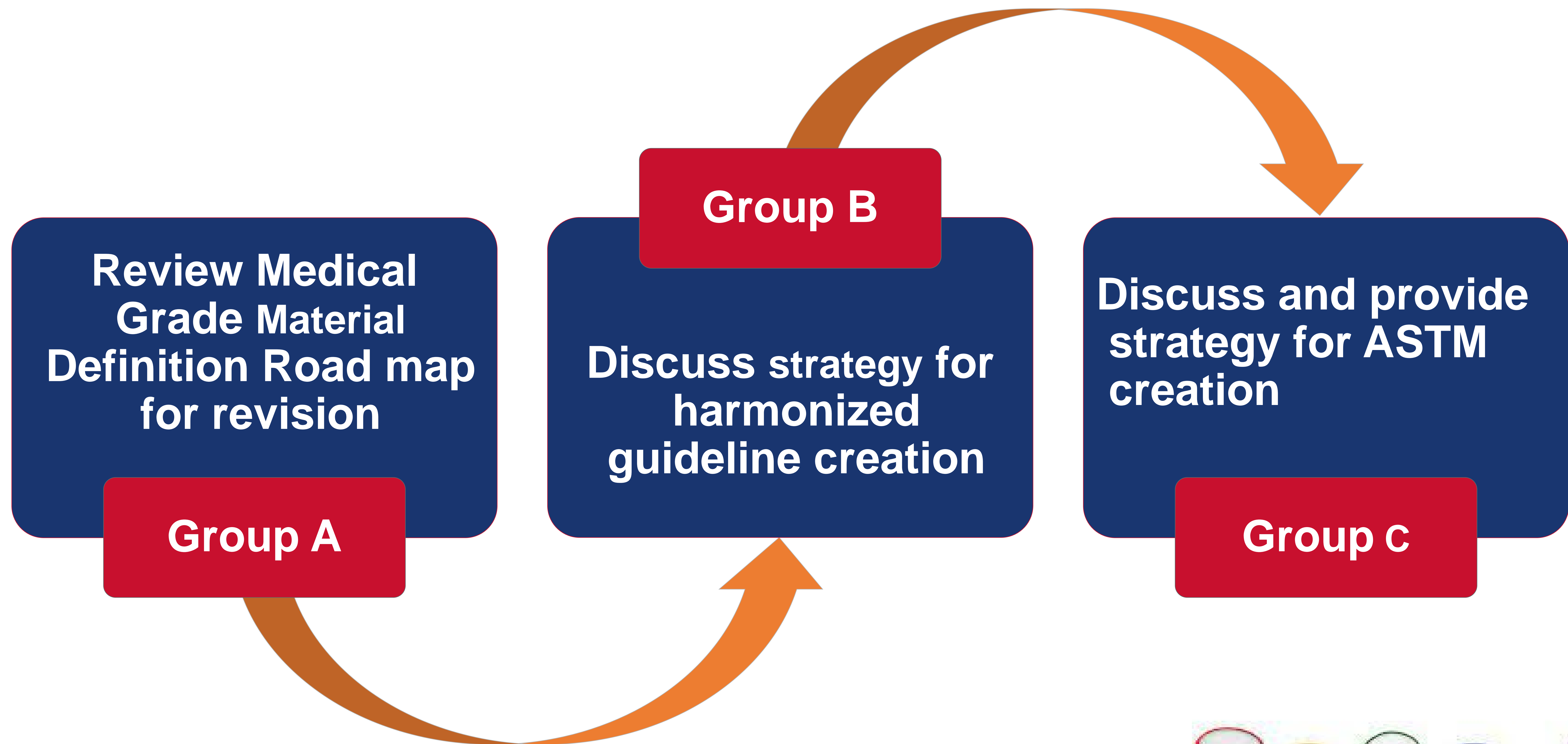


2023 – Mini Conference Breakout Topics



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.
- Considering the many government bodies and voluntary standards organizations relevant to the regulation of materials used in medical products, it is understandable that no unified definition of medical-grade plastics has previously been attempted.
- Progressive efforts to create such a definition now offer hope for simplified selection and application of such materials worldwide.
- Nevertheless, evolving regulations are a moving target, and it should not be expected that a harmonized definition will be easy to achieve.
- 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.
- 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).

Device Registration and Regulatory Requirement

- Material Biocomp that vendor responsibility
- Device safety is the device OEM's responsibility
- Actual testing of the device
- Use of vendor provide chemistry data per ISO 10993-18
- Through positive disclosure or negative disclosure
 - ❖ Positive disclosure we have the secured data base to protect vendor information-GEMS
 - ❖ Team called the DC&G Team that has access to the secured data base with a key lead
 - ❖ Ethicon DC&G is responsible for contacting applicable vendors for this critical activities