Medical Grade Material Definition Mini-Conference & Fair

Breakout Session – Day #1

Medical Grade Definition

August 23rd, 2023

Hosted by JNJ In Collaboration with Vendor Partners

ETHICON
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R&D Materials
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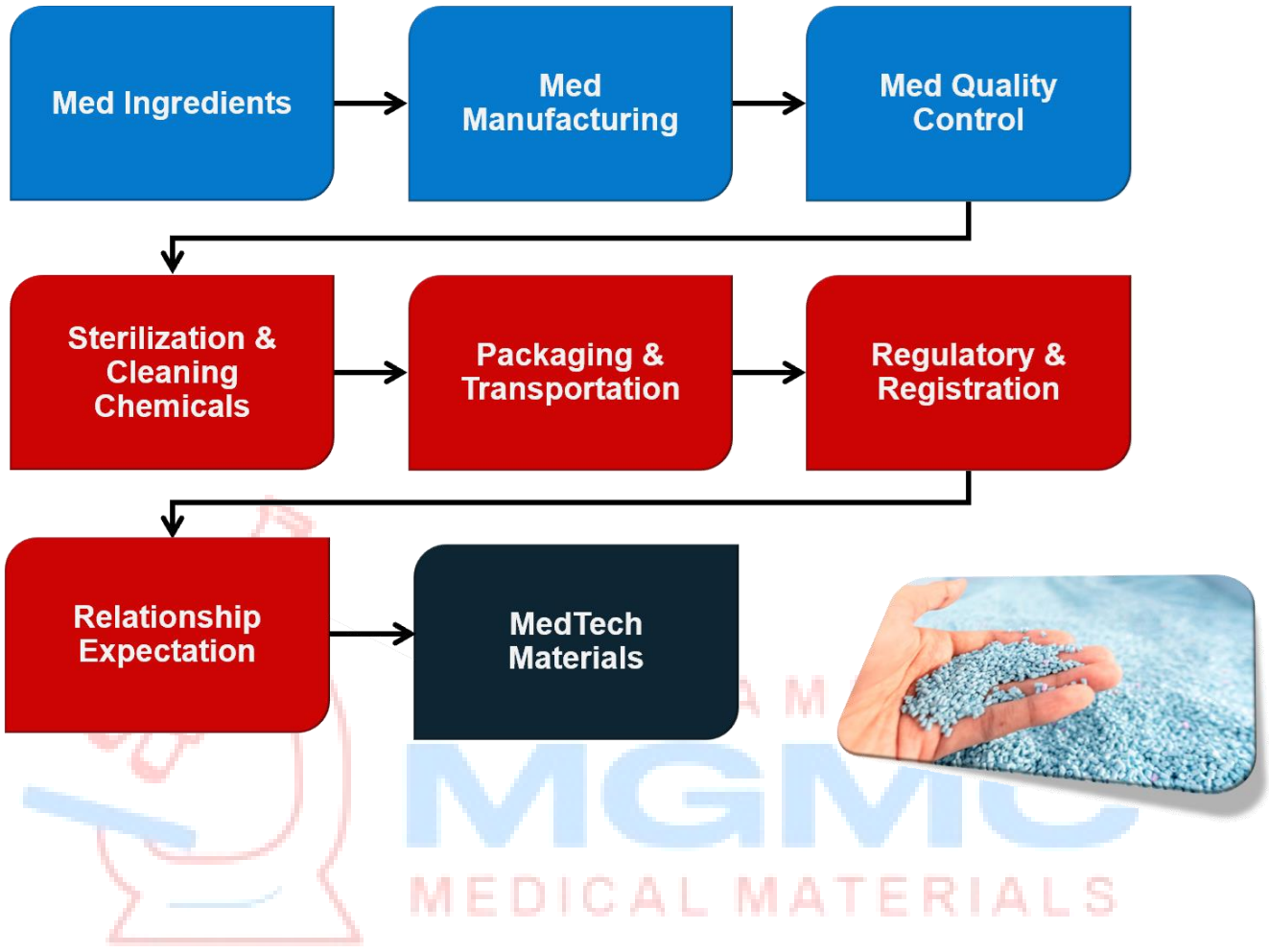
Spec Engineering

Medical Grade Material Definition Road Map



Day#1 Medical Grade Definition Breakout Session

Background:

In the attempt to develop a harmonized definition for medical grade materials, the above road map was developed in 2019. During the same conference, the items in blue were discussed in a breakout section of three different groups. Individual groups further agreed and documented their ideas which was later published in the form of a white paper by Medical Briefs Publication ref NAMGMC.org.

In 2022, attendees at the conference breakout session determined that the scope of their initiative should focus on topics indicated in red on the road map above. The participant deliberated for hours and captured their ideas and documented it in a second white paper published by Medical Briefs Publication to be evaluated as part of the harmonized guideline for defining medical grade materials. ref NAMGMC.org.

