

Creative Catalyst: Summary of 2023 Breakout Session Ideation

**4th Annual Medical Grade Material Definition
Mini Conference**

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Day #1: Medical Grade Definition Breakout Session

Our Goal:

- Review the two MGMC white papers published in 2019 and 2022 respectively for any missing content towards our mission statement.
- Review the initial road map concerning the task of creating and releasing a soft consolidated guideline.
- Provide a strategy for the next steps toward developing a standard ASTM definition for non-implantable materials.



Breakout Session Topics – 2023 Conference

Group #1

**Review
medical grade
material
definition
roadmap for
suggestions /
revisions**

Group #2

**Strategy for
harmonized
standard
guideline
creation**

Group #3

**Develop a
strategy for
ASTM standard
creation**

Group #1: Review Medical Grade Material Definition Roadmap for Suggestions/Revisions

- Need to address subjectivity in dispersion assessment.
- Suggested separating contractual requirements from other expectations.
- Emphasized strategic partnerships between compounders and OEM SMEs.
- Preferred standards: 21 CFR pigment/colorant and potential interest in food-grade biocompatibility testing.
- Discussion on pigment heat resistance for injection molding and realistic notification of change timelines (24 months ideal, 12 months questioned).
- Inclusion of current practices, i.e. infer data from industrial grades, lacking specific testing on medical grade candidates.

Group #2: Suggest Strategy for Harmonized Standard Guideline Creation

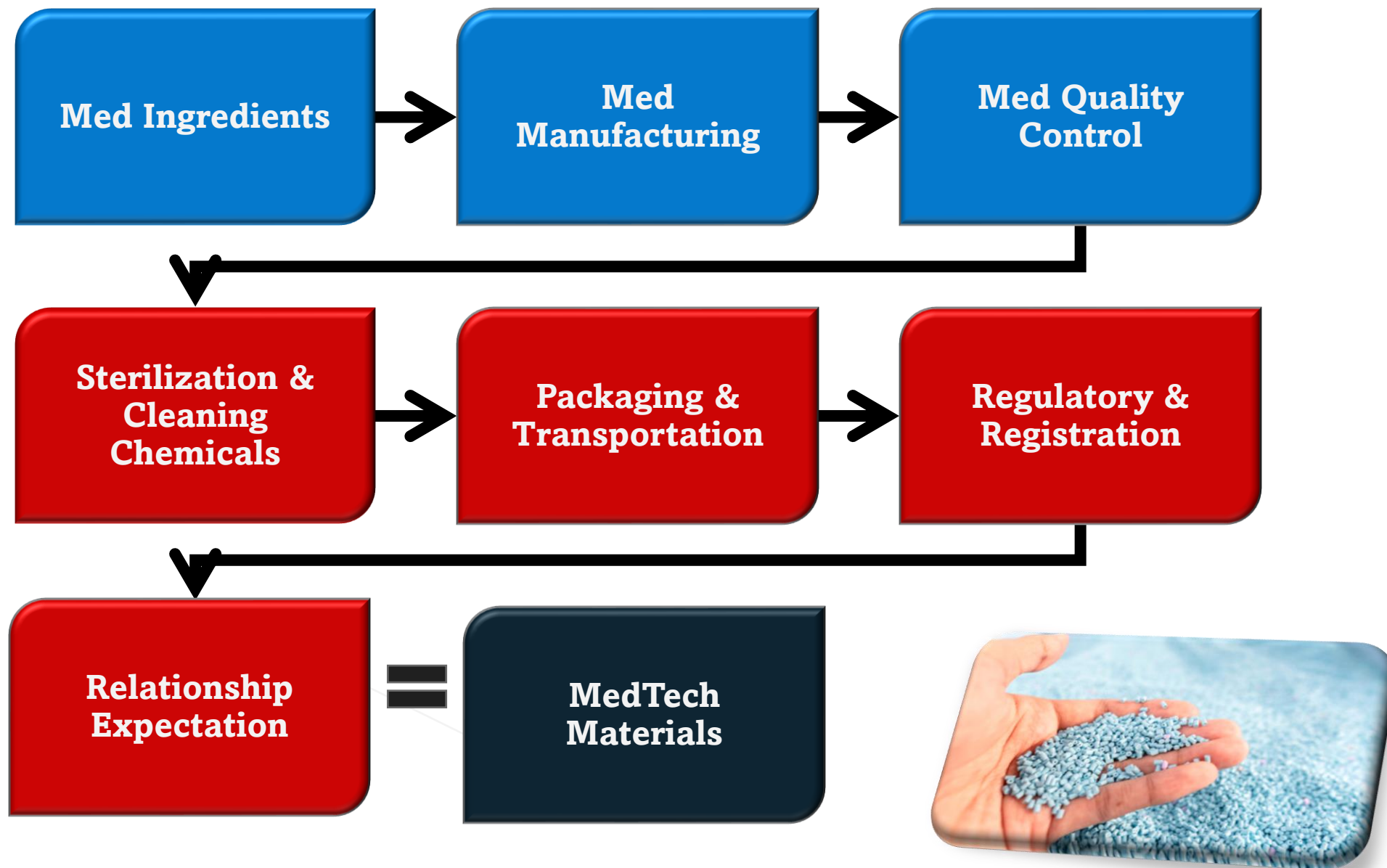
- Focused on aligning parties and integrating processes into ASTM/ISO.
- Emphasized the need for buy-in from OEMs and the involvement of industry groups and regulatory bodies.
- Proposed neutral forums for discussions and adoption of existing standards (e.g., ASTM F477).
- Discussed creating guidelines via alternative routes: ASTM, GMP, SPE, or collaborations with large labs.
- Highlighted the necessity of auditing current states and establishing a revision system.
- Suggested separate guidelines based on use class (Class I/II/III) and expanding grades in white papers (e.g., lockdown, skin contact, pharmaceutical packaging).

