

CASE STUDY

Medical Device Manufacturing

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on design and manufacturing of
new eye care delivery system*

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Product Resources provides turnkey product development and manufacturing solutions to the medical device industry.

Clients come to us at various stages of the product development process. Sometimes, it's an idea or concept that needs to be designed from scratch. Sometimes, it's a working prototype that needs to be prepared for manufacturing.

In this case study, our client came to us with a proven technology in its very early stages of development.

Background

Until recently, patients who suffered with eye disease had limited options for drug therapy treatment. Traditional treatments such as injections to the eye or eye drops had limited effectiveness.

Topical treatments had difficulty reaching the inner part of the eye. And because treatments often require many applications, patients were inconsistent with their own treatment.

An alternative approach has been developed using transscleral iontophoresis. This approach has the benefit of delivering optimal quantities of the prescribed drug directly into targeted ocular tissue in both the anterior and posterior locations of the eye.

The Challenge

Iontophoresis isn't a new technology. It has been used in the medical field for many years.

But the technology was only accessible to a small number of highly trained specialists with expensive equipment.

Our client wanted to bring this technology to a wider audience of eye-care specialists where treatment could be administered in the office. This required the development of a product that was easy to use, small enough for office use and affordable for a large number of eye-care practitioners.

A 3-Phase Process

The Product Resources team has been an integral participant in this project from its earliest stages.

Phase 1 – In the beginning, our engineering and manufacturing teams were asked to develop and build different devices for the client to use in conducting its own research and testing. While the central technology was proven, the client needed to complete a number of scientific investigations to take the product to its newer applications.

To assist the client’s research team in this investigatory and testing process, we developed customized instrumentation and software.

Phase 2 – With the scientific investigation complete, we then helped to develop a clinical testing version of the product to be used by practitioners in the field.

In collaboration with our client, our engineering design team assisted in developing a handheld treatment generator utilizing low-level electrical current for this non-invasive delivery system.

The clinical version has been used in the field by a select group of eye care professionals. User feedback has been collected and is ongoing for use in development of the commercial version of this product, as well as for data for its FDA submission.

Phase 3 – We are currently in the earlier engineering stages for the final commercial product. While overall functionality has been positively received, we continue to look for new feature sets and device forms to improve the user experience.

The final product will likely include changes in the user interface, the power source and the embedded software.

A Focus on Quality

Product Resources has an outstanding reputation of maintaining the highest levels of quality both in house and in the field. Because this project is a medical device, our ISO 13485 certification plays a significant role in this relationship.

“This has been a terrific partnership,” said John Caruso, Partner and Chief Quality Officer. “We’ve had full participation in this project from the very beginning. And it’s helped to improve the overall process from industrial design and engineering to manufacturing and compliance.”

Learn More

Find out more about Product Resources and how our design, engineering and manufacturing services could fit into your product development process.

To request a quote or schedule an initial discussion, contact John Erickson at 978 225 4994 or jerickson@prodres.com.

About Product Resources

Product Resources is a product development and contract manufacturing company specializing in complex products for the scientific, medical and industrial markets.

Product Resources provides a full range of design and manufacturing services that include:

- Industrial Design
- Prototype Development
- Design for Manufacturability (DFM)
- Manufacturing Assembly and Supply Chain Management
- Post-Manufacturing Support & Service
- Product Testing & Compliance
- Sustained Engineering
- Design for Explosive Atmospheres

Customer projects may include complete products, sub-systems or sub-assemblies.

Product Resources is located in Newburyport, MA – about 35 miles north of Boston. All testing and assembly work is done in its 33,000 square foot manufacturing plant.

ISO-certified product manufacturing

Recognizing the importance of quality, Product Resources has earned and maintained the following quality certifications:

- **ISO 9001**-approved for engineering design, development, manufacturing and service – certified by TUV.
- **ISO 13485**-approved for medical device manufacturing and service – certified by TUV.
- **ISO/IEC 80079-34** approved for engineering design, manufacturing and service, audited by TRaC Global, for equipment and instrumentation used in explosive atmospheres.