

DAHLFELTCONSULTING

SENIOR CONSULTANT CV QA, RA, RISK PROJECT MANAGEMENT

CONTACT INFORMATION

Software development and documentation

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Gender Male
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NAME - CURRICULUM VITAE

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Medical device development

My journey with medical devices began with a deep-rooted curiosity and a desire to make a tangible impact on healthcare. Over the years I have developed many different medical devices in such diverse areas as hematology, urology, gastroenterology, POC biomarkers, antibiotics susceptibility testing and hearing aids. I have been part of development teams both as a developer and as R&D manager and I therefore am able to see a development project from multiple perspectives, blending technical expertise with strategic vision to ensure successful execution and innovation. My experience in the realm of medical device development has also ensured me a thorough understanding of the regulatory landscape and the importance of adhering to stringent industry standards.

Software development

I have developed software for more than two decades. My expertise covers both firmware development for the simplest PIC processors with only 512 bytes of storage, all the way to Windows application programming. I have programmed in several programming languages such as C, C++, C#, Java, JavaScript, PHP and assembler to name a few, and developed for different operating systems such as Windows, Windows CE, Android and ROS. When it comes to web development my experience covers topics such as AJAX, JQuery, JSON, MySQL, PostgreSQL, ASP.NET, HTML/CSS3, Facebook API and other web technologies. I have made printer drivers, algorithms for tracking objects in 3D space, UI for hearing aid fitting software, interfaces for nano sensor hardware, and much more.

Project management

My proficiency in project management further enables me to drive complex initiatives forward, ensuring timely delivery and successful outcomes. Throughout my career, I have had the privilege of collaborating with diverse teams and stakeholders to overcome obstacles and achieve shared objectives. I pride myself on my ability to communicate effectively, build strong relationships, and inspire others to strive for excellence. With a results-driven approach and a commitment to continuous improvement, I am poised to tackle the next challenge and make a meaningful impact in the field of healthcare innovation.

In summary, I am a dynamic professional with a multifaceted skill set and a passion for driving positive change in the healthcare industry. Whether it's consulting on medical

device development, leading R&D initiatives, or being part of a software development project, I am dedicated to delivering value and exceeding expectations at every turn.

STRENGTHS ❖ Proactive and outgoing personality

QUALITIES ❖ Team player as well as self-sorted

- ❖ Positive attitude,
- ❖ Solution oriented and trouble shooter
- ❖ Think out of box when needed

EXPERIENCE ❖ 20+ Yrs experience within Medical Device development, from various positions

TECHNICAL SKILLS ❖ Broad and deep understanding of all areas within QA, as well as Regulatory

- ❖ Risk management with a pragmatic guidelines to secure compliance
- ❖ Broad experience of both software development as well as documentation
- ❖ FDA 510 K and European Notified body demands
- ❖ Participated in several submission towards FDA and NB

IT ❖ Microsoft office

SOFTWARE SKILLS ❖ Software programs from several suppliers

- ❖ various QMS systems at all levels

EDUCATION AND DEGREES 1997 B.Sc. Electrical Engineering – Technical University of Denmark

LANGUAGE SKILLS	Danish	Written & spoken	Native
	English	Written & spoken	Fluent

PROFESSIONAL BACKGROUND

2023 - Present

[Dahlfelt Consulting](#) | Senior Consultant ...

Consultancy tasks within Pharma and medical Device.

Tele Technology

Founder of Tele Technology, working with contract development and consulting services

Founder & Senior Consultant

1996 – present

As the founder of Tele Technology, I am making use of my skills within research and development, QA/RA and project management. My specialty is development and approval of medical devices, but I also use my experience from such areas as telecommunications, robots, nano-sensors, vertical farming and fitness gear, to help other companies for shorter and longer periods.

