

MDDI

Medical Device & Diagnostic Industry®



NOTABLE PEOPLE

Who matters, and why, in and around
the medical device industry

Roger Stern
Stellartech Research Corp.



What made you decide to start your own business?

One of my professors had started a medical device company in New York. I worked with him one summer on Holter monitors and ECG analysis, and this gave me the bug to one day start my own company.

What was the most difficult challenge you've faced as an entrepreneur?

Funding our company by the bootstrap method and taking no outside investment capital. Getting others to believe is very difficult. Many device businesses survive by undertaking only incremental improvements to known technologies. We made the decision to fund it ourselves.

What is the most important thing you've done to ensure the survival of your business?

The most important thing has been to ensure that we are operating under a sustainable business model. Some start-up companies are only developing one product, then looking to be acquired by one of the larger medical device companies. By developing many new technologies simultaneously, we maintain a pipeline of new products to sustain our growth.

Stellartech

RESEARCH CORPORATION



Roger Stern
President
Stellartech
Research Corp.
Founded company to design, develop,

and manufacture medical devices under contract to device companies... designs and manufactures ablation and thermal therapy devices and systems.

Stellartech Research Corporation provides design, development, and manufacturing services under contract to start-up, mature, and virtual companies for electronic and disposable medical devices. Stellartech specializes in working with investment groups or start-up companies to take a product idea or concept and develop it through proof of principle, clinical evaluation, regulatory approval, and manufacture. Stellartech is experienced in the special requirements of medical devices including United States Food and Drug Administration regulations for 510(k) clearance, IDE approval, PMA approval, and Quality System Regulation compliance as well as European regulations for CE approval and EN 13485 quality system compliance. Stellartech is registered with the United State FDA as a contract manufacturer of medical devices, holds a State of California FDB medical device manufacturing license, and is EN 13485 Quality System certified for the manufacture of medical devices.