Biomedical Polymers & Compounds™

Johnson & Johnson Medical-Grade Material Mini-Conference

August 8, 2019

About Foster Corporation

- Founded in 1989 by CEO Larry Acquarulo
- Specializing in custom formulated compounds for minimally invasive medical device manufacturing
- Established polymer distribution business in 2005
- Began drug & implant compounding in 2006
- Global footprint: Customers in 42 states and over 30 countries
- ~130 employees between three facilities

Fosters Value Features

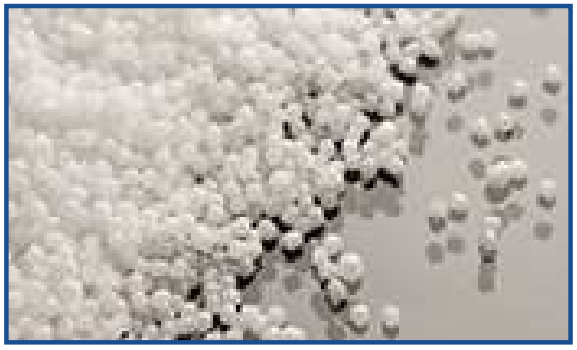
- Foster adds value to polymer materials in the medical market
  - Addition of fillers, functionalization, formulation through melt blending
  - Addition of pharmaceutical excipients through Foster Delivery Science (FDS)
  - Easy market access to medical polymers through distribution
- Tailored developmental marketing and selling of biomaterials
- **Critical applications/critical compounding**
  - **Predominantly FDA Class II & III applications**
- Small to medium size medical market needs

Foster Focus…We Do Four Things

Medical Compounds

Implantable Polymers

Drug/Polymer Blends



Polymer Distribution

Foster Facilities

Foster Corporation

45 Ridge Road
Putnam, CT 06260

- ISO 13485:2016

Foster West Corporation

4336 Losee Road, Suite 7
North Las Vegas, NV 89030

- ISO 13485:2016

Foster Delivery Science

36 Ridge Road
Putnam, CT 06260

- ISO 13485:2016
- FDA Registration,
- DEA Registration for Class II-V substances

Foster is Building a new 56,000 ft^2 facility across the street from our headquarters…opens in November 2019

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Why Do Customers Choose Foster?

We are Medical!

- The vast majority of Foster applications are used in contact with the body including temporary/permanent implants in all parts of the body

Risk Abatement

- Foster has two ISO 13485 and ISO 9001 plant facilities (Putnam, CT & Las Vegas, NV) as well as the infrastructure that assures critical application safety

Experience & Expertise

- Foster has worked with virtually every polymer and additive/filler on the market and is highly "engineering" focused

Capability

- Extreme capability based on our customers needs including Formulation, melt blending, and prototyping services

Support Infrastructure

- Foster's infrastructure has been constructed for the highly critical medical market including a full product stewardship staff

People

- Every Foster employee receives 40 – 80 hours of training per year

Foster Polymer Experience

Commodity

- Polyolefins: LDPE, HDPE, PP, EVA
- Styrenics: GPPS, HIPS, ABS, SMMA
- Vinyls: Flexible PVC

Engineering

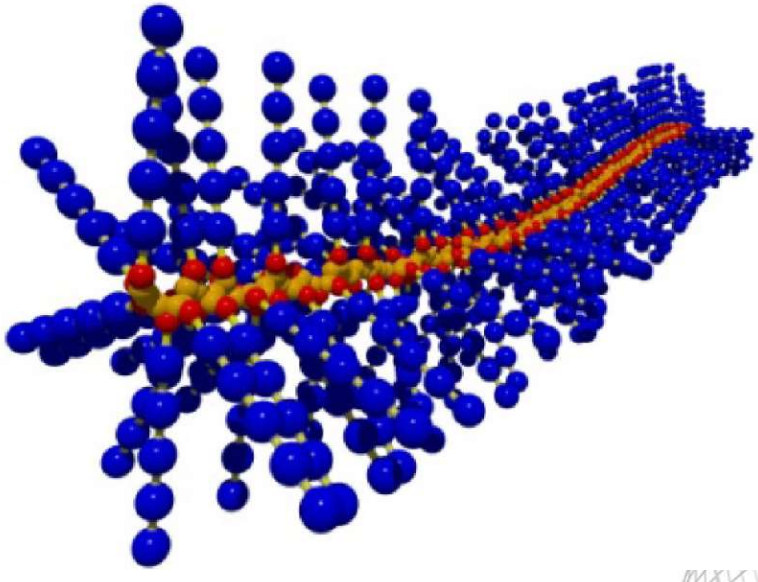
- Polyamides: 6, 66, 6/10, 11, 12, specialty
- Polyesters: PET, PBT, PETG
- Acetals: Homopolymer and Copolymer
- Polycarbonate: PC, HHPC, Alloys
- Thermoplastic Elastomers: TPU, PEBA, COPE, SEBS, TPV
- Acrylic: PMMA

Performance

- High temperature: PAEK, PESU, PPS, PSU, LCP, PEI
- Fluoropolymers: FEP, PVDF, ETFE, MFA, PFA, etc.

Implantable

- Bioabsorbable: PLA, PGA, Copolymers
- Durable: PAEK, Sulfones, PP, EVA, TPU
- Water Soluble: PEO, PVP



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Medical Grade Material

What Does That Mean?