My core expertise include:

- **Project management** – I have extensive experience with project management, hereunder:
 - **Project planning:** Defining project scope, objectives and deliverables. Develop project plans, timelines and resource allocation.
 - **Team management:** Assemble project teams, assign tasks, and set clear expectations. Motivate and support team members to ensure they have the resources needed to complete their work effectively.
 - **Communication:** Facilitate communication between team members and other project stakeholders. Provide regular updates on project progress, risks and issues.
 - **Risk management:** Identify potential risks and develop strategies to mitigate them. Monitor risks throughout the project lifecycle and implement contingency plans as needed.
 - **Budget:** Develop project budgets and track expenses. Monitor costs throughout the project and ensure that the project stays within the budget.

- **Software development** – I have 15+ years of experience with both embedded application programming and have programmed in several languages such as C++, C#, PHP, Java, JavaScript and assembler. I have developed software for Windows, Windows CE, Android, and web (AJAX, JQuery, JSON, MySQL, PostgreSQL, ASP.NET, HTML/CSS3, Facebook API and other web technologies). I have made printer drivers, algorithms for 3D models, UI for hearing aid fitting software, interface for nano sensor hardware, and much more.
- **QA/RA** – I have substantial experience developing medical devices under a FDA 510(k) and I have worked in areas such as hematology, gastroenterology, biochemistry, urology, antibiotic susceptibility testing and hearing aids. My QA/RA experience include:
 - Development according to ISO 13485, MDD and 21 CFR Part 820,
 - Development of medical device software according to ISO 62304
 - Design Inputs – Functional Requirement Specifications, Software Requirements according to ISO 62304, Risk Analysis and User needs
 - Design outputs – Design Verification planning, System Risk Evaluation
 - Design Verification – Design Verification report, Test protocols
 - Maintaining the DHF
 - Risk management according to ISO14971



NextFood Aps

NextFood developed, manufactured and sold vertical farming systems

Operations Manager

September 2020 – February 2023

NextFood was a small start-up company that developed, manufactured and sold vertical farming systems. In addition to the core business, NextFood also built a demo farm to prove the functionality of the technology stack. As Operations Manager my key objective was to ensure that the organization operated smoothly and in alignment with NextFood's goals. And as in most small start-ups my responsibilities constantly changed and evolved. Besides day-to-day administrative activities, my responsibilities included these areas:

- **Project management** - hereunder planning assembly of new vertical farms, resource allocation, procurement of equipment, communication with outside stakeholders such as facility managers, and hosting project meetings.
- **Support** for existing customers (Carlsberg, Meny, Sunset Boulevard, Inco, various restaurants and office canteens), mainly technical support, e.g. determining root cause of system break downs and dispatching technicians as needed, but also support for plant growth in in-store systems.
- **Orders, logistics and invoice management** - responsible for handling orders in Nextfood's proprietary order handling system, and for ensuring proper deliveries of all fresh produce (herbs) for all customers. This included making delivery schedules for NextFood's internal and external drivers. Also, I created a new customer pick-up solution equivalent to parcel shops, but for fresh herbs instead. Also responsible for ensuring invoices were issued and paid.
- **Procurement and sourcing** - responsible for keeping sufficient stock levels of packaging material, e.g., labels, cardboard boxes and plastic bags and boxes for packaging fresh herbs. Also responsible for sourcing components for building farm systems such as valves, pumps, tubes, electrical components, LED lamps, steel frames, grow boxes etc. Identifying new second source suppliers for critical components, and getting quotes and arranging freight from suppliers in China, Lithuania, etc.
- **Inventory management** - implemented a new inventory system (ODOO) and ensured that the inventory always was accounted for and adequate for building a set number of farm systems.
- **Packaging solutions** - managed research and development of several packaging solutions for cut and rooted fresh herbs.
- **Sales** - did in-store product promotions, did cost-benefit analyses and calculated required margins for fresh produce to be sold in supermarkets, wrote marketing material, product presentations and project proposals for new customers, made contracts including budgets for subscription based models and capex models, set up and participated at exhibition booth at TechBBQ, monitored sales and acted as KAM, and to a lesser degree did direct canvassing for new customers.
- **General administrative tasks** – day-to-day general administrative tasks included getting service for the company car, arranging social events for the employees, transport of 40 feet cooling containers, ensuring a valid APV and being part of the AMO, managing email and office 365 subscriptions and accounts for all employees, and taking care of the lunch catering for the staff

