Cytophil, Inc.

Contract Manufacturing Services

Company Overview

Cytophil was founded in 2005 by Dr. William Hubbard with the mission to design, develop, and manufacture innovative and cost-effective solutions for orthopedic, dental, and aesthetic markets. Dr. Hubbard's research regarding synthetic ceramics became the foundation for an entire class of biomaterials.

Cytophil has an established history of bringing products to market, holding multiple 510(k) and CE-mark product clearances and supporting multiple contract partners from concept through regulatory clearance.

Commitment to Quality

Cytophil maintains Quality Management System certification to ISO 13485:2016 & EN ISO 13485:2016 for the design, manufacture, and distribution on non-active implantable bone and soft tissue filler devices as well as the contract design, manufacture, and/or distribution of non-active implantable bone void filler devices, soft tissue filler devices, and single use delivery devices.

Cytophil utilizes its independently certified ISO Class 8 controlled environment to ensure contamination control in all critical processes.

Integration of each customer within Cytophil's QMS ensures seamless communication of production records, investigations, and change control.

Let us know how we can bring your ideas to market today!

Contact Information:

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Turn Key Solutions

Cytophil has a suite of standardized test methods and operating procedures ready to implement within your process.

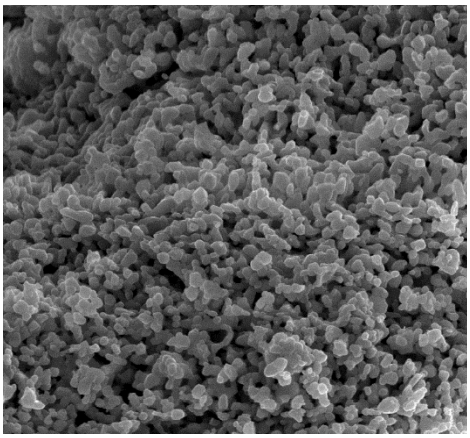
- Device Assembly
- Formulation and Batching
- Sterile Barrier Formation
- ASTM Seal Strength & Leak Testing
- Label & UDI Generation
- Contamination Control
- Terminal Packaging & Labeling
- Sterilization & Dose Audits

Standardized validation templates ensure your process is stable, capable, and compliant with minimal overhead.

Cytophil maintains 110+ approved suppliers for raw materials, service provision, and expert consulting to source everything your project requires.

Cytophil provides temperature controlled storage, inventory control, and routine reporting for all customer owned materials.

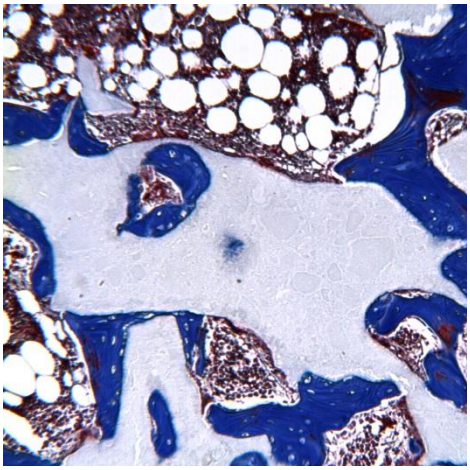
Cytophil delivers a complete SOP package to support your design files and comprehensive documentation for each production batch.



Example of SEM imaging obtained by Cytophil for design verification of implant surface morphology.

Allow our experts to help define the critical attributes of your product & process.

- Specification development
- Scaling and transfer for commercialization
- Troubleshooting
- Validation strategy & execution
- Quality control testing
- Biocompatibility testing
- Formulation refinement



Cytophil can facilitate collection of data to demonstrate device safety & efficacy for regulatory submissions.

Development & Manufacturing Expertise

Cytophil has extensive experience working with a wide variety of medical devices.

- Synthetic Bone Graft Substitutes
- Bone Cements
- Injectable Implants
- Hydrogels
- Polymer Carriers
- Instrument Kits
- Injection Accessories

Cytophil offers industrial mixing and packaging solutions for multiple product configurations.

Our background and industry contacts allow us to support every phase of product implementation.

- Materials selection and procurement
- Vendor controls & auditing
- Supply chain and inventory management
- Process controls and product monitoring
- Outsourced product testing
- Sterilization & dose audit management
- CAPA and nonconformance investigation