

From Nicolaas C. Besseling:

As a consultant with more than 30 years of experience working in the medical device industry, I have created BesTech to be a flexible and nimble operation to meet the needs of a rapidly evolving business climate.

In the course of working with your company, I will combine my extensive business management experience and affiliations with various groups of expert consultants, tapping into their wide range of knowledge, to respond to your needs and concerns.

BesTech is the ethically focused consultancy your company needs to get your medical device to the market. My experience as an engineer is enhanced with a scientific curiosity to solve unique problems with real solutions for the marketplace.

With my advanced certification through many years of continuing education in regulatory affairs, your product's opportunities to successfully reach the target audience will be greatly enhanced.

It is my profound desire to assist in making your company successful by applying my in-depth knowledge of the industry and my experience in navigating the ins and outs of the bureaucratic processes.

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Inventing a great medical device takes the highest levels of imagination, tenacity and a lot of money. BesTech will guide you through the FDA and CE compliance processes and your idea will become a reality.

Bestech Consulting Services

Expertise in the following:

Nuclear Medicine

Diagnostic Imaging

Implantable Devices

Commercial X-Ray

Digital Laser Imaging

Medical Holography

Cardiovascular Stents

Photo Dynamic Therapy

Ophthalmic Imaging

Lung Ventilators

BesTech will provide your medical device company with expertise in the following:

Regulatory Compliance

- QSR Implementation
- Company Registrations
- 510(k) Submissions
- Risk Management

Product Safety

- Electrical Safety Testing
- Electromagnetic Compatibility
- CE-mark Testing
- International Certifications

Litigation Support

- FDA Law Expertise
- Product Design Expertise
- IP Technical Support
- Risk Management Analysis

Design and Development

- Medical Device Development
- FDA Design Controls
- Testing and FDA Submissions

To get your medical device to market, trust BesTech to safely guide your company through the myriad bureaucratic processes such as:

QSR Implementation

Medical companies must be registered with the FDA and have a Quality System in place. To make this possible, we will write your Quality Manual and Standard Operating Procedures, and teach you how to use these documents to your fullest advantage.

BesTech will handle the registration paper trail and assist you through your inspections.

510(k) Submissions

Your product must receive 510(k) clearance from the FDA. If your company cannot perform the testing procedures for this phase, BesTech will provide the testing along with the Submission Dossier and all necessary communications with the FDA.

Product Safety Testing

As part of the design process and/or the 510(k) submission process, the company will need to perform precise safety testing of the product. BesTech works with a few test laboratories specifically chosen to perform this vital series of tests compliant to the applicable safety standards.

Litigation Support

BesTech has provided expertise in FDA law and product safety in several cases of medical device malfunction where patients sustained irreversible injuries.

Training

BesTech has utilized years of expert knowledge to compile and teach seminars and lectures on **Design Control** and **Risk Management**. In the event your company requires instruction on a specific topic, BesTech will design a course to meet your needs and concerns.



The Roots of Expertise

BesTech was founded by Nicolaas C. Besseling, a native of The Netherlands, where he received his MSEE from the University of Delft. Shortly thereafter, he joined the prestigious medical team of Dr. Christiaan Barnard in Cape Town, South Africa, as a bio-engineer.

Upon his return to The Netherlands, he designed a neo-natal lung ventilator for Hoek Loos, a local company. So, in 1980, with his core experience designing an array of medical devices, he entered the complex world of product safety issues. To facili-

tate those needs of cutting-edge companies, he became a member of the IEC 62D Work Group to develop safety standards for infant incubators.

In 1981, Mr. Besseling joined Siemens Medical Solutions in Amsterdam where he led the Nuclear Medicine Engineering Department and implemented the IEC 60601-1 series safety standards. By 1984, Siemens realized Mr. Besseling's in-depth experience was needed at the company's Hoffman Estates (Chicago) facility where he developed additional lines of nuclear medicine equipment.

Mr. Besseling left Siemens when the opportunity materialized to design medical holographic imaging equipment for a start-up company in Southern California. He decided it was time to take his talent and experience to a significantly higher level.

It was at this company where he began to implement the FDA's Good Manufacturing Practice (GMP) requirements and developed the Voxcam, which received its 510(k) clearance just two weeks after submission.

Since 1996, BesTech Consulting Services has focused primarily on Regulatory Compliance and Product Safety for small and start-up medical device companies.

Mr. Besseling is active in the Orange County Regulatory Affairs (OCRA) discussion group and a member of OCTANe, the networking group for medical companies.