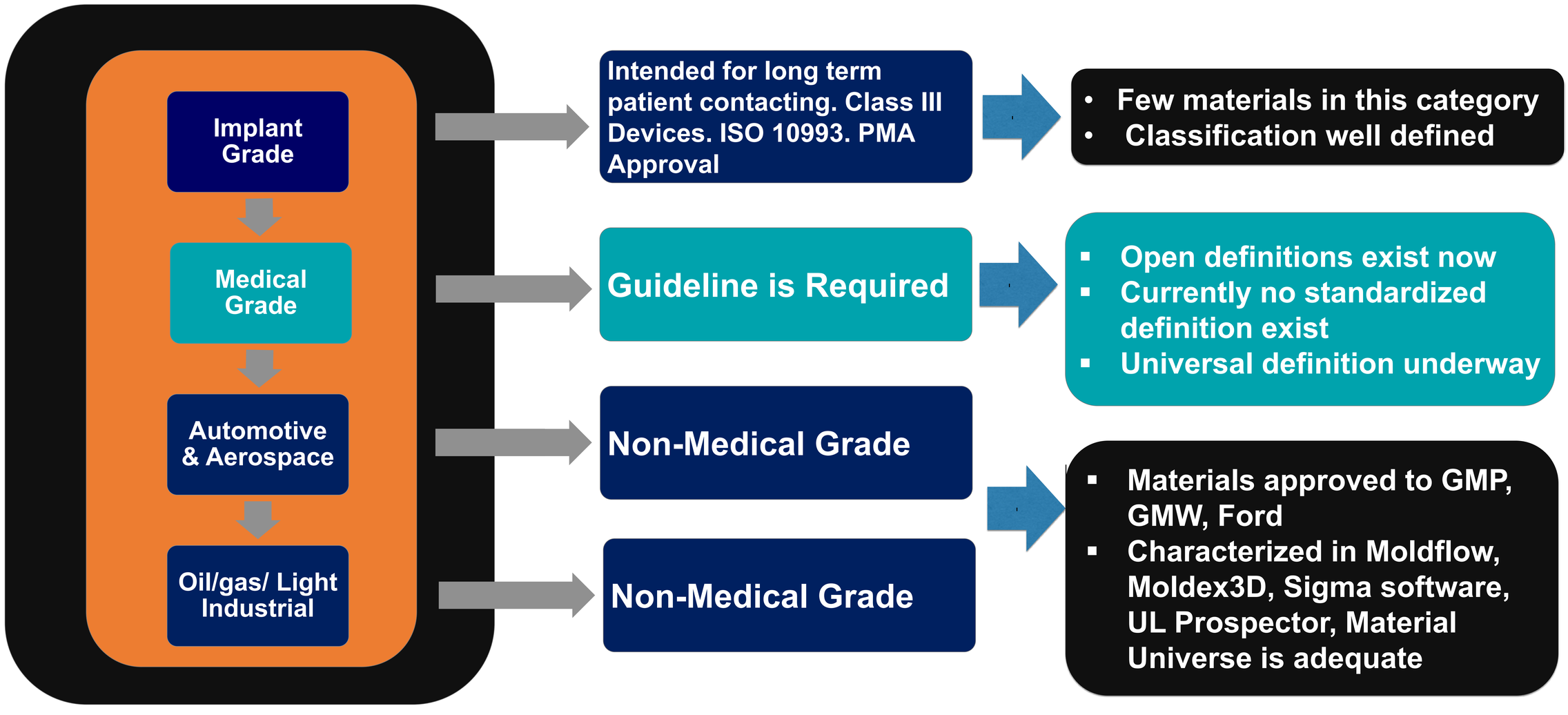
2019 – Mini conference

- Initial call to action presented at the 2017 Medical Design & Manufacturing Conference and Exposition in New York City.

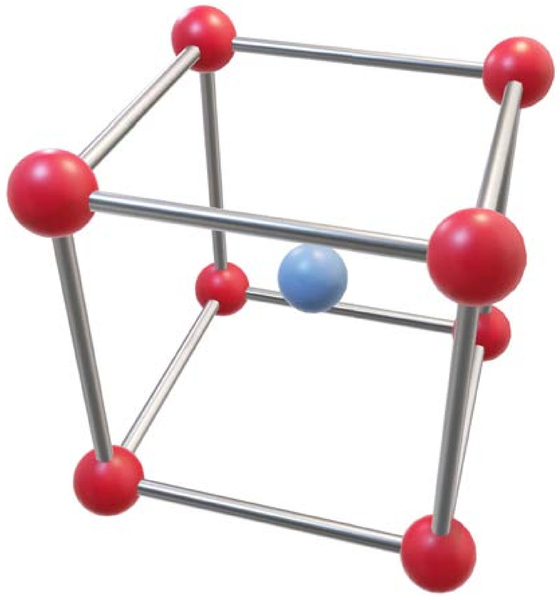
All material aren't the same



Changing regulation driving medtech material management



2022 – Mini Conference



Objectives of the MGMC Mini-Conference for 2022 was to establish a seat for the medtech industry within the portfolio of North American polymer producers.

•Anim J, Torain S. Medical-Grade Material Definition Mini-Conference; Summary Highlights for All North America Consortium Members. Cincinnati: Ethicon, 2022.

Johnson & Johnson MEDTECH
Spec Engineering

Industry wide Effort and Applause

Medical Grade Material Designation Guide

This is a list of various nomenclature/abbreviations which can help identify approved medical grade materials for specific uses.

2023 – Mini Conference Breakout Topics

Group A

Review Medical Grade Material Definition Road map for suggestion/revision

Group B

Discuss strategy for harmonized guideline creation

Group C

Discuss and provide strategy for ASTM creation

Meeting with VDI @ 2022 K-Show in Dusseldorf, Germany

- MGMC to create part II of white paper.
- MGMC to initiate creation of harmonized guideline for review.
- MGMC to lead the conception of strategy for the harmonized ASTM.
- MGMC to issue guideline in both English and Germany.
- May need an ISO version of final product to be created.
- Discuss review /signatories for guideline release

Photo:- MGMC & VDI at Trinseo Booth at K-show

Note:- May need a neutral location for all future meetings.

Conclusion

Current guidelines for polymers are driven predominantly by the automotive, aerospace, and oil and gas industries—offering little or no basis for considering issues that might affect patient safety.

Although raw material suppliers may be responsible for providing vetted grades, finished device manufacturers will remain responsible for ensuring the biological safety of their devices.

Progressive efforts to create such a definition now offer hope for simplified selection and application of such materials worldwide.

But having a validated menu of medical-grade plastics will provide manufacturers with confidence that their devices will pass biocompatibility testing following ISO 10993 or other standards.

This new approach will prevent labeling surprises by reducing the unknown factors related to the selection of materials for healthcare applications.

Careful selection and application of medical-grade materials will minimize potential use of chemicals that could be carcinogenic, mutagenic, or reprotoxic (CMRs), or endocrine disrupting compounds (EDCs).

Launch of North American MGMC Website

Https://namgmc.org

Thank you