In furtherance of that, attendees of the 2023 conference determined that in readiness to develop the North America standard definition guideline, the following topics in Table 1, should be targeted for the breakout section of three (3) groups (1, 2 & 3). Each group further agreed and captured their ideas for consideration in creating the universal harmonized guideline.

Table 1. Medical Grade Definition Breakout Working Group Topics

Group ID	Topic 2023
Group #1	Review Medical Grade material definition road map for suggestion and/ or revisions
Group #2	Discuss strategy for harmonized standard guideline creation
Group #3	Discuss and provide strategy for ASTM Creation

Group #1: Review Medical Grade Material Definition Road map for Suggestion / Revision.

Group #1 made the following suggestions to be added to the two white papers if not fully addressed already. The following below were captured and documented during their deliberation.

i. **For medical grade materials the ingredients should have the following added expectations**
   a. Dispersion – currently very subjective, so how do we minimize subject matter expects (SME) subjectivity?

b. Include 21 CFR pigment/colorant preference for Medtech grade.
c. Determine if food grade biocompatibility testing is an area of interest?
d. Pigment heat resistance – is this value add for injection molding – black speck elimination?
e. Suggest 24 months level of notification of change to be ideal (medical). Is 12 months realistic?

ii. **Partnership (Strategic) Creation for Medical Materials Suppliers**

The team also suggested, the need to build technology partnerships with the following since currently lacking in the industry: Partnership between compounders & OEM SME's

a. White paper should indicate that current sterilization, cleaning & chemical compatibility data/records is inferred from their industrial grade counterpart and may not have been tested on the actual medical grade candidate.
b. White paper should also indicate that the reusable, chemical compatibility data is driven by generic material or chemistry not necessarily on the actual Medical Grade candidates or the complete industrial grade compound.
c. Final suggestion, is to separate contractual requirement from other non-binding expectations.

Group #2: Discuss Strategy for the Harmonized Standard Guideline Creation

The following are the suggestions and thought-provoking questions generated from this group. Harmonized Standard Guideline means, the combination of the NAMGMC Guideline plus the VDI Guideline (German Plastics Group) combined.

a. How to get parties aligned?
b. How do you get into ASTM/ISO process flow?
c. Can we get advice/support from ASTM?

Needed steps:

a. Get buy in from other OEMs/Device manufacturers.
b. Industry groups/regulating body -should they be involved?
c. Need to host next mini conference at a neutral forum to pull other OEMs.
d. May have to adopt ASTM F477 example for sealing suppliers. As they need to show that they meet the standard

Alternative Route:

a. We may have to contact ASTM group to take the current white papers to a guideline status.

b. Or go the GMP route by adapting a new nomenclature for medical grade, pharmaceutical packaging grade, skin contact grade, locked down grade.
    1) Need a smaller group to further work on this throughout the year.
    2) Need chairperson to host virtual working meetings.
    3) Need a smaller group to explore/facilitate a neutral guideline creation.
c. Or SPE to use their platform to pull industry leaders to create the harmonized guideline.
d. Or tap into big labs with SME to provide/help to develop a guideline.

Summary of Group #2 Ideas:

a. We may have to contact SPE to facilitate.
b. Or consider an independent body
c. Pull other OEMs to contribute to create the standard guideline.
d. Auditing of current state may be necessary.
e. Establish revision system to the guideline.
f. Is there a threshold for the CMR for example?
g. Need expansion of the other grades in Part II white paper. Example the lockdown grade, skin contact grade & pharmaceutical packaging grade is missing in the second white paper

Ideas:

a. Need a separate guideline based on use: - Class I /II/III

Group #3. Discuss and Provide Strategy for ASTM Creation

This group thought the way forward is to start the creation of committees and other strategies.

a. May have to consider F04 Committee or F04.11 for next steps.
b. Will have to make content general so that the rest can adapt.
c. Start by pulling together a scope.
d. Need statement – Use the white paper content as statement.

Proposed Timeline for Next Steps – The team also suggested the following as timeline.

a. Nov "2023": Introduce topic to committee.
b. May"2024": Draft scope & Vote to proceed to standard writing.
c. Implant excluded.
d. Determine the "Floor"
    - Critical must have - medical grade.
    - Level of patient contact as a criterion to be included in the definition.

Scope/Goal: - is to create an ASTM Standard to define "medical grade".

Need Highlights:

a. Based on Class or patient contact
b. Min. COA guidelines to be included
c. Reference White paper for "Why"

Additional recommendation was to look at metal standard for Implant to get flavor of what to include.

Event in Photos

Review of road map

MedTech Material Application Presentation

Regulatory influence on med-materials

Progress report

MedTech material fair

Engineering-vendor consultation

Vendor Partners