

JNJ Medical Grade Resin Definition Mini-Conference

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Ethicon
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Current Identifies for Medical Grade Materials

- “Care Grade”
- “Dental Grade”
- “Health Care Grade”
- “Health Care Plus”
- “Implant Grade”
- FC – Food Contact Grade
- H – Health Care Grade
- HC – Health Care Grade
- HP – Health Care Policy Grade
- HU – Health Care Unit
- MED – Medical Grade
- MT – Medical Technology
- NS – Non Sub Grade
- PC – Premium Care
- Rx – Medical or Pharmaceutical Grade
- Pure – Pure Grade
- SC – Sustainable Grade
- SC – Specialty Grade
- SK – Skin Contact Grade



Courtesy of Vendor Product Data Sheets

Purpose

- Initial attempts to hear from suppliers relative to work done.
- Harmonies our definition around Medical and Locked down grade.
- Ultimately come up with a governance

JNJ Position

(a)	Provide biocompatible resin according to ISO 10993 standard
(b)	Manufacture and provide resin according to USP Class VI Methods
(c)	Change management to GMP-principles
(d)	Polymer and additives (fillers, pigments, etc.) compliance to FDA and EU requirements
(e)	Animal and latex free composition for polymer and colorants
(f)	Long term supply assurance without change of formulation (formulation lock)
(g)	No Substitute – single sourced base materials without customer notification
(h)	No Substitute – single sourced colorants & additives without customer notification
(i)	Expanded certificate of inspection or analysis (COA)
(j)	Contractual agreed notification of change e.g. 1,2 years etc.
(k)	Individual analytical test per lot/delivery (purity control) where appropriate
(l)	FDA MAF/DMF master file registration for polymer with letter of authorization support for device submission
(m)	Formula that is heavy metal- free chemistry

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JNJ Position

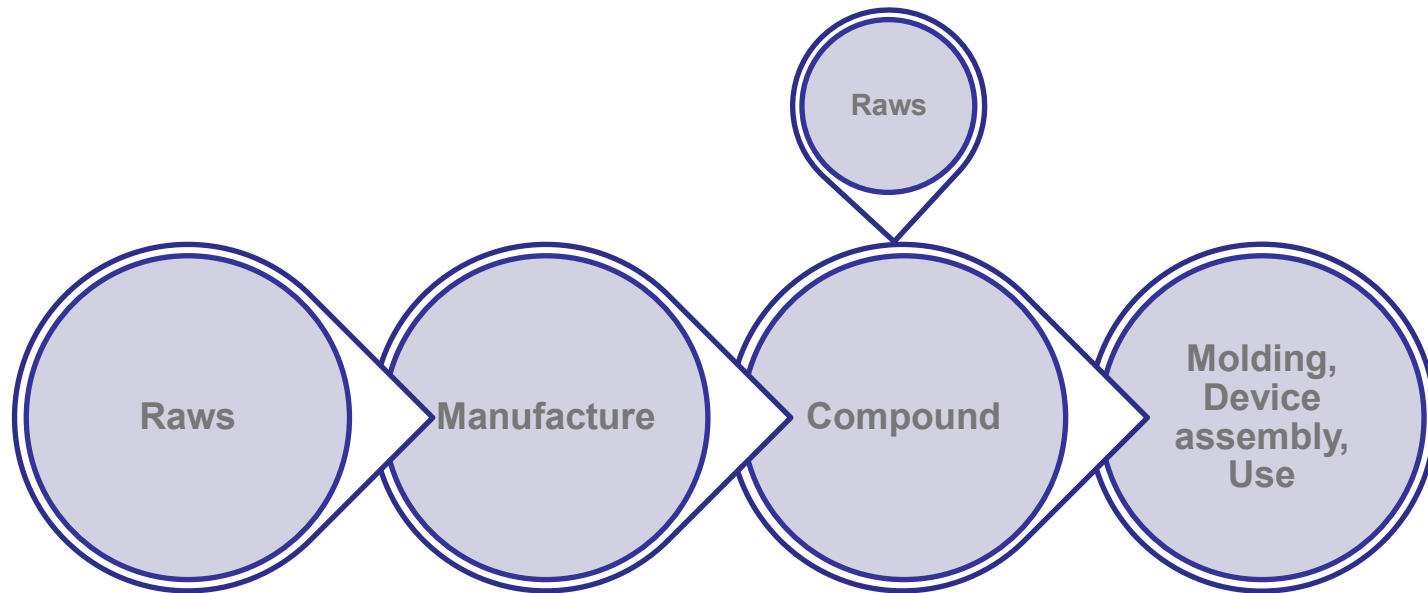
- Formula that is heavy metal- free chemistry
- Change management to GMP-principles
- Manufacture and provide resin according to USP Class VI Methods
- Provide biocompatic resin according to ISO 10993 standard
- Polymer and additives (fillers, pigments, etc.) compliance to FDA and EU requirements
- Latex free composition for polymer and colorants
- Animal derivative free composition for polymer and colorants
- FDA MAF/DMF master file registration for polymer with letter of authorization support for device submission
- Long term supply assurance without change of formulation (formulation lock)
- Contractual agreed notification of change e.g. 1,2 years etc.
- No Substitute – single sourced colorants & additives without customer notification
- Expanded certificate of inspection or analysis (COA)
- Individual analytical test per lot/delivery (purity control) where appropriate



