DAHLFELTCONSULTING

SENIOR CONSULTANT CV:

QA, RA, RISK, PROJECT MANAGEMENT

Software development and documentation

Name	Klaus Rune Andersen
Nationality	Danish
Gender	Male
Domicile	Denmark

CONTACT INFORMATION

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KLAUS RUNE ANDERSEN - CURRICULUM VITAE

PERSONAL LETTER

Medical device development

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

Software development

Klaus has developed software for more than two decades. His expertise covers both firmware development for the simplest PIC processors with only 512 bytes of storage, all the way to Windows application programming. Klaus has 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 Klaus' experience covers topics such as AJAX, JQuery, JSON, MySQL, PostgreSQL, ASP.NET, HTML/CSS3, Facebook API and other web technologies. He has 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

A great proficiency in project management further enables Klaus to drive complex initiatives forward, ensuring timely delivery and successful outcomes. Throughout his career, he has had the privilege of collaborating with diverse teams and stakeholders to overcome obstacles and achieve shared objectives. Klaus prides himself on his ability to communicate effectively and build strong relationships and inspire others to strive for excellence. With a results-driven approach and a commitment to continuous improvement. Klaus is ready to tackle the next challenge and make a meaningful impact in the field of healthcare innovation.

In summary

Klaus is a dynamic professional consultant 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, he is dedicated to delivering value and exceeding expectations at every turn.

STRENGTHS

- Proactive and outgoing personality
- Team player as well as self-sorted
- Positive attitude,
- Solution oriented and trouble shooter
- Think out of box when needed

EXPERTISE

- 20+ Yrs experience within Medical Device development, from various positions
- Broad and deep understanding of all areas within QA, as well as Regulatory
- Risk management with a pragmatic approach 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 SKILLS

- Microsoft office
- 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

2024 - Present

DahlfeltConsulting | Senior Consultant

Consultancy tasks within Pharma and medical Device.

1996 – present

Tele Technology | Founder & Senior Consultant

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

Expertise includes:

- Project management – Extensive experience with project management:
    - 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 – 15+ years of experience with both embedded and application programming and have programmed in several languages such C, C++, C#, PHP, Java, JavaScript and assembler. Klaus has developed software for Windows, Windows CE, Android, and web (AJAX, JQuery, JSON, MySQL, PostgreSQL, ASP.NET, HTML/CSS3, Facebook API and other web technologies). He has made printer drivers, algorithms for 3D models, UI for hearing aid fitting software, interface for nano sensor hardware, and much more.

⁘ QA/RA – Substantial experience developing medical devices under a QMS and 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
- Design Transfer - Maintaining DHF and DMR, define test strategy for incoming, in-process and final acceptance testing, procedures for identification and traceability of product, plan for monitoring of features identified as critical to quality.
- Review of electrical safety in accordance with ISO 60601
- Risk management according to ISO14971

June 2024 – Dec. 2024

GN – Hearing | Consultant

To support the regulatory product compliance team, Klaus worked with multiple tasks. The major tasks included:

⁘ Rewriting GN's Design Control Procedure - to be in accordance with requirements of ISO 13485 and CFR Part 820, the existing design control procedure was completely rewritten to cover the following topics: User Needs, Design Input, Design Output, Design Review, Design Verification, Design Validation, Design Transfer and Design Changes.

⁘ Updating documentation for an iPhone App - due to an update of IOS the app failed to pair with the hearing aids. This required a new version of the App and thereby

various documents had to be updated for FDA, hereunder Risk Analysis, test documentation and other documents.

- Updating documentation for fitting software – as part of a regularly scheduled release of the fitting software platform, all changes and new features were assessed for their impact on patient or user safety risks. Relevant documents were updated accordingly.
- Updating GN's Development Process - to be in accordance with the updated Design Control Procedure

August 2023 – May 2024

Blue Ocean Robotics | Consultant

BOR has developed a portfolio of mobile robots including the UVD, an autonomous disinfection robot. The task at BOR was to create the necessary documentation pertaining to the software (according to FDA's Content of Premarket Submissions for Device Software Functions) to get a 510k approval for the UVD robot. This task included writing the following documents:

- Software Requirements Specification – including user interface and safety system and in accordance with ISO 62304.
- Software Description – including overview of significant software features, functions, analyses, inputs, outputs, and hardware platforms. This also included review of the safety measures of the robot in accordance with ISO 60601
- System and Software Architecture Design – including detailed diagrams of the modules and interfaces, and data inputs/outputs and flow of data and interaction with the system
- Software Design Specification – including the technical design details of how the software functions and how the software design implements all the requirements of the SRS, and how the software design traces to the SRS in terms of intended use, functionality, safety, and effectiveness.
- Documentation Level Evaluation – a description and rationale for the documentation level (the UVD was Enhanced Documentation Level)
- Software Testing as Part of Verification and Validation - A summary description of the testing activities at the unit, integration and system levels, and unit and integration level test protocols including expected results, observed results, pass/fail determination, and unit and integration level test reports.

Sep. 2020 - Feb. 2023

NextFood Aps | Operations Manager

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 Klaus' 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.

Feb. 2019 - Aug. 2020

Medico Support A/S | Sales Manager – Products

Medico Support provides calibration services and is a distributor of equipment to pharma and energy industries:

- 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

Jan. 2017 - 2019

fittBell | Founder

FittBell develops fitness equipment for home training:

- Inventor of a new concept for home training using supervision by a personal virtual instructor
- Development of business plan including business model, go-to-market strategy, 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/server 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 fitness 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 technologies
- 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 proprietary fitness equipment
- Identification and validation of manufacturers of for high volume manufacturing in China and Vietnam

Sep. 2016 – Dec. 2016

Philips BioCell | Business Development Manager

Philips BioCell manufactured and sold digital microscopy equipment

- Built business cases for new business areas such as algae detection in drinking water, detection of crystals in pharmaceuticals, detection of parasites in pork 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

May 2013 - Aug. 2016

Philips BioCell | International Sales Manager

- 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 mailing 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

Jan. 2011 – May 2013

Philips BioCell | Project Manager

- Project manager for a new automated digital microscopy system. Management 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.

May 2008 - Nov. 2010

Chempaq A/S | R&D Manager

Chempaq manufactured POC hematology equipment:

- 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 submarines and 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

July 2007 – April 2008

Atonomics A/S | Project Manager

Atonomics develops and markets POC medical equipment for biomarker diagnostics:

- 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

Feb. 2007 – June 2007

Atonomics A/S | Software Architect

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

Feb. 2006 – Jan. 2007

XPonCard A/S | Software Architect

XponCard developed, manufactured and market SIM cards for mobile phones:

- 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

Oct. 2004 – Feb. 2006

Cantion A/S | Software Architect

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

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

Sep. 1998 - Sep. 2004

Medtronic / Trivirix | Software Application Engineer

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

- Responsible for technology transfer at the merger of Dantec Medical, Copenhagen and Synetics, Stockholm
- Team lead for release of Digitrapper – a pH monitors 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.

Mar. 1998 – Aug. 1998

Oticon | Project manager

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

Sep. 1997 – Feb. 1998

Oticon | Software Application Engineer

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