



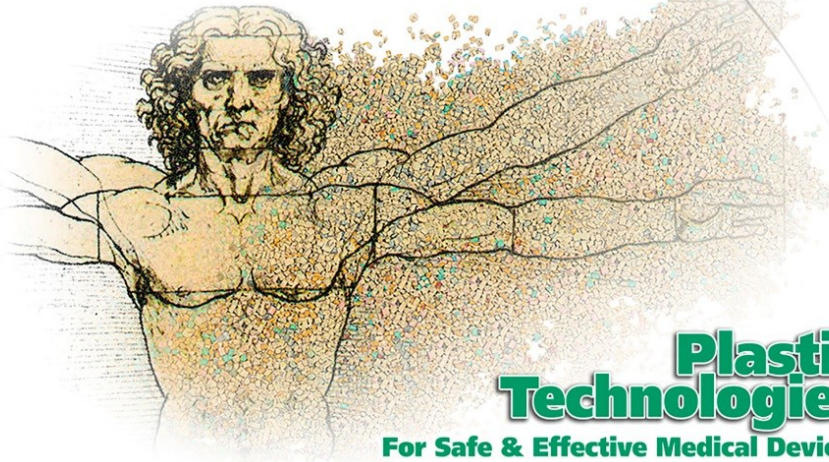
**STRUCTURAL • ELASTOMERS • WEAR • COLOR
CONDUCTIVE • FLAME RETARDANT • FILM/SHEET**



RTP Healthcare Workshop Medical Plastics Overview

Boston Massachusetts

April 2015



**Plastic
Technologies**
For Safe & Effective Medical Devices



What is a “Medical Device”?



RTP Company Confidential



DEVICE REGULATIONS

**1970's to
1980's**

**1980's to mid
1990's**

**Mid 1990's
& still developing**

2014 and Beyond

**FDA G-87-1
Tripartite
Guidance**

**USP Class VI
Biocompatibility
for bodily fluid contact**

**ISO 10993
International
harmonization
of biocompatibility**

**ISO 10993
Part 18
Reduced Animal Testing
Refinement**

USP Class VI, EP, JP testing –still accepted for raw materials but not finished devices.

1. Acute systemic toxicity
2. Intracutaneous toxicity
3. Short term implantation test

ISO 10993 testing –required for finished, molded and assembled devices.

- 26 biologic tests based on device function
- May use different test methods than USP
- Added specialty tests and other guidance

RTP Company has performed ISO 10993 testing on many compounds for Color, Conductive, Elastomers and others.



US FDA Regulatory Goals

- Medical devices in the USA are regulated by the Center for Device and Radiological Health (CDRH) which is a department within the FDA (Food & Drug Administration).
- CDRH Goals
- Approval Name: 510(k)
- Guidance: ISO 10993



GLOBAL REGULATORY BODIES

Europe
Medical devices are regulated by the European Commission.

Overriding Goal: To establish reasonable assurance of the **safety of medical devices**

Guidance: ISO 10993

Approval Name: CE Mark

Japan
Medical devices are regulated by the PMDA – Pharmaceuticals & Medical Device Agency.

Overriding Goal: To protect the public health by assuring **safety, efficacy and quality of pharmaceuticals and medical devices.**

Guidance: ISO 10993

Approval Name: RCB – Registered Certification Body





REGULATORY WEB SITES

All classifications go from least to most risk.

- USA – Class I, II and III medical devices
 - <http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/classifyyourdevice/default.htm>
- Europe - Class I, IIa, IIb and III medical devices
 - http://ec.europa.eu/consumers/sectors/medical-devices/files/meddev/2_4_1_rev_9_classification_en.pdf
- Japan – Class I, II, III, IV medical devices
 - <http://www.pmda.go.jp/english/>
- China – Class I, II and III medical devices
 - <http://eng.sfda.gov.cn/WS03/CL0768/61643.html>

