J&J MedTech
OneMDSpecEngineering

Soft Guideline for the Classification of Medical-Grade Polymers Used in Non-implantable Applications

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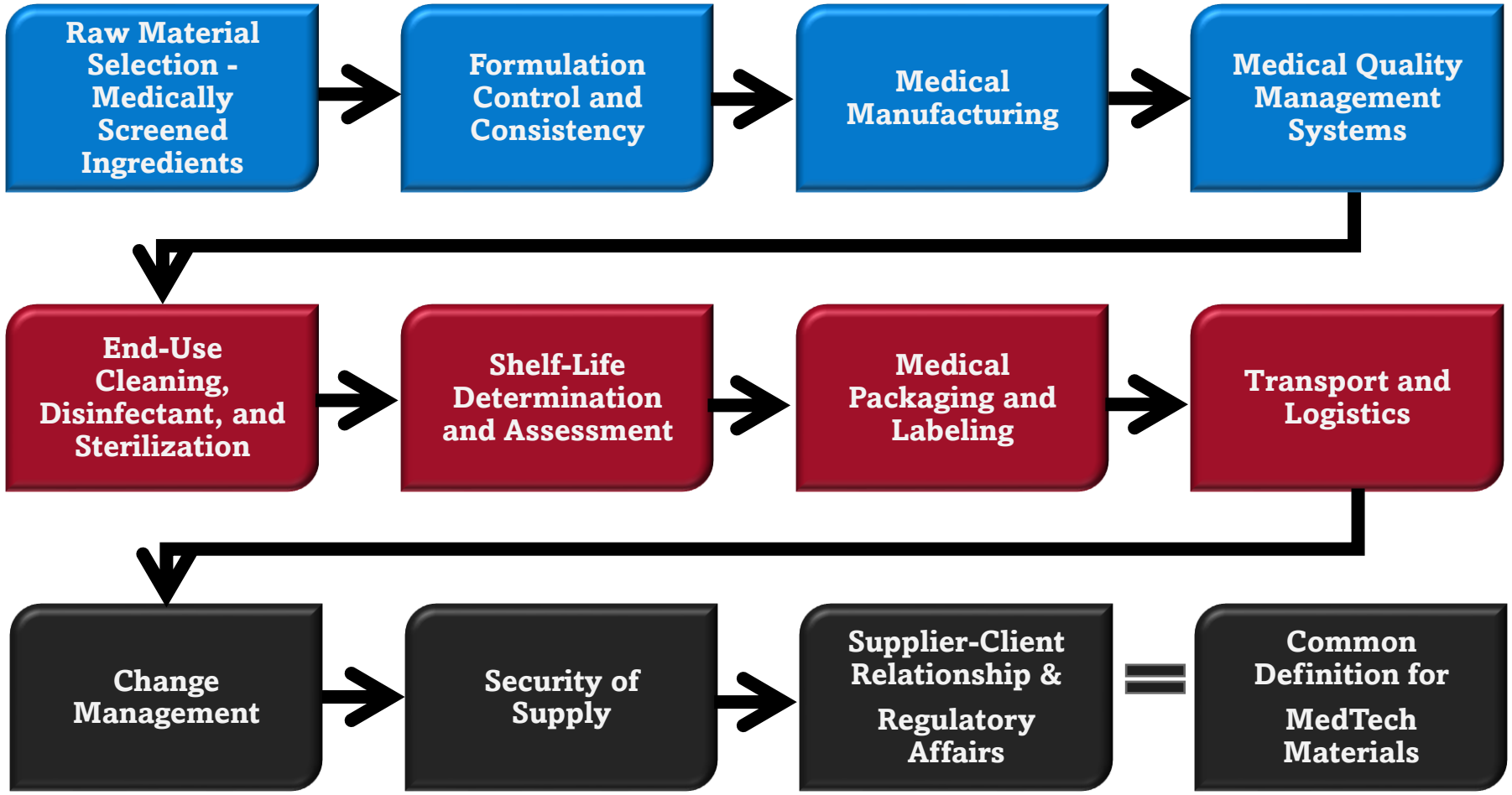
Revised Road Map for Next Steps for Soft Guideline



Introduction

- **Starting Point:** Conduct an overview of existent MGMC white papers, breakout session notes, and VDI guidelines
- **Purpose:** To establish an international standard for medical-grade materials
- **Goals:** Harmonize regional differences and create a consolidated document

