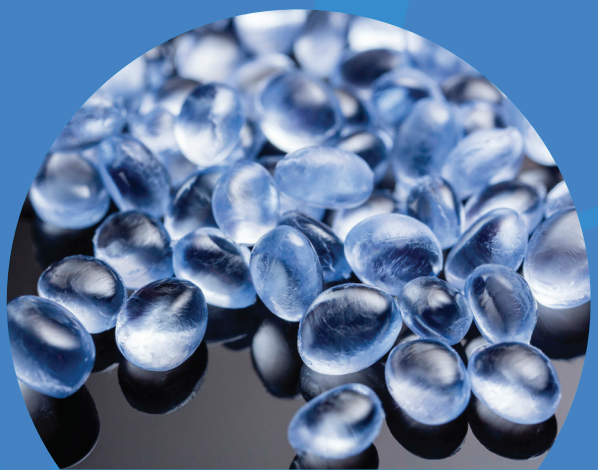

White Paper

Medical device manufacturers:

What capabilities should the ideal medical polymer compounder have?

Paul McShane, Ph.D., Global Technology Director
Heath Schmid, Director of Business Development

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What capabilities should the ideal medical polymer compounder have?

If you are a medical device OEM or a supplier subcontractor who has been entrusted with developing components for your client's new product, you may be uncertain as to how to evaluate a compounder with whom to partner. This white paper has been structured to provide you with a multi-discipline consideration to help you make the right decision.

Polymers in medical device applications

According to Medical Device Online, global demand for medical polymers reached nearly 5 million tons in 2013 and is expected to exceed 7 million tons by 2020.

The publication further notes that polymer selection plays a major role in the development and manufacture of medical devices. Attributes such as weight, cost, processing ease, flexibility and biocompatibility are driving both current and next generation implants, devices and related packaging technology.

The properties of base polymers are often not ideal for production or for the end use. When this is the case, additives are added to either reduce cost, improve function or enhance performance of the base polymer used for a specific medical device application. Therefore, consideration frequently needs to be given to polymer compounds where a range of additives are added to the base polymer during an intermediate compounding step.

Typical additives include: polymer alloys, plasticisers, radiopaque fillers, heat/light stabilizers, lubricants, antimicrobials, conductive agents, drugs and colorants.

This intermediate step is typically called melt compounding. It is defined as the incorporation of solid and liquid ingredients into a base polymer by converting the basic polymer from the solid state into a viscous mass or gel under the influence of both externally and internally applied heat from shearing and mixing actions. Thermomechanical energy generated by shearing and mixing actions during melt compounding disperses and distributes all formulation components at a microscopic / intermolecular level.

Examples of polymer compounds readily used in the medical device industry can be categorized into the following areas:

Thermoplastic: PVC, polyolefins and styrenic compounds

Elastomeric: TPO, TPE-S and TPV compounds

Engineering TPEs: COPE, COPA, TPU, polyamide and polyester compounds

Performance polymers: Fluoropolymers and high-temperature materials such as polycarbonates, PEEK and polysulfones

The selection of which polymer compound is suitable for the specific medical device is driven by the application, as well as physical, chemical, biological and regulatory requirements.

When selecting a compounding company, there are a number of important aspects that a medical device company and/or its subcontractors should consider in order to help ensure the best possible outcome.

How much experience does your compounder have?

Just like any other professional service provider, you will want to understand what type of track record the compounder has in supplying materials for medical devices. In addition to years in the business and a success record in supporting medical device commercializations, you will want to delve into specifics about the manufacturing environment.

For example, does your compounder have fully-dedicated production lines located in restricted access areas where only approved personnel and materials can enter? Is this backed by a clean environment that minimizes environmental pollutants such as dust, aerosol particles and chemical vapor?

What about their experience in managing medical production—specifically pertaining to Good Manufacturing Practices and Good Laboratory Practices which focus on cleanliness, traceability, reproducibility, procedures and change control.

What level of quality certification does the medical compounder have? At minimum, they should be ISO 9001-2015 certified with a strong understanding of medical device requirements.

Another critical manufacturing aspect is cross-functional support. The quality assurance laboratory, customer and technical service teams, regulatory support and sales staff all have to work in concert with each other to produce a medical compound that meets your objectives.

The raw material supply chain is another key aspect that needs to be evaluated. What suppliers does your compounder work with and do they have long-term agreements? Do they have access to highly biocompatible materials? How do they handle a notification of change and do they have backup suppliers validated?

