

DAHLFELTCONSULTING

CONSULTANT CV WITHIN QA, QMS, SUBMISSION, PM

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TIM DAMGAARD CHRISTENSEN - CURRICULUM VITAE

PERSONAL LETTER

Designer of Businesses, of strategies, tactics, operations, and of organizations, with a sense for turning bright ideas into innovation and new opportunities, tangible results, change and positive effect – always with a high ambition level. Change generalist with a keen eye for uncovering the impediments that needs attention when execution suffers, regardless of whether it is innovation itself, funneling innovation into a strategy, or the execution of strategy.

Project Management Professional and Program Manager with focus on doing the right thing, the right way. A focus that extends beyond formulated goals; a sense for change and for being an enabler of efforts that makes a difference.

With a holistic view of technology, goals, effects, benefits and desired changes. With extensive experience and results from high tech product development and medical device industries, including compliance with latest regulatory requirements and standards. Sought after coach and mentor for Program and Project Managers.

Results include:

- ❖ Cutting development execution timelines by up to 50%, without sacrificing quality or cost constraints.
- ❖ Launching products that showed a minimum 200% ROI within 1-2 years.
- ❖ Leading development teams, under extremely harsh constraints, to success, where others have failed.
- ❖ Transforming organizations, processes, and culture to adapt to an agile and rapidly changing reality.

STRENGTHS

Tims career is characterized by three distinct stages:

1. Development engineer (6 years). Engineering high tech solutions within software, embedded software, and software-hardware interfacing.
2. Project Management Professional (15 years). Managing and leading technology and product development projects and programs, with a wide range of budgets and team sizes. Obtained the PMP certification (in 2007) as part of this stage.
3. Management Consultant (6 years). Founder and Senior Consultant of management consultancy companies, with main focus on helping organizations with difficulty in project/program/strategy execution, as well as acceleration of early-

stage startups in the MedTech industry. Obtained the eMBA and MMT diplomas (in 2019) as part of this stage.

EXPERTISE

- ❖ eMBA, MMT, and Founder & Senior Consultant within Management Consulting, with main focus on helping organizations with difficulty in execution.
- ❖ Project Management Institute certified Project Management Professional since 2007, and volunteer to the Board of the Danish chapter.
- ❖ Leading change and transformation efforts in varying organizations very different in nature and size.
- ❖ Leading development efforts in multi-cultural and multi-disciplinary (incl. AGILE) environments. Some of very large scale, all business critical and with a high degree of complexity.
- ❖ Up to 200+ staff members, 20+ projects, and budgets up to 300 million DKK.
- ❖ Leading virtual teams with representatives from very different geographical locations.
- ❖ With varying expertise; Software, firmware, hardware, mechanical, biologic production, antibody, mobile apps, etc.
- ❖ Team lead for highly skilled technical experts.
- ❖ Building high performing project and project management teams.
- ❖ Development and implementation of performance measures.
- ❖ Development and implementation of lifecycle processes.
- ❖ Medical device development and quality management
- ❖ ISO 13485, 14971, 62366, MDD 93/42/EEC, MDR 2017/745, 21 CFR 820.
- ❖ Compliance with regulatory requirements for medical device and pharma manufacturing, and project managing medical device and pharma products maturity for production.
- ❖ Process validation (Medical Device/IVD), FMEA, PFMEA, GDP.
- ❖ GMP, GaMP, 21 CFR 210/211, EU Guidelines for GMP Part I/II.
- ❖ Wireless medical device requirements, FCC, RED/R&TTE, UDI.
- ❖ Coordination of, and participation in, competent authority's inspections and audits.
- ❖ Background in electrical engineering and digital audio and video signal processing.

EDUCATION AND DEGREES

2019 eMBA, Master in Management of Technology (DTU Business)

All aspects of business design and transformation, incl. strategy, marketing, financial analytics and management, organizational design and development, communications management, international business and management, service and operations management. This, with particular focus on management of technology, innovation management, and personal leadership.

2007 PMPTM, PMI project management model training and PMP training (DIEU; later known as Mannaz).

Project Management Institute project management model and Project Management methods, procedures and skill set.

1996 B.Sc.E.E. (Engineering College of Copenhagen)

Formal education for the "Bachelor of Science and Electronic Engineering" degree, specializing in Digital Signal Processing. English based, with lessons run in English, all written material in English and all exams in English. Top 5 grade level for that year.