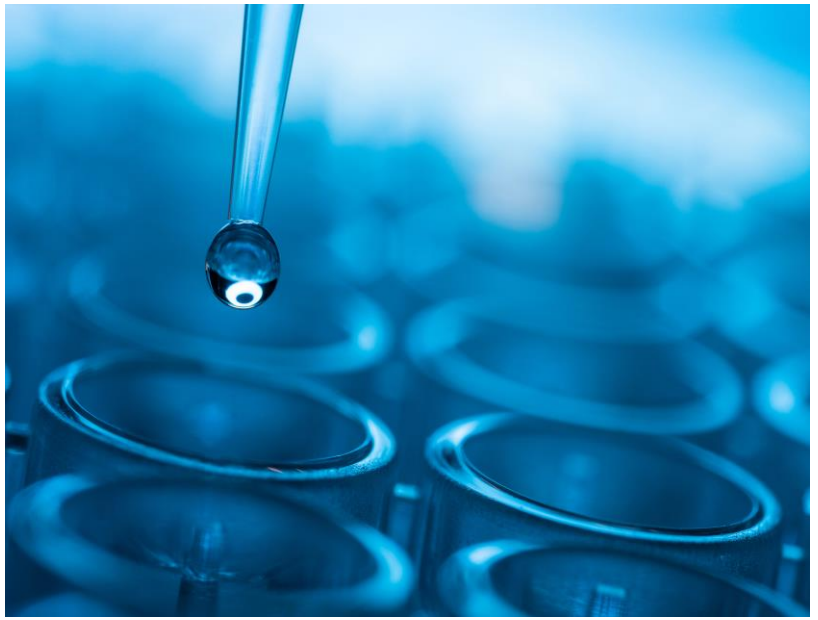
Terms and Operational Definitions

- Introduction to key terms and definitions was captured
- Highlight the importance of understanding these terms
- Examples: Client, Distributor, End-user, Manufacturer, Supplier etc.

Global Regulatory Requirements

For this section, a review of the regulatory requirements of VDI and MGMC shows comparable expectations.

- Regulatory requirements of medical device manufacturers were reviewed in both cases
- Evaluated the importance of regulatory compliance for raw material suppliers looking for any differences
- **Key points:** Testing, reporting, and audits for both VDI and MGMC converged



Medical-Grade Ingredients

- When it comes to the criteria for defining medical-grade ingredients, commonalities, and differences were noted
- VDI vs. MGMC approaches point to the following,
- **Testing requirements:** Biological, chemical, physical, and technical testing and references differ for medical grade, pharmaceutical, skin contact, and lock downgrade per MGMC.

Consistency of Formulations

- Under this criteria,
  - Both VDI and MGMC recommendations converge
- **Key elements to document**: Composition, sources, specifications, and process description

Manufacturing Processes

The soft guideline focuses on minimum requirements for medical-grade/pharmaceutical, lockdown grade plastics manufacturing

- VDI recommendations stresses on the manufacturing process and changes
- MGMC has additional criteria for manufacturing processes to be FDA complaint

Security of Supply

- VDI guidelines do ensure material supply through other means e.g., alternative plant operations and supplier-guaranteed agreements for up to 2 years.
- MGMC has mandatory requirements for supplier notifications, change management/ control, and last-time buy opportunities.
  - Also emphasizes the importance of long-term supply assurance and avoidance of vendor name changes

Change Management

There are few regional differences., per the VDI, raw materials suppliers must notify manufacturers of any changes to the formulation of their materials unless the changes have no discernible effects.

- VDI's requirements for change management in medical-grade plastics include,
  - Notification of changes: Formulation, manufacturing site, and regulatory status change notification
- MGMC’s added requirement includes, alignment with good manufacturing practices associated with change control

Packaging, Storage, and Logistics

- Risk assessment for packaging, storage, and logistics was consistent between the two standards.
- VDI and MGMC recommendations on handling and storage were similar in scope.
- The importance of proper labeling and transport conditions were also identical.

End-User Cleaning, Disinfection, Sterilization

- Per VDI's guidelines on sterilization testing is the responsibility of the device manufacturer
- MGMC's detailed discussion on compatibility with cleaning agents' stress on the importance of validating sterilization methods by the material supplier as well as the device manufacturer verification was noted as being critical

Supplier-Client Relationships

The importance of coordinated agreements between suppliers and clients was deemed critical by both VDI and MGMC

- Examples of agreements: Quality assurance, technical specifications, and declarations of conformity
- MGMC's focus on detailed material characterization/disclosure per ISO 10993-18, through the use of NDA and secrecy agreement

Quality Management Systems

- VDI's recommends the supplier may usefully assess the conformity of the material with regulatory. However, the manufacturer bears the ultimate responsibility for assessing the conformity of finished products with those requirements.
- MGMC's recommendation for maintaining a quality management system is more direct with ISO9001 as the minimum requirements. But state supplier with ISO13485 shall be given preference

Conclusion

Summary of the guidelines and their importance

- This provides great benefits in establishing a universally adopted standard
- Following the lead of VDI and MGMC, this document serves as a soft guideline, permitting materials suppliers to conduct business across a variety of regional markets
- Future steps for implementation and compliance to be discussed

Q&A

- Open floor for questions and discussions
- A copy of the soft guideline can be found at https://namgmc.org

Thank You