Medico Support A/S

Sales Manager – Products

February 2019 – August 2020



- Responsible for sales to pharma and energy sectors of equipment and sensors, hereunder particle counters, microbial air samplers, gas analyzers, temperature and pressure data loggers, dew-point transmitters, etc.
- Managing the full sales cycle from lead generation, over customer visits, proposal writing, deal closing, and after sales follow up
- Order management, responsible for receiving and entering orders in e-conomic, purchasing, and shipment to customers
- Lead generation through cold calling, cold emailing, attending conferences and through digital marketing
- Email campaigns to existing customer base, SEM campaign for generating new leads
- Responsible for development of sales and marketing strategies
- Responsible for IT systems related to sales including:
 - Analysis and introduction of CRM in the sales process
 - Project management and implementation of Calibry, a type of management tool designed for calibration/metrology companies to help track calibration processes and equipment certificate generation
- Responsible for forecasts to Medico Supports suppliers
- Support and follow up on customers



fittBell

fittBell develops fitness equipment for home training

Founder

January 2017 – January 2019

- Inventor of a new concept for home training using supervision by a persona virtual instructor
- Development of business plan including business model, go-to-market strat sales plan and market- and competitor analysis
- SoMe market investigation using Facebook and Google Forms
- Definition of requirements for, and development of, Android app including Bluetooth communication to proprietary fitness equipment and client/serve communication to exchange workout and user data
- Algorithm development utilizing neural networks, Kalman filters and mathematical concepts such as Rodrigues rotation formula, 3D matrix manipulation, Euler angles and quaternions
- Definition of database structure and server data exchange of customized fit programs
- Definition of requirements for, and development of, completely customized website using PHP server scripts, SQL (MariaDB), JavaScript, JQuery, CSS3, AJAX, JSON, Facebook API, MediaStream Recording and other web technol
- Definition of requirements, design and development of small embedded PIC microcontroller system for integration with fitness equipment, including electronics design, PCB design and embedded SW
- Construction and manufacturing of 3D printed mechanical parts for propriet fitness equipment

- Identification and validation of manufacturers of for high volume manufacturing in China and Vietnam



Philips BioCell

Philips BioCell manufactured and sold digital microscopy equipment

Business Development Manager

September 2016 – December 2016

- Built business cases for new business areas such as algae detection in drinking water, detection of crystals in pharmaceuticals, detection of parasites in poultry meat, detection of candida fungi in whole blood, a.o.
- Performed market analysis, investigated competing technologies/ companies and customer needs
- Identification, negotiation and contract drafting for new distributors

International Sales Manager

May 2013 - August 2016

- Sold capex equipment (digital microscopy systems for detection of bacterial growth) for academia and food industry (Dupont, PepsiCo Inc., Chr. Hansen CDC, a.o.)
- Successfully secured contracts up to 100k€. Total capex sales budget for the last year was 2M€, personally accounted for 35%.
- Covering North America, Europe and Asia.
- Built the sales organization from scratch and defined sales strategy, target segment and market introduction
- Developed marketing material (printed material, video presentation, digital marketing, etc.)
- Identified, planned and participated in international trade shows and conferences in US and Europe
- Identified and established contact with new leads by cold calling, cold mail and through conferences
- Responsible for sales reporting to CEO and forecast for production
- Performed job interviews and participated in hiring new account managers
- Responsible for training of new key account managers in how to use the system and how to approach new customers
- Assigned responsibility for training and support of existing customers to account managers using a country specific strategy
- Identification of new product applications
- Provided feedback for development for implementation of new features

Project Manager

January 2011 – May 2013

- Project manager for a new automated digital microscopy system. Manager of project team of 8 persons (SW, HW, mechanics, optics, testing, image processing)
- Project planning, risk management, user needs, requirement specification, documentation, working under ISO9001 and ISO13485.