CERTIFICATIONS AND COURSES

2019 eMBA - Master in Management of Technology

Innovation, digitalization, and leadership are essential to the growth and survival of companies. DTU's Executive MBA focuses on Leadership, Innovation, and New Business Creation using current and future technologies.

DTU Executive MBA is accredited by AMBA, the Association of MBAs.

2012 GN Great Nordic Advanced Leadership Development Program (Global Mindset; training contents defined in cooperation with GN management and HR).

Training in general leadership skills, both soft and hard skills, focused specifically at people management, and managing managers.

2009 Chinese Intercultural Understanding (Eduka; Hired by GN Great Nordic to implement different courses).

Training in Chinese culture and history, and how that affects today's Chinese culture, with focus on understanding Chinese behavior and work ethics.

2005 GN Great Nordic management training (GN Great Nordic; employer defined training).

Training in general leadership skills mainly focused at the soft skills. Tailored to the GN Great Nordic organization.

2003 - 2004 GN ReSound Project Navigator (Partly hosted by GN ReSound hand-picked management psychologists and partly hosted by AMA - American Management Association).

Training in project management disciplines, both soft and hard skills. Training tailored to GN ReSound, with focus on navigating in a global, multi-cultural environment.

1998-2002 Education provider defined exam's in a wide range of technical hard skills.

- ❖ Object Oriented Analysis & Design
- ❖ C++ Programming
- ❖ UML
- ❖ Rational Rose & Rational ClearCase

Superusers A/S, Microsoft Education Provider.

Teknologisk Institut A/S, Danish university level Education Provider.

LANGUAGE SKILLS

Danish	Written & spoken	Native
English	Written & spoken	Fluent
German	Written & spoken	Business

PROFESSIONAL BACKGROUND

2023 - Present

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

Consultancy tasks within Pharma and medical Device.

Jan. 2022 - Present

[MedTech Bridge ApS | Founder and Managing Partner](#)

We want to help realize the next \$1B EU MedTech company, and create a reality where EU MedTech innovation deliver quality solutions for the healthcare challenges of the future.

We do this by providing strategic and tactical advice and planning to EU MedTech companies seeking US market entry. We support the EU MedTech eco-systems becoming the preferred source of innovation for US MedTech companies.

Excerpt of accomplished work and tasks

- ❖ Connected leading innovator in AI based radiology with US partner.
- ❖ Connected leading innovator in AI based neuro based health assessment with US partner.
- ❖ Build 15+ US MedTech go-to-market strategies.
- ❖ Arranged 9 customized US visit to the world's #1 healthcare eco-system.
- ❖ Arranged 20+ educational webinars on US MedTech go-to-market strategy.

MedTech Bridge (ApS) is an independent entity and network, that works through partnership with the Medical Alley Association, and built with support from the Danish Industry Foundation, DTU Learn for Life, Medico Industrien, and Greater MSP.

Feb. 2017 - Present

[Damgaard Christensen Consulting ApS | Founder and Senior Consultant](#)

Provides consultancy services within all areas related to an organization's ability to execute, and execute according to the strategy. This could be in the areas of Innovation, Portfolio, Program or Project Management, Leadership, Project Office and Project Management Office, Governance, Organizational setup, Program and Project Management Models, Process analysis and development, Risk Management, and many other aspects, and always with a holistic approach towards a complete solution.

Excerpt of accomplished work and tasks

- ❖ Functioning Managing Partner for MedTech Bridge, accelerating and shortening the path to the US market for small innovative Danish, Swedish, and Finnish startups in the medical device industry.
- ❖ Managing a larger change effort, with a large OMXC25 company in the medical device industry, to transform the organization to work effectively with the new EU MDR (Medical Device Regulation), effective from May 2021.
- ❖ Assisting same company with the preparation for FDA inspection, incl. needed updates to existing device documentation, needed updates to quality management systems, and accompanying change management.

- ∴ Assisting same company with the preparation for notified body audit, incl. needed updates to existing device documentation, needed updates to quality management systems, and change management.
- ∴ Assisting a company, in medical business, with the transfer of selected business systems, and corresponding change management, as a result of the integration into a US based Mother Company.
- ∴ Define and implement a lean project management model in a high-tech engineering company, exhibiting large growth over many years, resulting in a need to execute business differently.

Damgaard Christensen Consulting (ApS), is a quality provider in the consultancy services industry.

