
Medical Grade Resin Mini-Conference & Material Fair Summary

August 8 2019

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Medical Grade Resin

Mini-Conference

Ethicon Medical Research Institute,

Cincinnati

August 8th, 2019

9:30 AM – 4:30 PM

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Scan here for handy materials designation guide.

Purpose

- ❑ Initial attempts to hear from suppliers relative to work done in defining medical grade materials.
- ❑ Harmonize our definition around “medical” ,“pharmaceutical packaging grade”, “skin contact grade” and “locked down” grade.
- ❑ To create and release a guideline for medical materials as there’s currently no standard.



JNJ Position to Initiate the Discussion - Draft

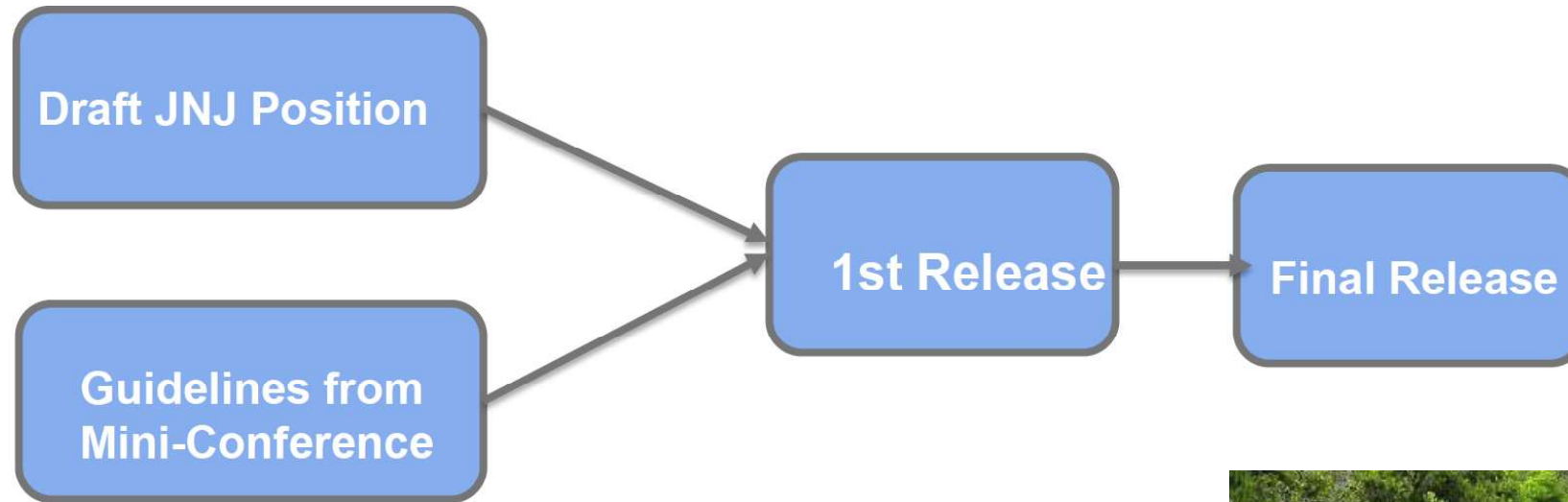
- ☐ Formula that is heavy metal- free chemistry
- ☐ Change management to GMP-principles
- ☐ Manufacture and provide resin according to USP Class VI Methods
- ☐ Provide biocompatic resin according to ISO 10993 standard
- ☐ Polymer and additives (fillers, pigments, etc.) compliance to FDA and EU requirements
- ☐ 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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Medical Grade Material Definition Plan



Agenda

Session 1			Session 2		
1	Introductions	9:30am - 10:00am	8	Lunch Break	12:00noon - 01:00pm
2	Conference Purpose - Chris Johns	10:00am - 10:20am	9	Vendor Presentation 2 – Nusil	01:00pm - 01:20pm
3	Ethicon Product Review – Stephen Torain	10:20am - 10:35am	10	Vendor Presentation 3 – Clariant	01:20pm - 01:40pm
4	Ethicon Product Review – Mark Yunger	10:35am - 11:00am	11	Vendor Presentation 4 – Trinseo	01:40pm - 02:00pm
5	Break	11:00am - 11:05am	12	Break	02:00pm - 02:05pm
6	Ethicon Panel Discussion – Ethicon	11:05am - 11:30am	13	Breakout session 3 – Groups	02:05pm - 02:20pm
7	Vendor Presentation 1 – Foster Corp.	11:30am - 12:00noon	14	Group/ASTM discussion	02:20pm - 03:00pm
			Session 3		
			1	Vendor Technology Display	10:00am – 4:30pm
			2	Net Working	10:00am – 4:30pm

Medical-Grade Definition Conference







Next Steps

Conference Take Aways?

- ❑ Maintenance of long term supply is a primary goal
- ❑ Criticality of resin selection and supplier support
- ❑ Change is an enemy

What are our next steps?

- ❑ Conduct part II of mini conference focusing on universal definition path
- ❑ Create a definition road map as a guide
- ❑ Investigate alternative avenue to allow more vendor participation

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