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Resin Supply Chain



- Risk occurs at multiple points for numerous causes
- Short term disruption vs. Obsolescence
- Lengthy, difficult, costly

Our Goal

Maintenance of long term supply is primary goal

- Criticality of resin selection and supplier support
- Change is the enemy

What constitutes a “product change”?

In a word, most anything can be a “product change”.

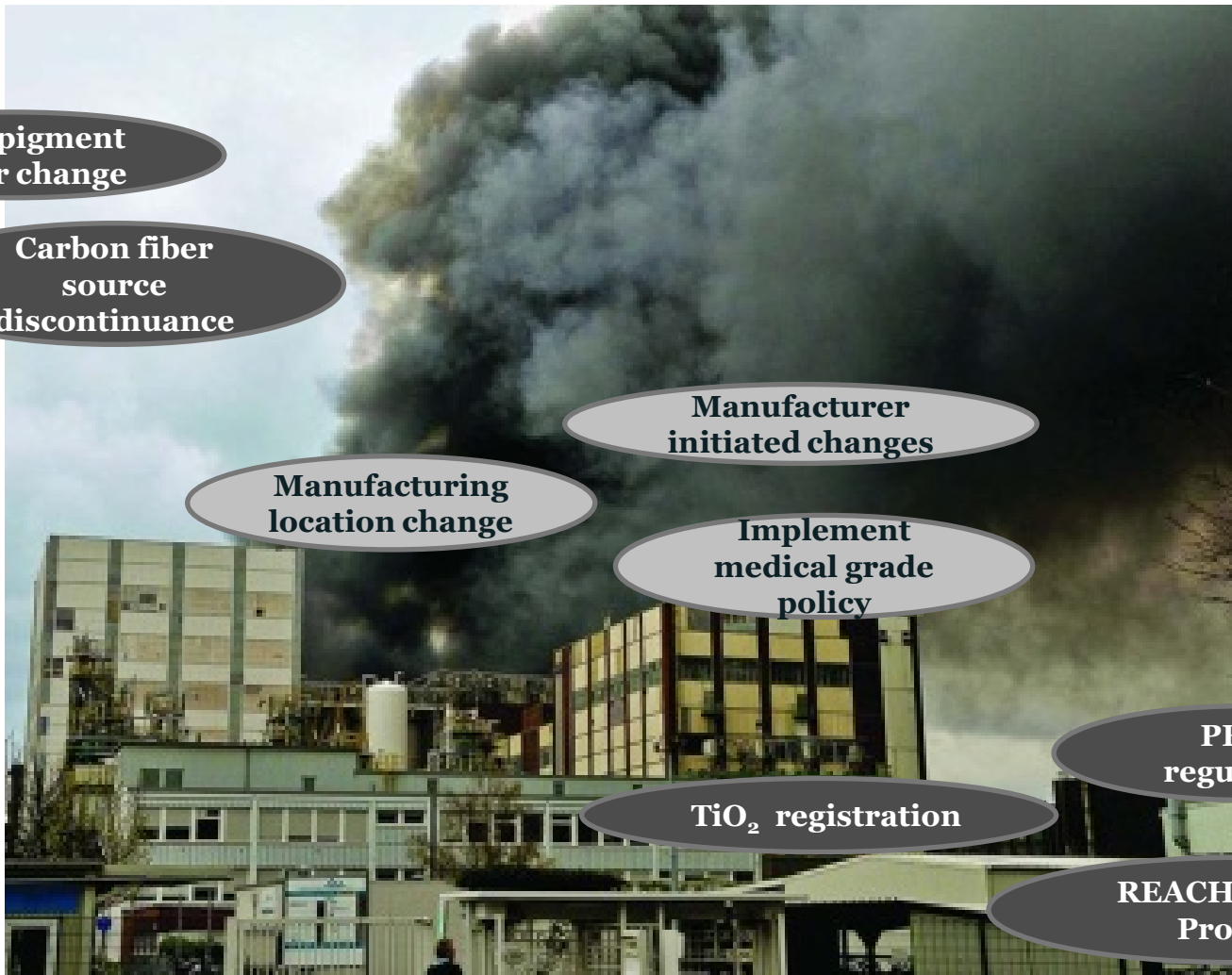
- Manufacturing location
- Alteration of formulation
- Manufacturing process
- Nomenclature
- Anything related to different CAS number