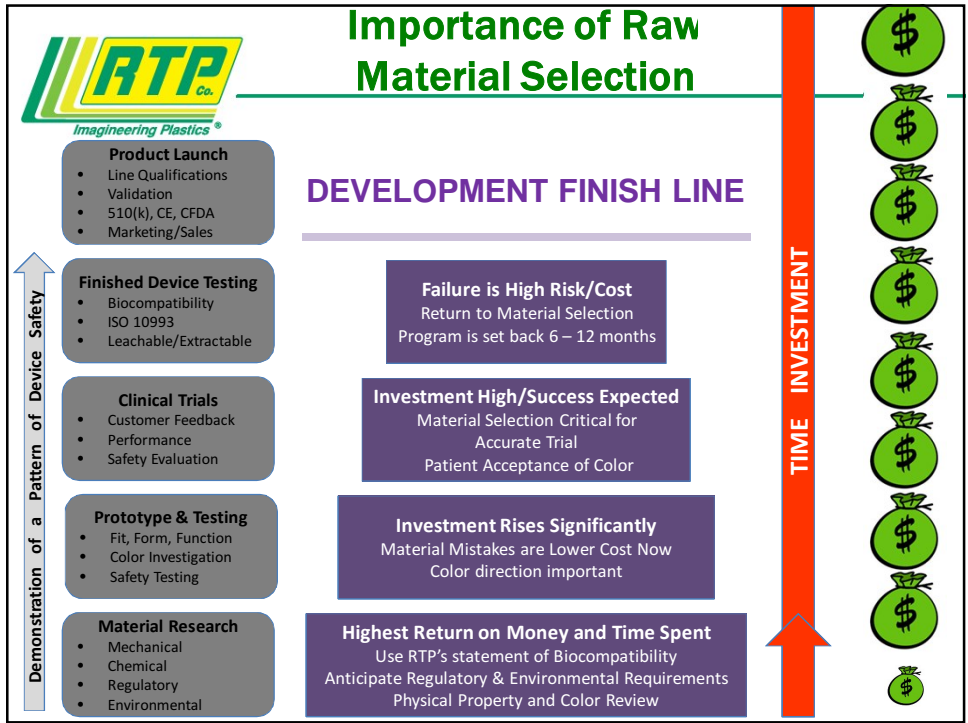


Other Healthcare Applications

Some applications fall into the healthcare category but are not regulated like a medical device.

- Beds, stretchers and wheel chairs
- Diagnostic equipment
- Electronic cigarettes
- Some dental devices
- Diagnostic consumables like pipettes
- Others





RTP Approach to Medical Devices

Capabilities • Formulations • Services

RTP HEALTHCARE

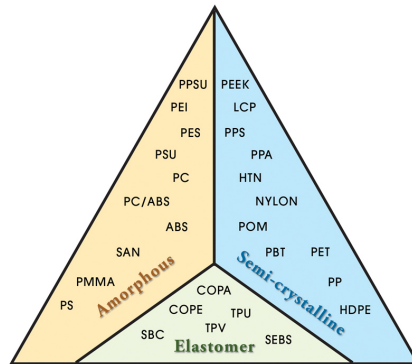


RTP PROFILE

- RTP Company is an **independent**, privately owned compounder
- Global manufacturing and engineering support
- Worldwide sales representation/distribution
- Established in 1982
- 1300+ employees
- \$450+ million annual sales



MEDICAL MATERIALS EXPERTISE



PLASTIC TECHNOLOGIES

| | | | | | |
|-------|------------|------------|-----------------|-----------------|-----------|
| Color | Structural | Conductive | Friction & Wear | Flame Retardant | Elastomer |
|-------|------------|------------|-----------------|-----------------|-----------|

MEDICAL PORTFOLIO

| | | | | | |
|--------------------------|-------------------|----------------------|-------------------------|------------------------|--------------|
| Bio-compatible Compounds | Change Management | Medical Grade Resins | Laser Marking & Welding | Tribology Test Results | Sheet & Film |
|--------------------------|-------------------|----------------------|-------------------------|------------------------|--------------|

Known bio-compatible database

Unmatched Resin & Additive Selection

- Virtually all resins; 60+ resins
- Thousands of additives
- Unbiased material selection

Biocompatibility

- Supplier tested
- RTP pre-tested
- Internal list known compounds

Formulation Control and Change Management

- Traceability
- ISO 9001 Certified
- Notification of Change





STATEMENT OF BIOCOMPATIBILITY



Corporate Headquarters
RTP Company
500 East Front Street
PO Box 5430
Winona, Minnesota

Statement of Biocompatibility ISO 10993-1 Biocompatibility Tests, *In Vivo* and *In Vitro*

This is to confirm that the pigments, resin(s), and additives(s) used in the following product manufactured by RTP Company,

(RTP Product Description)

have been used in compounds that have undergone the following studies by NAMSA, an independent laboratory. The tested compounds have been found to meet ISO 10993-1 and/or USP requirements.

ISO Intracutaneous Study – Extract, ISO 10993: Biological Evaluation of Medical Devices, Part 10: Test for Irritation and Delayed-type Hypersensitivity. The material extracts met the requirements of the test. There was no significant difference between the mean score of the test extracts and the mean score of the corresponding controls.

USP and ISO Systemic Toxicity Study – Extract, United States Pharmacopeia and ISO 10993: Biological Evaluation of Medical Devices, Part 11: Tests for Systemic Toxicity (ISO) Each test article extract met the test requirements. Under the conditions of this study, there was no mortality or evidence of systemic toxicity from the extracts.