- Manner in which the material is manufactured
  - Clean room/non-clean room
  - Line clearance
  - Etc.
- Property specifications - many times narrower than industrial grades
  - Black specs
  - Clarity
  - Yellowness index
  - Gel count and ratings
  - Moisture level
  - Pellet size
  - Viscosity
  - Specification customization options
  - Packaging
  - Pellet size
- Blending policy
- Polymer biocompatibility tested
  - USP Class VI or ISO 10993
- "No change agreement
  - Formulation constituents
  - Production

Manufacturing Resources

- 12 twin screw extrusion lines between the two facilities
  - Range from 16mm-50mm diameter
    - Includes fluoropolymer blending capability (27mm @ FE and 40MM @ FW)
  - Output ranges from ~5 lb/hr- 800lb/hr.
  - Utilize both two and three lobe mixing technologies
- 16 mm Thermo Scientific R&D twin screw extruder allows for small trials and color match sampling
- Loss in Weight feeders (LIW) integrated on all machines
- Process data acquisition
- Class 7 (10,000) Clean Room

Manufacturing Resources

Miscellaneous Capabilities

- Polymer drying capacity - 18 desiccant hopper dryers ranging in size from ~10lb - 2000lb
- Desiccant tray dryer can handle up to ~1000lb
- Polymer grinding capability for developmental trials
- Liquid injection capability
- Multiple pelletizing capabilities
  - Underwater cut
  - Strand cut
  - Custom strand length capability
  - Hot face die cutting
- Pellet dedusting
- Melt filtering
- Programmable screw configurations
- Milling

Batch Traceability

- Batching software
  - Ensures correct ingredient and amount is batched
  - Allows batch traceability for lots
    - Batch #
    - What was weighed
    - How much was weighed
    - What scales were used
    - By whom
    - Date/Time

Medical Plastics Innovation Center

The Innovation Center is an inclusive facility for formulation development

- **Polymer Compounding**
- **Injection Molding**
- **Extrusion Processing (Tubing & Film)**
- **Material Final Property Testing**
- **Analytical & Physical Testing Lab Services**

*Our in-house development capabilities reduce customer outsource demands and time to market

Implantable Polymers

- Foster compounds functionality into polymers for permanently implantable applications
  - Radiopacity
  - Color
  - Osteoconductivity
- Durable
  - PEEK, sulfones, etc.
- Non-durables
  - Bioabsorbable polymers
- Cleanroom and non-cleanroom

Dental, orthopedic, tissue engineering, women's health, vascular, medical textiles, cardiac, etc.

Material Testing Capabilities

- Ash (filler content analysis)
- Bulk Density
- Color analysis via visual
- Spectrophotometer (Delta E, L*a*b*)
- Dispersion (TAPPI method)
- Durometer (Shore A or D)
- Melt Index
- Pellet size
- Porosity
- Specific Gravity
- Strand Surface
- Visual impurities (contamination)
- Tensile & Elongation
- GC (FDS)

Material Testing Capabilities (cont'd)

- Capillary Rheometer
- Flexural Modulus
- Conductivity & Resistively
- FTIR – Fourier Transform Infrared Spectroscopy
- Surface roughness via Profilometer
- Izod Impact
- Aging Studies
- HPLC - High-performance liquid chromatography (FDS)
- DSC - Differential scanning calorimetry (FDS)
- TGA - Thermogravimetric analysis (FDS)
- IV (FDS)
- HDT

Foster Delivery Science

Helping Pharmaceuticals Work Smarter

Part of Foster Corporation

- Started in 1989
- Located in Putnam, CT
- Privately held
- Three business
  - Medical blending science
  - Distribution
  - Delivery Science

Delivery Science located in Putnam, CT

- Brand new 32,000 ft^2 pharmaceutical facility
- Class 7 cleanroom
- Quality
  - Pharmaceutical cGMP
  - ISO 13485:2003/9001:2008
  - FDA registered
  - DEA schedule II - V

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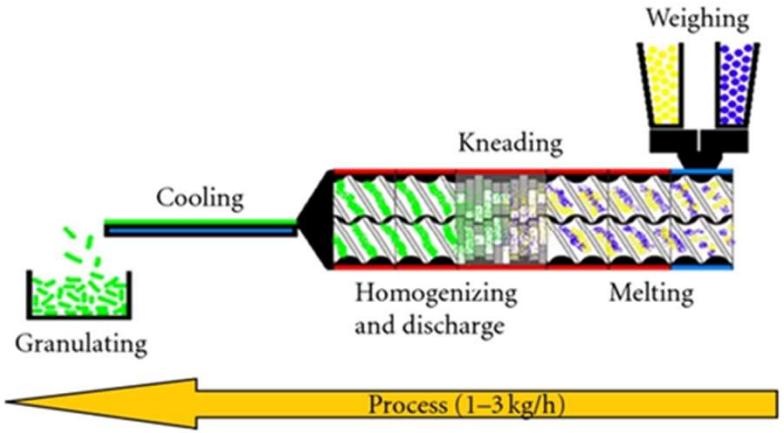
Pharmaceutical Hot Melt Extrusion

What? Is It and Why Use it

- **Extrusion "melt blending platform using an extruder**
- **Melt blends a pharmaceutical API with excipients**
- **Better result**
  - Increased bioavailability
  - Enhanced efficiency and effectiveness of API
  - Platform for poorly soluble drugs
  - Stable and uniform dosage form
  - No "dose dumping"
  - Taste enhancement
  - Fewer process steps
  - No solvents
  - Supports multiple dosage forms
  - Enhanced dispersion of active
  - Can be used with numerous excipients



Foster Current Distribution Portfolio

Medical Grade Polymers (USP Class VI/ISO 10993)

REPSOL

Mitsui Chemicals

GRECO

EASTMAN

MX-NYLON
MITSUBISHI GAS CHEMICAL AMERICA, INC.

SOLVAY
asking more from chemistry®

ARKEMA
INNOVATIVE CHEMISTRY

SUNSTAR
Degradable Solutions AG

LOTTE
ADVANCED MATERIALS

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Thank You!

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