Nov. 2015 - Jan. 2017

[GN Otometrics](#) | Program Manager, Global Research & Development

Leading a team of highly skilled and technical experts within their area of expertise, providing engineering for the world's best instruments within audiometry, tympanometry, immittance and hearing instrument fitting.

Program and project managing complex product development Programs and Projects, covering the entire lifecycle of product development, from Idea to Launch, and involving project teams of up to 25 team members.

As a part of the management team in Research & Development, participate in the development of the strategy for R&D, as well as initiating improvement projects. Also, participation in the Steering Committee for R&D, initiating and closing projects, based on project status, priority (incl. financial assessment) and capacity.

Excerpt of accomplished work and tasks:

- ∴ Project planning and execution of firmware development for GN Otometrics' latest immittance instrument, the "Madsen Zodiac".
- ∴ Project planning and execution of a platform project to develop the foundation for GN Otometrics' next generation audiometers.

GN Otometrics is one of the world's leading companies within the audiology industry. GN Otometrics is known for supplying complete solutions with a high degree of user centricity, and solutions within all aspects of audiology.

Sep. 2015 - Oct. 2015

[NNE Pharmaplan](#) | Project Manager

Leading and managing projects, as defined in agreements and contracts with customer, in the consulting engineering business. Projects are very divergent, and complexity and size depends 100% on customer needs. Some projects are very complex, and need involvement of in-house project team members with high technical and specific expertise. Other projects deal with changes to operational setup, and need a high degree of involvement from customer staff. Common for all types of projects is a very narrow window of opportunity for operationalizing project outcomes in customers' facilities; Facilities that cannot afford to have noticeable downtime.

Excerpt of accomplished work and tasks:

- ∴ Project planning of separation of cooling water used in insulin production, from district heating cool water.

NNE Pharmaplan is a spin-off of Novo Nordisk and is one of world's premier pharma engineering companies.

June 2013 - May 2015

[DAKO - Agilent Technologies](#) | Senior Project Manager, Diagnostics and Genomics Project Management

Project leading and managing product development projects, covering the entire lifecycle of product development, from Initiation to Post Launch reviews and closure. Some of complex nature, involving project teams of highly skilled technical experts. Project management of in-house product development projects, out of development centers in Denmark and USA. With that follows introduction of newly developed products to production facilities in Denmark and USA also, and by use of a global base of sub-suppliers, depending on the market segment of the product under development.

Excerpt of accomplished work and tasks:

- ∴ Project managing Dako's first Class III medical device for the fully automated, IVD qualified stainer, the Dako Omnis: HER2 IQ FISH FarmDx for Omnis.
- ∴ Project managing a set of Dakolink software releases. A pathology laboratory office and workflow software for minimizing effort between tissue sampling and first diagnosis.

Pathologic cancer diagnostics based on Immunohistochemistry, Molecular Pathology, Flow Cytometry, and other technologies. Dako is globally known for its market leading technologies and quality of diagnosis.

May 2012 - May 2013

[GN ReSound A/S](#) | Program Manager, ReSound and Interton Product Integration/Product Development, Research & Development

Program managing complex product development programs, covering the entire lifecycle of product development, from Initiation to Launch, and involving project management teams of 4-8 project managers.

Excerpt of accomplished work and tasks:

- ∴ Program managing a major ReSound brand product development program to launch a new generation of cosmetic, miniature, micro BTE's, "ReSound LiNX", with accompanying accessories and apps, e.g. the "ReSound Control" app.
- ∴ Program managing a major ReSound and Beltone brand product development program to launch ReSound Group's first open platform digital super power products in both budget and premium price point families; "ReSound Up", "ReSound Verso", "Beltone Origin" and "Beltone Promise".

∴ Participate in workgroup to define GN ReSound's new program management product development process, the NPD.

Hearing Healthcare. GN ReSound A/S is a provider of high-tech hearing aids and solutions for the hearing impaired.

Oct. 2010 - Apr. 2012

[GN ReSound A/S | Senior Project Manager, ReSound and Interton Product Integration, Research & Development](#)

Project managing product development projects, covering the entire lifecycle of product development projects, from Initiation to Launch.

Excerpt of accomplished work and tasks:

∴ Project managing a series of ReSound brand product development projects to further build on the success of the "ReSound Alera" and "ReSound Unite" products, as well as introduce a new product, "ReSound Lex".

