

DAHLFELTCONSULTING

CONSULTANT CV WITHIN LABELLING, IFU, RA & PM

Name Birgitte T. Engelsen
Nationality Danish
Gender Female
Domicile Denmark

CONTACT INFORMATION

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BIRGITTE T. ENGELSEN - CURRICULUM VITAE

PERSONAL LETTER

Result-oriented, dynamic, and structured with solid experience from MedTech, medical device and pharma as well as significant international insight within Products, Users, Regulatory Compliance, and Communication.

Birgittes mission is to have best-in-class customer experience and communication and that all users, despite age and education, can easily understand and safely use the product.

People describe her as a trustworthy, action- and result-oriented person. She has an open and outgoing mind and her way of communicating is clear and direct with a positive approach. Her integrity is high; however, she also has the managerial courage to challenge others and herself to think of new ways of doing things.

STRENGTHS

Birgitte has extensive knowledge within Product, Project, and Process Management while at the same time holding the baton in Labelling and Regulatory Compliance. This makes her the successful link between Marketing and Regulatory Affairs.

EXPERTISE

Birgitte has strong business understanding with great ability to work with complexity and data. She thrives in analysing problems and finding suitable solutions, defining, and simplifying processes and with managing and facilitating projects. Through her high drive and stakeholder management skills, she build good cross-functional relations, ensure commitment, and deliver effective results with high quality.

IT SKILLS

Microsoft Word, Excel and PowerPoint at normal average level

EDUCATION AND DEGREES

1990 - 1992 Copenhagen Business School
Graduate Diploma (HD) in Marketing Management

1987 - 1990 University of Southern Denmark
HA - HD 1. del, Economics HA - HD 1. del, Economics

1986 - 1987 Handelsskolen i København
HH, Economics

1982 - 1985 Helsingør Gymnasium
Student

LANGUAGE
SKILLS

Danish	Written & spoken	Native
English	Written & spoken	Fluent

PROFESSIONAL
BACKGROUND

Jul. 2023 - Present

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

Consultancy tasks within Pharma and medical Device - Labelling, IFU, RA and PM

Mar. 2021 - Jun. 2023

[Sigma Connectivity Denmark](#) | **Senior Consultant**

Project consultant in a big Danish Pharma/Medical Device company's R&D department. Working in the final phase of the project, up till the FDA approval, preparing documents and plans for the launch milestone meeting.

Senior RA consultant in a US based Medical Device company. Working with MDR and IVDR compliance especially on SOPs, Labelling, UDI, Basic UDI-DI, Eudamed, Intended Use, and DoC.

Senior RA consultant in a big Danish Medtech company working in the QC team with labelling projects and regulatory requirements, and with updating from MDD to MDR compliances.

2009 - 2020

[Oticon](#) | **Senior Project Manager**

- ∴ Strategic responsibility for mandatory materials (labelling)
- ∴ Successful link between Marketing & Regulatory Affairs
- ∴ Ensuring global regulatory compliance, for Product to Market SOPs and processes
- ∴ Product launches - to ensure products were efficiently brought to market
- ∴ Product to Market project planning, alignment and facilitation
- ∴ Strategic projects to enhance systems and processes
- ∴ Optimising global marketing launch process to reflect most efficient way of going to market
- ∴ Subject Matter Expert (SME) for labelling
- ∴ QMS / FDA Project core team member
- ∴ Product to Market SOP's, instructions, and templates
- ∴ Process definition and ensuring training of our processes
- ∴ Close cooperation with Regulatory Affairs & R&D
- ∴ Product to Market project planning
- ∴ Product launches

- ⋄ Product Manager for two launches
- ⋄ Subject Matter Expert (SME) with focus on labelling
- ⋄ Launch & labelling planning responsible
- ⋄ Responsible for and writer of Oticon Product Portfolio brochure
- ⋄ Project coordination for product launches

2001 - 2009

[Abbott Laboratories | Product Manager](#)

- ⋄ Responsible for product portfolio to healthcare professionals, diabetics and distributors
- ⋄ Developing and strengthening the brand by new campaigns and product launches
- ⋄ Marketing plans and budgets
- ⋄ Website Project Manager
- ⋄ Developed database for market research and direct mailing
- ⋄ Implemented Abbott Diabetes Forum, an annual event for nurses
- ⋄ Cooperated closely with the sales force and external suppliers
- ⋄ Prepared product portfolio forecast
- ⋄ Collaborated across the Nordic organization, and with the European headquarters
- ⋄ Inter-organizational implementation of new branding (Corporate Identity)
- ⋄ Management of the customer service team

1999 - 2001

[Ambu A/S | International Product Manager](#)

- ⋄ Responsible for one of the company's most important growth portfolios
- ⋄ Developed and implemented international marketing strategies, launches and - campaigns
- ⋄ Chairman for the cross-departmental product group, which controlled the product assortment
- ⋄ Responsible for product and market training of local sales and marketing teams
- ⋄ Achieved to improve a minor product area to one of the company's most important growth areas
- ⋄ Negotiated with and supported our international OEM customers
- ⋄ Managed to obtain the world opinion leader within neurophysiology as our customer
- ⋄ People management of a Junior Product Manager.

1998 - 1999

[UK resident | Family Household](#)

Lived with my husband in UK

1996 - 1998

[Astellas Pharma | Junior Product Manager](#)

- ⋄ Controlled the complete marketing mix and budget for antibiotics and dermatology

- ∴ Developed and implemented local and pan-Nordic marketing campaigns
- ∴ First line support for the Nordic subsidiaries
- ∴ Trained the sales representatives in product and market strategies
- ∴ Increased the penicillin market share and turnover in Finland, despite intense price war
- ∴ Successfully re-launched an antibiotic in Denmark, despite declining prices due to parallel import

1994 - 1996

[Astellas Pharma | Nordic Marketing Coordinator](#)

- ∴ Coordinated mailings and advertising within prescriptions- and OTC products
- ∴ Assisted in the development of marketing plans
- ∴ Strengthened the strategy planning through monitoring and analysing the market dynamics
- ∴ Arranged internal conferences and external congresses
- ∴ Designed and managed the marketing databases

1992 - 1994

[Bruel & Kjaer Sound & Vibration Measurement A/S | International Marketing Coordinator](#)

- ∴ Developed campaign material, controlled the internal production and technical literature
- ∴ Participated in strategy projects and new product development projects
- ∴ Assisted the product managers in developing marketing plans
- ∴ Arranged internal courses and external exhibitions
- ∴ Developed the external newsletter

1991 - 1992

[Bruel & Kjaer Sound & Vibration Measurement A/S | Business Analyst](#)

- ∴ Consultant in strategic and tactic decisions to senior, product and sales management
- ∴ Developed international market research and analysis
- ∴ Consultant in strategic and tactic decisions to senior, product and sales management
- ∴ Developed international market research and analysis

1990 - 1991

[Bruel & Kjaer Sound & Vibration Measurement A/S | Marketing assistant](#)

- ∴ Managed the international sales and customer database
- ∴ Developed international sales and customer analysis

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