Chempaq A/S

Chempaq manufactured POC hematology equipment

R&D Manager

May 2008 – November 2010

- Responsible for product development, platform strategy and innovation
- Project management of team of 9 (SW, HW, test, external consultants) and responsible for budget (3.5m€)
- Coordinated with QA/RA, production, sales and marketing
- Identification of technologies and components for cost reductions
- Specification of instrument for international partner, and coordination of all activities relating to this project. (Potential value of this project: 10 m€)
- Contacted, supported and negotiated with international distributors, suppliers and customers. E.g. contact to US Navy and US State Department in order to seek out the opportunities for using the Chempaq technology in submarine embassies worldwide
- Hands-on experience with various software technologies: Client/Server architecture, ASP.NET, SQL, Windows CE 6.0, .NET/C# and embedded programming
- Working according to 21 CFR 820, MDD 93/42/EEC, ISO62304, ISO9001 and ISO13485

Atonomics A/S

Atonomics develops and markets POC medical equipment for biomarker diagnostic

Project Manager

July 2007 – April 2008

- Project Manager for team of 7 (SW, HW, external consultants)
- Developed prototype of new instrument based on new measurement principle and reached critical milestone
- Co-inventor of patented principles for disposable cartridge containing blood filtration unit and detection by use of magnetic particles
- Working according to ISO9001 and ISO13485

Software Architect

February 2007 – June 2007

- Responsible for embedded SW in *Atolyzer*, covering areas such as specific design, implementation, test and localization
- Developed algorithms for calculation of result and execution of assay procedure for "heart attack marker" (BNP)
- Developed software modules for control of stepper-motor, LCD, keyboard, U communication with PC (slave) and barcode scanner and mouse (host), and measurement of PMT (Photo Multiplier Tube)



XPonCard A/S

XPonCard developed, manufactured and market SIM cards for mobile phones

Software Architect

February 2006 – January 2007

- Definition of new software architecture for processor-independent SIM platform
- General maintenance of existing code and configuration of customer defined menus in mobile phones
- Developed ASP.NET application and PostgreSQL database for storing, sorting and retrieval of mobile phone features



Cantion A/S

Cantion developed nano-cantilever bio-chips for life-science and homeland security

Software Architect

October 2004 – February 2006

- Responsible for all phases of PC application development of *CantiView* and *CantiLab*
- Transfer of know-how about embedded software used for data acquisition bio-chip
- Developed DSP code for SW implementation of lock-in amplifiers and FIR f
- Developed C code for control of pumps and valves on RS232/RS485, PID temperature control and USB slave controller



Medtronic / Trivirix

Medtronic develops and manufactures diagnostic equipment for gastrointestinal, urological and neuromuscular illnesses and disorders in the digestive tract, the urin tract and in the nervous and muscular systems

Software Application Engineer

September 1998 - September 2004

- Responsible for technology transfer at the merger of Dantec Medical, Copenhagen and Synetics, Stockholm
- Team lead for release of *Digitrapper* – a pH monitor for the esophagus
- Team lead for release of *Urodyne* – a urine flow meter
- Developed Windows CE real time programming, GUI, localization, driver development and documentation
- Technical responsible at acquisition of Endonetics, San Diego, CA.



Oticon

Oticon develop and market hearing aids

Project manager

March 1998 – August 1998

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- Project manager for *EasyFit* – a handheld device for configuration of digital hearing aids
 - Collaboration with consultants, electro acoustics, IC-developers, audiologists and marketing

Software Application Engineer

September 1997 – February 1998

- Development of GUI for Windows application for configuration of digital hearing aids
 - Development of mathematical models in cooperation with electro acoustics
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