

BesTech guides medical companies through the regulatory compliance processes to ensure their business success

BesTech's 30+ years of experience will assure compliance with FDA and ISO requirements to help bring your product to market quickly.

Expertise in:

Regulatory compliance

Product Safety

Litigation support

Auditing

Design and Development



Registrations and Implementations:

QSR implementation

ISO Quality Management registration support

510(k) Premarket Notification

PMA Premarket Approval

Medical Device Manufacturer listing

Cutting edge knowledge:

Section 510 of the FD&C Act

ISO 14971:2000

21CFR11

21CFR812

21CFR820

MDD 93-42-EEC

IEC 60601-1 series

ISO 13485:2003

[510(k)]

(Risk management)

(Electronic records)

(IDE, PMA)

(Quality System Regulation)

(CE-marking)

(Product safety)

(Quality Management System)

Nicolaas C. Besseling, founder BesTech Consulting Services

A brief curriculum vitae

1974: Mr. Besseling designed and built an implantable six-channel transmitter.

In Cape Town, South Africa, Mr. Besseling teamed with world-renowned heart surgeon Dr. Christiaan Barnard to design implantable transmitters for use in experimental dual-heart surgery.



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BesTech
Consulting Services
a dutchwork inc. company

Nicolaas C. Besseling, founder BesTech Consulting Services

Back in The Netherlands, he developed neo-natal lung ventilators, and as a member of the IEC 62D Work Group, developed safety standards for infant incubators.

**Managed Engineering Department at Siemens Medical Solutions.
Developed Nuclear Medicine equipment
Implemented IEC 60601-1 safety standards.**

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BesTech
Consulting Services
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Nicolaas C. Besseling, founder BesTech Consulting Services

Since 1984: Mr. Besseling came to the US and developed several gamma cameras & applied UL 540, CSA 22-2.

Developed Laser Imagers for the medical market and designed Siemens' Export Control System to satisfy the DoD's export regulations.

Introduced professional project management software packages.

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Bestech
Consulting Services
a dutchwork inc. company



Nicolaas C. Besseling, founder BesTech Consulting Services

**Developed Holographic Laser Imager
for a startup company. 510(k)
clearance was granted within just
two weeks after submission.**

**BesTech Consulting Services:
Started BesTech to provide FDA
Guidance, Regulatory Affairs, and
Product Safety solutions to Medical
Device Companies.**

BesTech
Consulting Services
a dutchwork inc. company



THE VOXCAM®



Solutions - QSR implementation

- Situation** A startup medical device company was developing a laser-based diagnostic system.
- Problem** The company was unaware of the FDA regulations for medical manufacturers, and had no quality control system in place. Without it, registration as a medical device manufacturer cannot be obtained, and the company cannot sell any product.
- Solution** Bestech designed the Quality System, and wrote the Quality Manual, Design Control Manual, and all supporting Standard Operating Procedures, forms and checklists.
- Result** The company was ready to apply for registration as a medical device manufacturer on time and within budget.

Solutions - Product safety

- Situation** A startup medical device company was developing a catheter-based measurement system. The company's expertise was in catheters and the electronics were being developed by a contract engineering firm.
- Problem** Before being able to do clinical human testing, the electronics needed to pass all IEC 60601-1 safety tests.
- Solution** BesTech designed and performed all tests, and wrote the test reports. The system repeatedly failed one of the tests, and BesTech was able to diagnose the root cause and help the engineering firm with the redesign.
- Result** The unit passed the IEC tests and the company was able to start its clinical testing.

Solutions - Litigation support

- Situation** During arthroscopic shoulder surgery using an RF coagulation device the patient's axillary nerve was damaged.
- Problem** The patient experienced continuous, excruciating pain and sued the device's manufacturer. Her attorney hired BesTech to provide FDA- and product design expertise.
- Solution** BesTech found that the manufacturer had violated several FDA statutes. The manufacturer also had designed the product improperly, resulting in an unnecessarily dangerous product.
- Result** The lawsuit was settled in favor of the patient for an undisclosed amount.



Solutions - Auditing

- Situation** A major medical company had a Quality System deemed non-compliant by the FDA. The company had received several warning letters from the FDA.
- Problem** The company needed to overhaul its Quality System quickly and thoroughly, but lacked the manpower, expertise, and objectivity to analyze their deficiencies properly.
- Solution** Bestech served as Lead Auditor for two of the company's European plants, performing a Gap Analysis for the Material Movement operations.
- Result** The company received a Gap Analysis report on time.