Cytotoxicity Study Using the ISO Elution Method (IX MEM Extract), ISO 10993: Biological Evaluation of Medical Devices, Part 5: Test for Cytotoxicity *in vitro* Methods guidelines. Under the conditions of this study, the IX MEM test extract showed no evidence of causing cell lysis or toxicity. The IX MEM test extract met the requirements of the test since the grade was less than 2 (mild reactivity).

March, 2007

Winona, MN • South Boston, VA • Fort Worth, TX • Indianapolis, IN • Beaune, France • Singapore • Suzhou, China



PRODUCT FAMILIES

COMPREHENSIVE PRODUCT LINE



STRUCTURAL



WEAR RESISTANT



CONDUCTIVE



THERMOPLASTIC ELASTOMERS



FLAME RETARDANT



COLOR



FILM AND SHEET





GLOBAL SERVICE

CONSISTENT PRODUCTION ACROSS THE GLOBE



Scalability: Develop your solution on a small scale and produce your solution in larger quantities

ISO 9001:2008 Registered Facilities

Plant-to-plant consistency

Worldwide technical support

Identical machinery, processing, QA testing

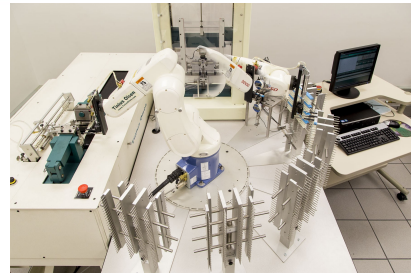
Local customer service



QUALITY CONTROL & ANALYSIS

RTP Quality Policy

Through the continual improvement of our quality system, processes and products, RTP Company is committed to delivering on-time, defect-free products which meet or exceed the requirements of our internal and external customers.



State of the Art - Robotic Testing

RTP Company supports its commitment to quality with ISO 9001:2000 Registered Facilities in Winona, MN; South Boston, VA; Fort Worth, TX; Indianapolis, IN; Monterey, Mexico; Ladenburg, Germany; Beaune, France; Singapore; Shenzhen and Suzhou, China.



World-Class Quality & Capability





CAE Design & Tech Service

COMPUTER-AIDED ENGINEERING & MOLDING SUPPORT

CAE Design

- Metal to Plastic Conversion
- Filling Analysis
- Structural Analysis
- Warpage Analysis
- Computer-Aided Engineering
- Saves Time & Money



Technical Service

- Fast Start Up
- Mold Trials
- Trouble Shooting
- Process Optimization
- More than 20+ Engineers
- Global Service Capability



PRODUCT DEVELOPMENT/R&D

UNPARALLELED PRODUCT ENGINEERING CAPABILITIES

- 50+ engineers worldwide
- Formulation development
- Regional engineers for local support
- Dedicated global pilot plants – run and scheduled by R&D engineers





ULTRA CLEAN COMPOUNDING CENTER

AVAILABLE FOR PRODUCTS REQUIRING ULTRA CLEAN COMPOUNDING



Environmentally controlled manufacturing capability:

- Positive air pressure
- Ultra CLEAN compounding
- Highly controlled production process
- Limited materials in production area



QUANTITIES THAT MEET YOUR NEEDS



Bags to Truckloads

YOUR GLOBAL COMPOUNDER OF CUSTOM ENGINEERED THERMOPLASTICS





MEDICAL MATERIALS EXPERTISE

LARGEST MATERIAL SELECTION IN THE HEALTHCARE INDUSTRY

Unmatched Resin and Additive Selection

- Virtually all base resins used for compounding
- Thousands of additives and colorants
- Unbiased material selection based on application need.
- Radel® PPSU Trademark Color Compounds

Biocompatibility

- Internal list of known biocompatible compounds
- Resin and additives that meet ISO 10993 or USP Class VI
- RTP pre-tested ISO 10993 Compounds

ISO 9001 Manufacturing Quality Certification

- Formulation Control and Change Management Service
- Lot traceability
- Notification of Change

Radel® PPSU and UDEL® are trademarks of the Solvay Specialty Polymers USA, LLC



RTP COMPANY MEDICAL POLICY

- **Contact with internal bodily tissues/fluids**
 - Temporary (<30 days) – OK, if agreed to in writing
 - Permanent (> 30 days) – **Not permitted**
- **For more information please request a copy of the RTP Company medical application policy.**
- **No RTP compounds have been determined as safe for contact with internal bodily fluid or tissues.**
 - Customers rely upon their own legal and medical judgment.
 - Customers are responsible to perform biocompatibility testing required by local or applicable regulatory bodies.





MEET NEW PEOPLE

- It's not **WHO** you know, it's who knows **YOU**.
- *If you want to go **fast**, go alone. If you want to go **far**, go with others.*
- **The currency of networking is not greed but *generosity*.**
- **IRON SHARPENS IRON.**



Feel free to ask questions...
Consult offline with RTP R&D...

Enjoy the Day.

Thanks for being here.