Group #3: Development of a strategy for ASTM Standard Creation

- Proposed forming committees (e.g., F04 or F04.11) to draft a generalizable scope.
- Suggested using white paper content as a statement and timeline milestones.
- November 2023: Introduce the topic to the committee.
- May 2024: Draft scope and vote to proceed with standard writing.
- Excluded implants and proposed criteria based on patient contact.
- Recommended referencing metal standards for implant materials.

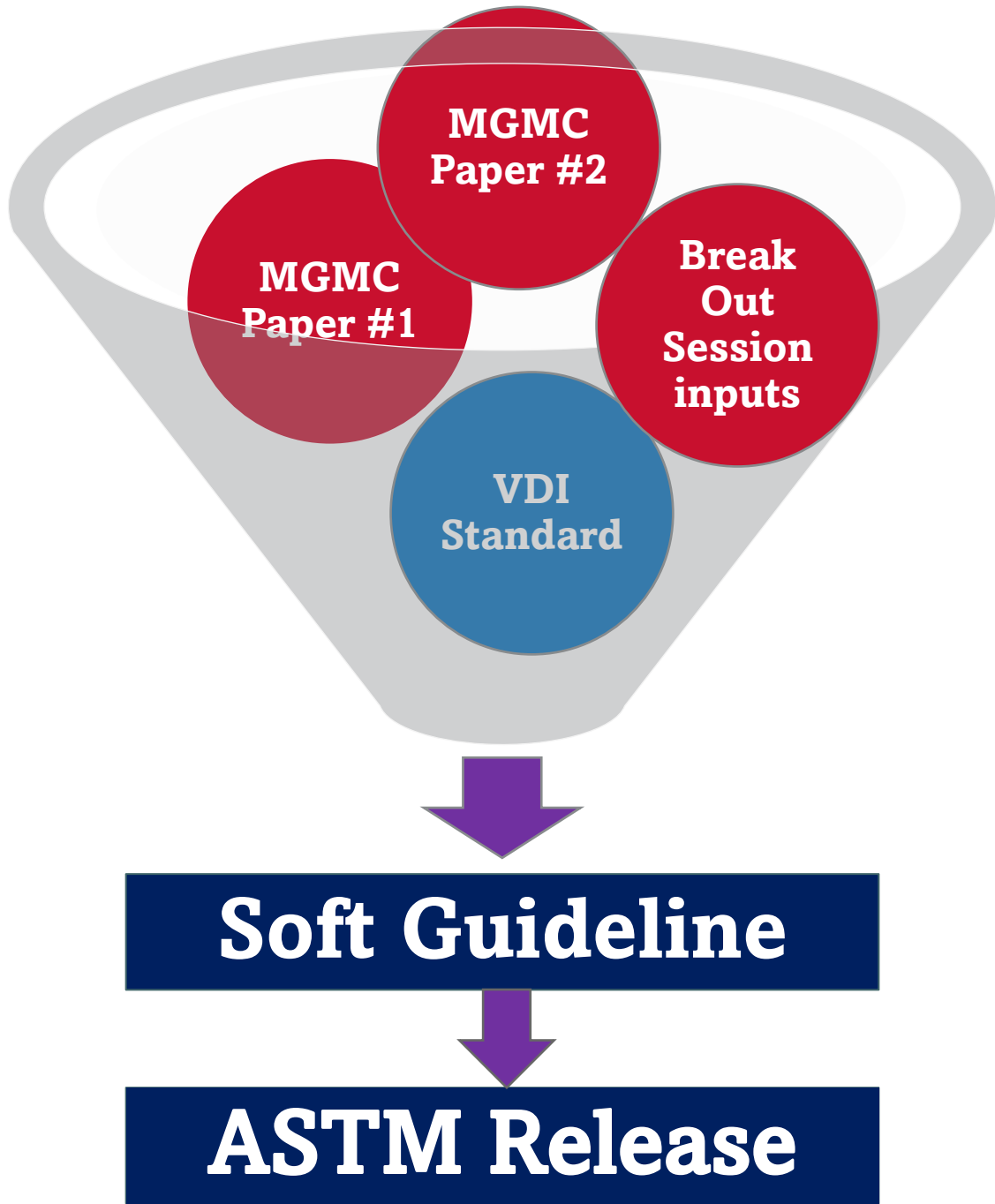


Original Medical Grade Material Definition Road Map

