

# DAHLFELTCONSULTING

SENIOR CONSULTANT WITHIN QA, VALIDATION, RISK  
PM, STERILISATION AND REGULATORY AFFAIRS

CONTACT INFORMATION

Name           Palle Ravnsted-Larsen  
Nationality    Danish  
Gender         Male  
Domicile       Denmark

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## PALLE RAVNSTED-LARSEN - CURRICULUM VITAE

### PERSONAL LETTER

Palle is a Senior Quality Management Professional with substantial experience in Quality Management and people management from the medico industry covering medical devices, in-vitro diagnostic devices and manufacturing equipment for pharmaceutical production.

He has a strong focus on setting high standards and achieving the goals which supports company goals. Vision is that the management system of the company reaches best praxis and can be used as benchmark for similar companies.

As Quality Management Professional, Palle has a good knowledge of Quality Management Systems, Risk Management, Change management & Validation Activities (products and processes), Sterilization, Validation and verification Testing. All of the abovementioned systems were compliant with ISO standards (ISO 9001, ISO 13485, ISO 14971, ISO 11137), EU Directives (Devices and Pharmaceutical Production), and US GMP (for Devices and Pharma). New MDR and IVDR has been read, but no products certified to them.

Further emphasis has been on establishing i.e. documentation to be used in Quality Management Systems, Pre-Market Applications, Design History Files and Technical Files.

Supplier Audits, Internal Audits, Customer Audits, Regulatory Inspections by European and US Authorities and, participation in Regulatory Compliance Remediation Projects is also familiar to Palle.

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### STRENGTHS

#### Experience with development and manufacturing products

- ❖ Sterile In-vitro fertilization medical device
- ❖ In-vitro diagnostic medical device
- ❖ Sterile single use devices designed for in-vitro diagnostic
- ❖ Pharmaceutical production equipment for aseptic production, manufactured in clean room
- ❖ Biopsy equipment SIMS type (electronic and sterile equipment)
- ❖ Hearing aids, components for hearing aids and accessories to hearing aids
- ❖ Laser equipment for dermatology use
- ❖ Rubber products for the automotive industry

## EXPERTISE

### Professional competences and experience

- ❖ Working as consultant in FDA remediation program
- ❖ Working as consultant in Incoming Quality at Novo Nordic (Hillerød).
- ❖ Quality & Risk Management
- ❖ Project management and change management
- ❖ Product & Process Validation
- ❖ Sterilization Process Management
- ❖ Software Validation engagement
- ❖ Software, Validation & Auditing Management
- ❖ Supply quality Management
- ❖ Product Test Planning
- ❖ Practical Process Improvement Projects (PPI)
- ❖ Working in a multicultural environment, participation in development of national standards, participation in Danish standard association mirror groups
- ❖ Writing and collecting data for market application 510K, development of generic GMP documentation, cGMP for medical device 21 CFR 820, EU regulation on pharmaceutical production
- ❖ Medical device class III production of equipment for clinical evaluation
- ❖ Design history file and product documentation covering class I, II/IIa and III
- ❖ Travelling experience in Europe and the USA
- ❖ Communication with Notified Bodies and Auditing by Notified Bodies, and experience with Inspections by National Authorities

### Management responsibilities

- ❖ Direct line management, Experience in managing multiple departments
- ❖ Hiring and discharging experience, Practice in employee development and appraisal programs
- ❖ Experience in managing employees from hourly paid to Ph.Ds.
- ❖ Practice managing multiple production sites abroad and domestic
- ❖ Management of cross functional projects with eg. 15 project members across the value chain
- ❖ Member of the management team, Budget responsibility, Strategy process involvement

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## IT SKILLS

- ❖ Trackwise
- ❖ Agile
- ❖ MS Office
- ❖ D4 infonet

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## EDUCATION AND DEGREES

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|-------------|---|
| 1987 - 1990 | Teknonom in Quality management                                |
| 1986 - 1987 | Education as Technical Metrologist at Slagelse Tekniske Skole |
| 1985 - 1986 | Laboratory technician trainee, Tobias Jensen A/S, Glostrup    |