Anatomy of a resin supply disruption

A supply disruption can be short/mid-term and require *little* action

An obsolescence is long term and requires significant time/resources

- Resin supply disruptions tend to occur for one of four reasons
 - Upstream material discontinuance or change
 - Often 4th tier or higher supplier event
 - Resin supplier decision
 - Business decision regarding products and policies
 - Governmental/NGO regulations
 - Stewardship, EHS, MDR
 - Catastrophic event or Force Majeure



**Resin pigment
carrier change**

**Carbon fiber
source
discontinuance**

**Manufacturing
location change**

**Manufacturer
initiated changes**

**Implement
medical grade
policy**

**PFOA
regulation**

TiO₂ registration

**REACH, ROHS,
Prop 65**

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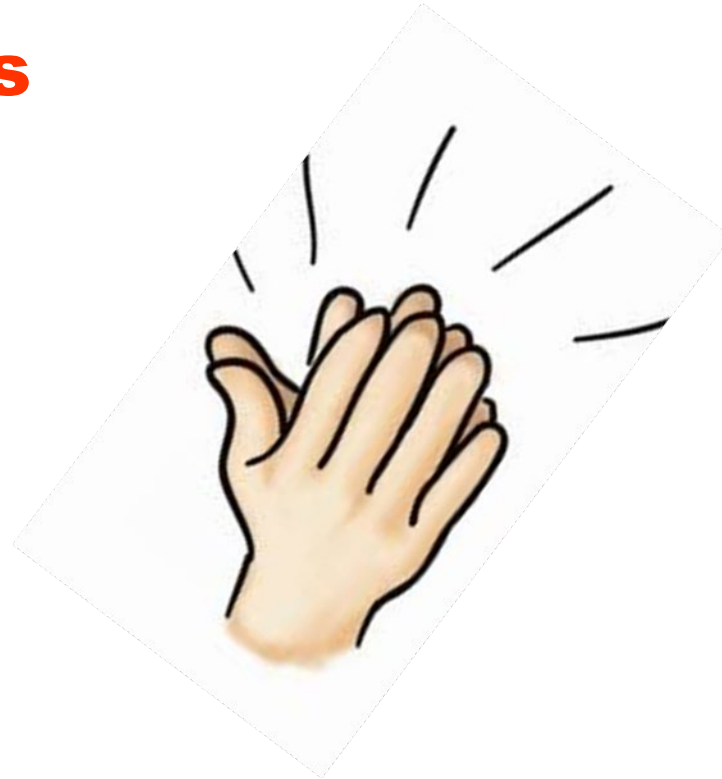
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How can you help?

- Let's turn off the spigot!
 - All new resins specified must be suitable for our medical application
 - Provide medical grade/policy alternatives
- Protect us a best as possible for existing materials
 - Proactive communication of potential changes
 - Notification of change
 - Last time buy opportunities
 - Don't change anything – we love things just the way they are!

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- Amy Doddy



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**Thank You
Q&A**