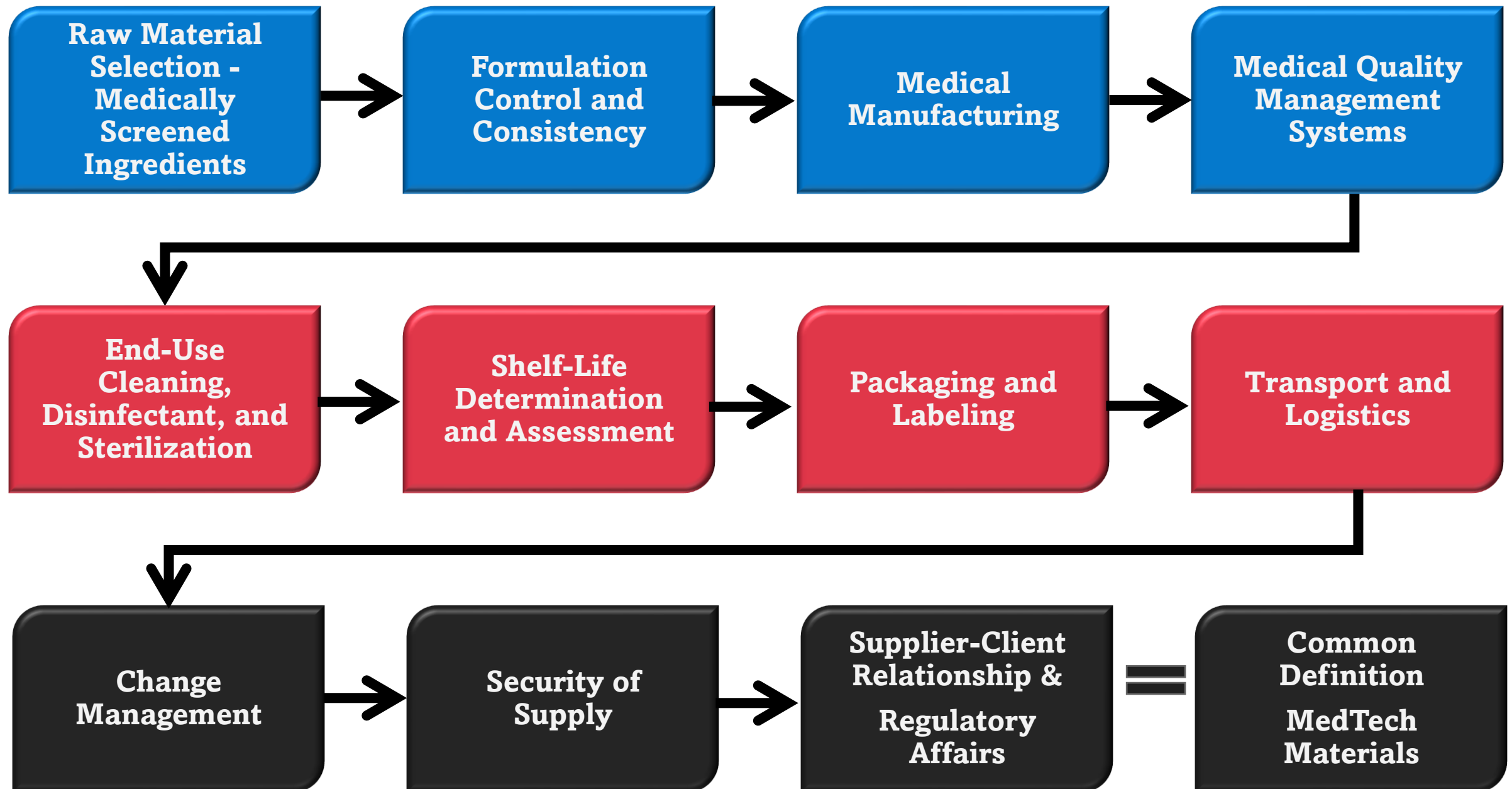


Part I of the conference focused on items in blue boxes
Part II of the conference focused on items in red boxes

Blueprint



Revised Road Map for Next Steps



Merits & Next Steps

This summary highlights the key points and suggestions from the breakout sessions for the following purposes;

1. Incorporate into the development of the soft guideline definition for medical-grade materials.
2. Provide a holistic roadmap for defining ASTM criteria and classification of medical-grade polymers for Non-Implantable Applications.



Thank you

