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Trinseo Medical Grade Resins

Cheryl Weckle, Development Scientist

Trinseo Resins for the Medical Market



CALIBRE™ Polycarbonate Resins



CALIBRE™ MEGARAD™ Polycarbonate Resins



MAGNUM™ ABS Resins



STYRON™ Polystyrene Resins



EMERGE™ Advanced Resins



MEGOL™ TPS-SEBS Compounds

Resin Classifications

- Food Contact Grades



- Skin Contact Grade (SK)



- Medical Grades (MED)





Skin Contact

- ISO 10993
Parts 5 & 10
- Standard NOC
Policy
- ISO 9001 & cGMP
- Trinseo Medical
Policy



Medical Grade

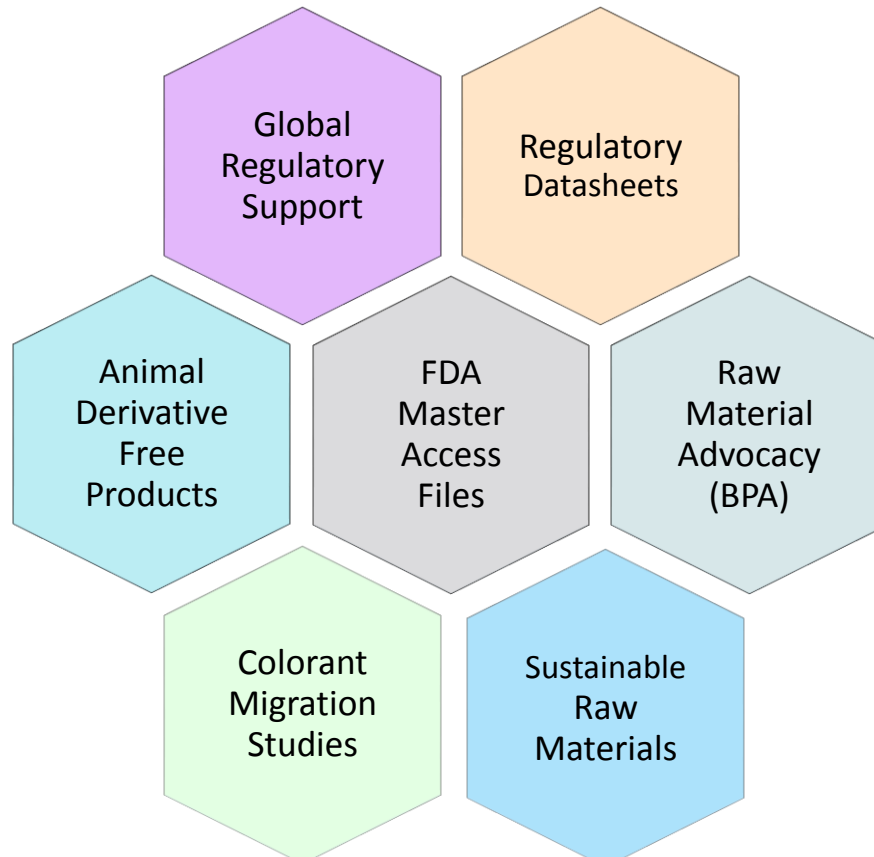
- ISO 10993
Full Testing
- Medical NOC
Policy
- ISO 13485*
& cGMP
- Trinseo Medical
Policy

** Not required*

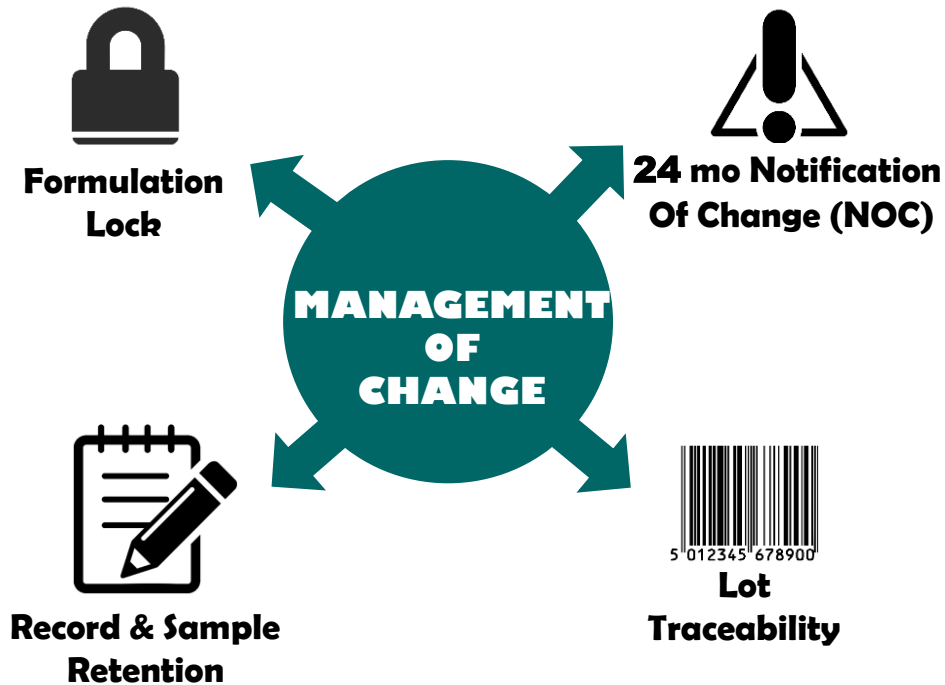
Quality and Regulatory Support for Medical Resins



- Quality Management System ISO13485:2016
 - Design and Development of polymer compounds for medical applications
 - Manufacturing and Compounding facilities in US, Europe, Asia
- Global Product Stewardship & Regulatory Support



Medical Resin Management of Change



Biocompatibility Testing for Medical Resins

ISO 10993

Trinseo Medical Grade resins have been tested to ISO 10993 standards.

Covers various resin grades and color combinations

Testing includes additives, colorants and dyes

Typical Biocompatibility Testing:

TEST	METHOD ^a
In Vitro Hemolysis: Extraction Method	ISO 10993 Part 4/Modified ASTM
In Vitro Hemolysis: Direct Contact Method	ISO 10993 Part 4/Modified ASTM
Cytotoxicity, Elution Method	ISO 10993 Part 5
Muscle Implantation – 1 week	ISO 10993 Part 6
Guinea Pig Maximization Sensitization	ISO 10993 Part 10
Intracutaneous	ISO 10993 Part 10
Systemic Toxicity	ISO 10993 Part 11
Physicochemical Test	USP<661>

^a ISO = International Organization of Standardization 10993: Biological Evaluation of Medical Devices

^a ASTM = American Society of Testing Materials

^a USP = United States Pharmacopeia