Nov. 2009 – Oct. 2010

[GN ReSound A/S | Senior Project Manager, ReSound and Interton Product Integration, Research & Development](#)

Project managing the largest product integration project in ReSound history. Directing all related sub-projects, both technology projects and platforms projects, involving more than 20 development projects, combined project teams of more than 200 people, and a combined project budget of more than 500 million DKK. All to ensure ReSound's position as the technology leader in the industry. Ensuring full project transparency and providing the direction needed to succeed in a complex cross-discipline project environment suffering from a history of multiple delays and budget overruns. Same ownership as mentioned in job description above.

Excerpt of accomplished work and tasks:

∴ Managing product integration project to ensure timely delivery of "ReSound Alera" and "ReSound Unite" products with quality. This includes managing all legal, FCC, IEC, RTT and Medical Device Directive approvals in time for product introduction at the AAA convention in April 2010, and for global launch in July 2010.

∴ Project directing all platforms and technology projects, aimed at the "ReSound Alera" and "ReSound Unite" products.

Oct. 2007 – Nov. 2009

[GN ReSound A/S | Project Manager, ReSound and Interton Product Integration, Research & Development](#)

Project managing product development projects, covering the entire lifecycle of a product development project, from Initiation to Launch. Same ownership as mentioned in job description above.

Excerpt of accomplished work and tasks:

- ∴ Project managing a wide range of ReSound brand product development projects to either develop new products or extend existing product ranges, including (but not limited to) the product projects: "dot by resound", "ReSound Essence", "ReSound Essence Lite" and "ReSound Azure". The projects are cross-functional with involvement of many technical disciplines, including hardware design and construction, software design and development, electro-acoustic design and verification. Interface to projects extends out of the Research & Development department and includes project management of, and communication and requirements handling in cooperation with Product Management, Global Marketing and Corporate Quality.
- ∴ Participation in updating and formulating the development process used in R&D projects, the PLC. Aim: Common product development methodology compliant with requirements for medical device development: ISO, MDD and FDA.
- ∴ Defining training material and conducting training, in Project Management methodology for company departments outside R&D: Product Management and Global Marketing.

Dec. 2002 – Oct. 2007

[GN ReSound A/S | Software Project Manager, Fitting Software Group, Research & Development](#)

Leading 4-6 individual development projects per year, all covering the entire lifecycle of a product software configuration project from Definition to Support.

Excerpt of accomplished work and tasks

- ∴ Managing several product software configuration projects for the ReSound and Beltone brands, including (but not limited to) the software configurations for the products: "Resound Metrix", "Resound Pixel", "Resound Plus5", "ResoundAir", "Resound Azure", "Resound X-plore", "ReSound Ziga", "Beltone Oria", "Beltone Mira", "Beltone Arca", and "Beltone Corus". Most of the projects were managed in close cooperation with a fitting software development unit in Chicago, USA, as well as product management in Copenhagen, Denmark.
- ∴ Instrumental in designing, planning and implementing a software development lifecycle process (SDLC) in GN ReSound. This process was used in multiple development groups in the R&D organization. Aim: Common software development methodology and common quality standards.
- ∴ Instrumental in designing, planning, implementing and training in a project performance measures process. Aim: Providing a vehicle for a performance driven culture in product development projects.

Nov. 1998 – Nov. 2002

[GN ReSound A/S | DSP and systems software developer, DSP & System Software Group, Research & Development](#)

Developing highly specialized and highly optimized algorithms for hearing aids as well as PC software for hearing aid communication protocols and controls.

Excerpt of accomplished work and tasks:

- ❖ Co-architect on next generation hearing aid processor communications protocols and controls.
- ❖ Development of battery-life-time focused algorithms for a hearing aid processor.
- ❖ Hybrid test systems and final device test systems development.
- ❖ Factory acceptance testing software development.

Nov. 1996 – Nov. 1998

Reson A/S | Development Engineer, Research & Development

Development of both software and hardware solutions for various aspects of the R&D responsibilities, both development work and production equipment.

Excerpt of accomplished work and tasks:

- ❖ High speed data acquisition and data compression software for the "Reson SeaBat" multi beam sonar system processor.
- ❖ Part of an EU project to development software for assessing and measuring fish biomass using multi beam sonar equipment, including interfacing to navigation and "heave/pitch/ roll" physical movement sensors.
- ❖ Development of software and hardware controls for applying multi beam sonar use in a mine sweeper application, including installation in Navy mine sweeping boats (NATO).

Underwater Acoustic Solutions - Reson A/S is a provider of high-tech underwater high frequency measurement equipment for the off-shore oil industry, dredging and mining.

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