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Medical-grade polymers for medical device manufacturers: regulatory considerations

Whitepaper

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Introduction

High performance polymers have transformed medicine over the last 100 years.

Polymer beads are used in some of the most demanding applications, such as bone cements and maxillofacial fillers.

Acrylic beads for medical applications undergo rigorous conformance checks and extensive quality control measures, due to the nature of their use. Accredited documentation is critical for registering a medical device, but this is not a straightforward process.

Determining the relevant information required by a certified body may include everything from product registration from all raw materials providers to quality assurance process information.

Every region represents a unique challenge, especially in markets where these requirements are more stringent.

Makevale's experience with medical device manufacturers means that our scientists are well versed in the complexities that come with regulations and certifications.

This is the case to such an extent that the company's manufacturing processes all conform with the most stringent requirements for medical device manufacturing.

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Producing medical-grade polymers

Not all medical polymers are made equal. As there is no international definition of 'medical-grade' polymers, many companies claim to produce acrylic beads to an appropriate standard.

However, there is growing evidence that international regulations are becoming more stern. This creates an additional difficulty for medical device manufacturers: what exactly should you look for in a raw materials manufacturer?

Company registration details

Regulators require that medical device manufacturers record (and submit, in some cases) a full profile of raw materials suppliers, sometimes including:

A track record of experience within the industry

In some markets, manufacturers are required to submit a descriptive statement of all suppliers' experience within the specific niche or application. Finding suppliers with vast industry experience can make the regulatory hurdles much easier.

Established, documented and established processes

Manufacturing sites with respected certification body approval are another good sign: it indicates that they follow highquality processes. Makevale's global sites are FDA registered and comply with various medical device directives;

Compliance with leading international standards

Medical devices should be manufactured in accordance with ISO 13485. This directive necessitates raw materials sourced from organisations that also hold the certification.

Details of manufacturing steps and equipment

Orthopaedic manufacturers require supplementary information concerning the manufacturing steps and equipment used for polymer production.

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Quality agreements for medical-grade high performance polymers

In the field of orthopedics, as with other medical applications, consistency and quality are essential characteristics of materials.

A quality agreement is an essential document, which outlines agreed quality control and quality assurance procedures between manufacturers and suppliers. The contents of this document should cover topics such as:

1. **Specific composition of the product.** For raw materials, this usually includes relative percentages within an agreed range, such as the liquid formulation or relative ratios of monomers used for making co-polymers.

2. **Agreed product specification.** Exact performance is extremely important for Medical grade polymers, thus they often have specification ranges that are tighter compared to industrial grade polymers. There may even be bespoke tests conducted for applications that necessitate them.

3. **Safety data sheet.** These need to be relevant to the region where the medical device is registered..

4. **Shelf life information.**

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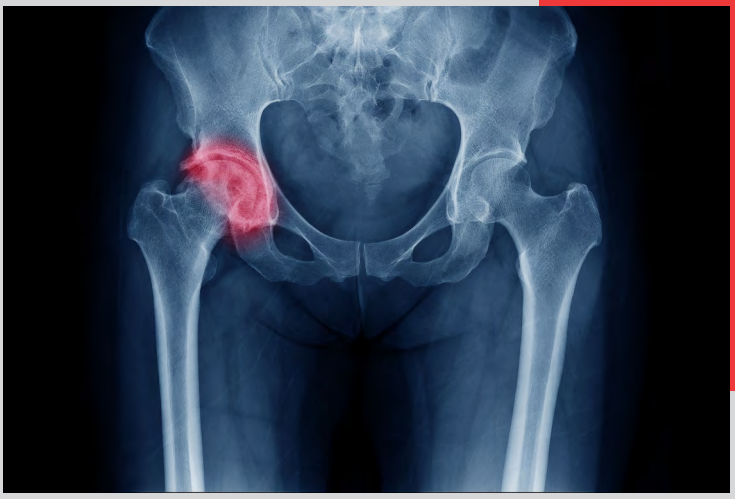
Logistics and delivery: the supplier agreement

The medical industry requires unique supplier agreements.

The main differences are that some medical companies need a pre-sample which needs to be approved before the shipment is authorised for release.

There are also more stringent clauses regarding intellectual property and sharing of information, particularly given Makevale's materials are typically designed for an exact application.



> "There are also more stringent clauses regarding intellectual property and sharing of information."

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Looking for medical device materials and support with regulatory hurdles?

The requirements of medical device companies vary all over the world.

The differences between each region's certified body means that there's no one straightforward process for hurdling regulatory challenges. To meet the needs of regulatory bodies, it is of courseadvantageous to aim for manufacturing and materials excellence.

Makevale's medical-grade polymers are used in all of the world's major markets. Due to our international client base, Makevale's scientists are well-versed in the international requirements of medical device manufacturers.

We have a specific team that specialise in creating best-in-class processes that exceed regulatory requirements.

If you want to speak with any of our experts; either in chemistry, regulatory requirements or manufacturing, then get in touch:

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