

xeridien

Your Vision.
Designed. Delivered.



 **xeridien**[™]
MEDICAL DEVICES



Your ideas. Designed and developed.

Every day around the world, medical device innovators are envisioning next-generation solutions. Many are engineers employed by established health care companies of all sizes and seeking to solve existing or emerging medical challenges.

Others are clinicians with an entrepreneurial spirit, people who have an idea spawned by a real need identified in their own practices. Still others are individual inventors of medical devices who are sometimes represented by venture capitalists prepared to finance a project from concept to commercialization.

Yet all share common dilemmas.

- What's the best way to take a concept, step by step, through a complex technical process?
- Who can provide the knowledge and discipline to accommodate regulatory requirements and fully document compliance for the US, Canada, and EU?
- Where can the device be verified and well-validated for safety and functionality?
- And how can all of this be done in an orchestrated way so that a great idea can become a market leader? On time. On budget. No surprises.

It all comes together at Xeridien Medical Devices.



Xeridiam Medical Devices orchestrates the entire program management process.

Under product design and development are several phases, from design inputs to validation, product testing, materials selection, and creation of a manufacturing process. Regulatory documentation, to meet the requirements of the US, Canada and EU, occurs simultaneously with design and development. Xeridiam can also provide highly flexible manufacturing to support a client's successful product launch.

A tradition of service. A legacy of success.

With roots dating back more than a quarter century, Xeridiam Medical Devices combines strict process discipline with industry-leading innovation. We design and develop complex medical devices that can become well-established and widely used around the world.

Xeridiam works hand in hand as a partner to the companies and individuals who entrust their ideas to us. Our clients expect engineering expertise, with an accent on personalized service. We deliver.

Founded as MRI (Manufacturing & Research, Inc.), the company was acquired by the multinational Fenner plc in 2010. Today we are backed by the technical and financial strength of our parent company and are now named Xeridiam Medical Devices to reflect our expanded client services and strategic growth plan.

Sound supply chain solutions. From a trusted single source. Xeridiam.

Execution Expertise

An agile business model; a proven design and development process; longstanding experience in silicone injection molding; and, in conjunction with our parent company, Fenner, extensive knowledge of advanced polymers, magnets and metals, medical textiles, thermoplastics, and more.

Product Classes

Complex, minimally invasive, disposable medical devices, Class I, Class II, and Class III.

Medical Applications

Delivery and access devices for urology, cardiology, gastroenterology, cardiothoracic surgery, minimally invasive surgery, energy delivery, and obstetrics/gynecology.

Regulatory Documentation

Complete, clearly organized documentation for our clients to submit to US, Canada, and EU regulatory bodies.

**Your complex medical device.
Delivered by Xeridiam.**

On schedule.
Under strict budget controls.
Meeting all regulatory requirements.
With no unwelcome surprises.

**Well-defined. Cost-effective.
Fully orchestrated. Start to finish.**

The Xeridiam program management system, clearly defining the responsibilities of our client and our internal team, provides an orderly guide and timetable for each critical phase, including:

- Design inputs
- Design history file
- Risk management
- Biocompatibility testing/cytotoxicity testing
- Design validation
- Design verification
- Optimized manufacturing process development
- Flexible manufacturing
- Packaging and sterilization
- Launch logistics
- Order fulfillment

Let's work together on making people better.
Contact Xeridiam anytime.

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FDA-registered