CASE STUDY

# BREAKTHROUGH TECHNOLOGY

## THE OPPORTUNITY

A company approached ERI Group with a design for a new medical device intended to treat those patients with a deep bone and tissue infection when other standard medical treatments have been unsuccessful. Treatment for patients with deep bone and tissue infection typically involves administration of prescription antibiotics to resolve the infection. However, in cases when prescription antibiotics are not successful, deep tissue infection in the bone can often ultimately lead to amputation of the limb. A minimally invasive, repeatable therapy to effectively treat bone and tissue infections in situations when a patient is facing a limb amputation has the potential to render that amputation unnecessary. In addition, by early intervention to enhance the initial antibiotic therapy, multiple costly surgical procedures can be avoided.

## THE SOLUTION

- ERI Group suggested the client consider a "Breakthrough Technology" designation and presented the client's novel, promising technology to the FDA's Center for Devices and Radiological Health.
- In 2017, the "Breakthrough Devices Program" was created by the US Food and Drug Administration to accelerate the review process for promising new technologies that meet certain criteria. When a product is designated by the FDA as a Breakthrough Device, the sponsor receives priority review of their product application, rather than waiting in line behind other submissions that the FDA needs to review. In addition, and sometimes just as importantly, there is a marketing advantage for the sponsor to be able to state that the device has been designated by the FDA as a breakthrough. This can help the product get that vital visibility, both in the clinic and on Wall Street.
- ERI's submission, on behalf of the client, described in detail the clinical need for a solution in this area, the possible benefits to society and to individual patients, the design and operation of this new device, and the clinical impact of its use relative to that of existing technologies. Presenting a request for designation as a Breakthrough Technology is complex and not often successful. Far more requests for Breakthrough designation are received by the FDA than are granted. A compelling case must be developed to convince the FDA not only that each criteria for this designation has been met but that such a designation is in the best interests of the FDA and of the American public.

## THE RESULTS

Within several weeks, the client's request was approved and Breakthrough Technology designation was granted for this unusual new medical therapy. This designation positioned the small group of employees in the sponsor's start-up company to organize, fundraise, and further refine their design.

## SERVICES

- Regulatory Strategy & Submission

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