*Responsibility covered inspection of finished products, semi-finished products and incoming raw-material. Products were capacitors in a wide range used all over the industry from blast furnace to production of house hold equipment's and medical device pacemaker.*

1984 – 1985	Laboratory Technician course (ABCF), Slagelse Tekniske Skole
1982 - 1984	Hospital porter at Stege hospital
1981 – 1982	Sergeant, Royal Danish Navy
1979 – 1981	Hospital porter at Stege hospital
1978- 1979	Basic Industry education (EFG-basisår, Jern og Metal)

## CERTIFICATIONS AND COURSES

2024	EU-MDR 2017/745 Training, QbD group
2020	Auditor/lead auditor, Key2compliance.
2016	Regulering af medicinsk udstyr, Insights Events, conference.
2014	Regulering af medicinsk udstyr, IBC Euroforum, conference.
2012	Process Validation Widex training lectured by Bea Salis, external consultant
2012	Handling of customer complaints Widex training lectured by Bea Salis external consultant
2010	RAPS, Medical device directives: Lessons learned and the way forward.
2008	Implementing EN ISO 13485:2003 a Strategic decision at DS Certification.
2007	Thermo Fisher scientific. Management course module 2.
2006	Thermo Fisher scientific. Management course module 1.
2006	Thermo Fisher scientific. Process validation lectured by medical device Consult.
2006	Thermo Fisher scientific. Auditor re-training Lectured by ISO consult
2006	DS certified. Geometrical Product Specifications (GPS)
2003	The Manager as a Coach (2.4). The Danish Association of Managers and Executives
2002	FDA Premarket Notification 510(k) at DGM
2002	Auditing Sterile Medical Device Manufactures – CMD /Manchester University
2000	3.2 Lederens personlige ressource – The Danish Association of Managers and Executives
1999	2 EU Direktiver Medical Devices – DGM.
1998	4.2 Change Management – The Danish Association of Managers and Executives
1997	European and International Standardisation – Danish Standard Association
1997	Effective participation in Standardisation, Danish Standard Association
1996	Risk Assessment of Medical Devices, DGM
1995	Introduction to Quality, GMP and The Regulatory Environment, PUF
1995	Medical Devices – GMP and the basic requirements, DIEU nr. 2727, /
1995	GMP in praxis for Production, Maintenance and QC, DIEU nr. 2762
1993	Project Management course at Nunc 3 days
1992	Gilberts Quality Auditor course
1990	Quality Management systems DIEU nr. 3390
1987 – 1990	Teknonom in Quality Management

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

**PROFESSIONAL  
BACKGROUND**

2024 - Present

[Dahlfelt Consulting](#) | [Senior Consultant within QA, Validation, Risk, PM, Sterilisation and Regulatory Affairs](#)

Senior Consultancy tasks within Pharma and medical Device.

Mar. 2024 – Sep. 2024

[Thermo Fisher Scientific](#) | [Technical Quality Manager](#)

Responsible for team of 5 directs. Team responsibility Software validation, sterile barrier validation, RCA complaints and internal NCR and Risk management. Review and approval of validation documents from rest of local operation.

Support to QMS manger, local RA department and QC laboratory leader.

Arranging teambuilding days for all the Quality teams and the team manager from the site.

Interim SR.Quality Manager & operational Quality manager from 2024 feb. Overall responsible Quality on site.

**Results:** Success in hiring new employees, updating many documents to current level of GDP. Effective in the interim SR, QA Manger period and success in changing the teams understanding of their role so that they can work more independent an without direct management.

June 2018 – Feb. 2022

[GN hearing](#) | [Site Quality Assurance Manager QAM](#)

Responsible for updating of Quality Management System to ISO13485:2016 and implementing global process in local process. QAM has responsibility for RA, QA, IQC, OQC, SQM and contact to direct external customers.