Not all compounding orders start off large. Can your compounder scale from small to large requirements? Can they support varying volume levels?

Ideally, you also want to work with a compounder who is “polymer neutral.” They don’t have a vested interested in recommending one material over the other, but are driven by finding the right solution for your medical device application. As a companion to that capability, it is ideal to work with a compounder that has customization capability. Your device may require a polymer solution that requires out-of-the-box thinking to meet performance attributes, so look for compounders than can help you push boundaries.

Product/business development support infrastructure

Medical device manufacturers continue to push boundaries regarding the capabilities that their products can offer physicians and patients. Aging population and economic gains in developing countries are driving medical device manufacturers across the globe to improve productivity, minimize secondary processes and reduce overall system costs.

Unique material requirements are frequently a critical component of these next-generation devices. This requires a medical compounder who is aware of market requirements and has the technical know-how and subject matter experts to be a true innovator. These capabilities need to be augmented by the following disciplines: analytical, mechanical, rheological, morphology and permeation.

In early-stage product development, medical device OEMs can also benefit by suppliers who understand mono- and multilayer tube or film extrusion, as well as injection molding.

Another benefit would be working with a compounder who is vertically-integrated downstream and/or has a close relationship with scaling partners.

Before entering into a relationship with a medical compounder, it's important to understand their manufacturing technology capabilities. For example, do they have state-of-the art technology to pre- or post-dry materials? Can they premix materials? What does their direct material feed look like? Do they have "loss in weight" feeders that provide a high degree of accuracy when feeding polymers, injecting liquids or adding fillers and minor additives?

Further, can they customize shear and resistance time via a flexible screw design or customized pellet size to meet customer needs? Can they offer you post-pelletization dusting capabilities should that be required?

The level of automation is also a key consideration for compounding manufacturing technology. Temperature and process control, data acquisition software and ensuring lot-to-lot consistency and traceability are important automation deliverables.

Medical device manufacturing processes and application knowledge

Polymers and polymer compounds play a central role in the manufacture and development of a wide range of medical devices. Understanding your customers' needs, processes and applications, and translating these requirements into material properties, is critical to making the correct compounding recommendation.

You want to partner with a technical team that has expert knowledge/experience in helping to commercialize a broad spectrum of medical devices including:

- Non-invasive (single use) / Invasive (implant) / primary or secondary packaging
- Non-contact with human fluids or body
- Short-term contact—less than 30 days
- Long-term contact – implant greater than 30 days
- Body-contact applications (heart, central nervous system, central circulatory system, skin, blood, mucosal membrane, tissue, bone, dentin)

Critical product requirements: durometer, appearance, color, thermomechanical, rheology and electrical properties

Primary processes: extrusion (tubing), film, blow or injection molding

Secondary processes: solvent bonding, adhesion, product testing, printing/labeling

Environmental challenges: biocompatibility with tissues or drugs, sterilization techniques (gamma, ETO and autoclaving), chemical and thermal resistance, weathering, humidity, material compatibility and shelf-life requirements

Globalization and regulatory compliance/support

With an increasing number of medical device companies marketing their products globally, manufacturing is oftentimes not confined to one region. In those instances, it is important to work with a compounder that also has a global footprint. Research to see if your compounder offers technical and sales support in other regions. Do they have access to raw materials in various parts of the world and can they replicate the grades?

Regulatory requirements for medical devices are also part of the global discussion. They are becoming increasingly dynamic and more stringent around the world with different regulations at a continental, national and sometimes regional/state level.

Therefore, it is critical that OEMs partner with compounders that have an in-house regulatory team that is not only cognizant of the applicable regulatory requirements across the globe, but is also tracking potential proposed changes in the codes.

It is the team's responsibility to ensure that the raw materials being used and the finished product meet all regulatory requirements of that specific application in the particular region or country.

Here are examples of some region- or country-specific regulations:

Food contact
- FDA 21CFR
- EC 1935/2004
- EC 2023/2006
- EU 10/2011
- CFDA

Medical devices
- USP <88> Class VI
- ISO 10993
- European Pharmacopeia
- CFDA
- Japanese Pharmacopeia

General chemicals legislation
- Reach
- CA Prop 65
- RoHS
- Heavy Metals (CONEG and 94/62/EC)

Conclusion

Selecting the right medical device compounder is critical not only to the commercial success of the product, but also to the commercialization timeline and related costs. Doing your due diligence up front so that you are confident that the medical device compounder you select has all of the core competencies you require, can mean the difference between product success and failure.