ADVANTAGES OF MEDICAL POLYMERS

COMMERCIAL / INDUSTRIAL MATERIAL

Formulation Control

- Changes to product or process could be made unilaterally at any time.
- Raw material substitutions could be made without prior authorization.

Change Management

- No notification of change whatsoever.
- Changes to product or process can be implemented immediately and without prior notice.
- Limited or no options to manage the change.

Regulatory Support

- No regulatory master file with the FDA.
- No biocompatibility, USP Class VI or ISO 10993 testing.
- RoHS, Latex-free, BPA-free, conflict mineral free, etc. certification statements.
- Express policy by material suppliers prohibiting the use of industrial grades for medical applications, raising a medical OEM's potential liability by use in prohibited applications and / or market segments.

MEDICAL MATERIALS

Formulation Control

- No change agreements for formulation stability, including process changes.
- No raw material changes or substitutions allowed unless authorized.

Change Management

- Notification of change minimum 12-36 months ahead of time should a change be necessary.
- Information provided about the type of change, the timing of the change and options to manage the change, such as an end-of-life buy.

Regulatory Support

- FDA DMF (Drug Master File) containing all data necessary to characterize the material, including specific formulation information available to FDA reviewers.
- Biocompatibility certification and USP Class VI and / or ISO 10993 certification statements for Cytotoxicity, Sensitivity and Irritation at a minimum.
- RoHS, Latex-free, BPA-free, conflict mineral free, etc. certification statements.

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