Member of management team.

**Results:** Updating the current QMS system and passing re-certification in Oct 2018. Implementation of risk-based process in the QMS system

Sep. 2017 – May 20218

[Advaligth Ballerup](#) | [Senior QA & RA manager](#)

Supporting the team in the change from a development company to a manufacture of medical device class 2B and class II. Review and QA approval of product documentation. Maintaining current management certification approval.

Responsible for RA & QA. Member of management team.

**Results:** Updating the current QMS system and product documentation to enable that Advalight successfully passed both recertification to ISO13585:2016 and FDA inspection in April 2018.

June 2015 – Aug. 2017

[Scandinavian Plastic Technology – SPTVILECON](#) | [Senior consultant](#)

Supporting customers with supplier management, risk management, project quality assurance. Working as consultant at Novo Nordisk Hillerød.

Responsible for external quality management and customer support.

May 2014 – May 2015

[AlfaNordic](#) | [Senior consultant within QA and Risk management](#)

Worked as a consultant at Agilent (Dako) Denmark in the FDA remediation program.

The work covered process risk assessment and test method risk assessment using FMEA, training Dako staff and external consultants in FMEA, general support of Dako staff on QA issues. Creation and implementing procedures for Supplier selection, evaluation, approval and monitoring. Interim Head of Supplier Quality Team.

**Results:** The documentation created successfully passed FDA inspection and NB ISO 13485 re-certification in spring 2015.

Apr. 2011 – Apr. 2014

[Widex A/S](#) | [Vice President of Quality Assurance](#)

Member of the Management Team.

**Results:** Regulatory affairs & QMS responsibility added after only 2 months of employment. Modernized the Quality System and brought it up to 2011 standard.

Obtained re-certification to ISO 13485 and certificate expansion to cover sites in Estonia. Established a Quality function in 4 departments covering QMS, QE, QC & RA.

Jan. 2008 – Apr. 2011

[Sonion MDC \(Sonion medical\)](#) | [Senior manager](#)

Roskilde, Denmark & Stettin, Poland

Contract Developer and Manufacturer of Medical Devices. Quality Manager & Regulatory Affairs.

**Results:** Expansion of current QMS from ISO 9001 to ISO 13485.

Key Customer received the 510K approval from FDA and production starts at 2 sites in Poland. Setting up production in clean room class 10.000 at supplier.

Personnel management responsibilities.

Covered by Customers Bonus Program as a credit for the achievement's made.

Aug. 1990 – Dec. 2007

[NUNC/Thermo Fisher Scientific](#) | [Regulatory Affairs Manager](#)

Manufacture of Nunc brand sterile medical devices, in-vitro diagnostic medical devices, equipment for pharmaceutical production and OEM production.

**Results:** Identification and surveillance of external requirement with relation to Products and Quality, communication to Regulatory Bodies.

Achieving the first 510(k) approval at Nunc.

Personnel management. Management of cross functional project teams with the scope to achieve product quality improvement and cost reduction. This was based on Lean and Practical Process Improvement methods.

Special responsibility for quality assurance of Irradiation plant and introduction of GMP in production and sterilization processes based on US medical device GMP and EU pharmaceutical regulation.

Establishing documentation fulfilling EN 552 and ISO 11137 for sterilization processes in house and at suppliers.

Nov. 1988 – Juli 1990

[Codan Gummi A/S | Quality Technician](#)

Supplier of rubber components for the automotive industry, most of which are "delta" products.

Responsible for incoming inspection, documentation of first article inspection and process capability. Sparring with QA manager in connection with ISO 9001 certification. Support to customer complaint process, quality reports, calibration and documenting SOP's.

Jan. 1988 – Oct. 1988

[C.C.M. Olsen, Roskilde | Measuring technician](#)

Established Owner's Manual for customers and developed offers for new buildings.

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