Camilla Wamberg Munkesø Curriculum Vitae

Highlights of qualifications:

- 12 years of specialist and leadership experience with Regulatory Affairs for Medical Devices, incl. Regulatory Strategies, Development, Clinical Affairs, Quality Management, collaboration with Notified Bodies and the FDA.
- Scientific Writing – Marketing Applications, Clinical Evaluation Reports, Literature Reviews, FDA meeting packages, Post Market Regulatory Reporting of adverse events and recalls.
- Experience from several Start-Up companies as well as larger companies and Matrix Management.
- Expertise in Product Development and Market Approvals of Medical Devices, IVD and Drug/Device Combination Products.
- Experience with various device types, such as cardiovascular implants, active devices, medical software and various drug delivery devices, including pre-filled syringes and auto-injectors.

Theoretical background within Economy/International Business, and Natural Science.

Representative accomplishments:

- US: IDE, PMA and 510(k) submissions
- CE marking of class I-III Medical Devices
- Market approvals globally
- ISO 13485:2016 certification
- FDA Inspections and communication
- Notified Body audits and communication
- General Management

Education and credentials:

2013 Project Management, Cook Medical
2012 Leadership, Cook Medical
2010 HD, International Business, Copenhagen Business School
2007 Leadership Development Programme, AkzoNobel
2001 M.Sc. Biology, University of Copenhagen, Denmark

Professional experience:

2018 – 2020	**Independent Consultant**	**Senior Consultant, Deviceadvice.dk**
2016 – 2018	**IWA Consulting ApS**	**Head Medical Device RA & QA**
2014 – 2016	**Widex A/S**	**Director, Global Regulatory Affairs**
2011 – 2014	**William Cook Europe ApS**	**Manager, Regulatory Affairs**
2008 – 2011	**Contura International A/S**	**Director, Regulatory Affairs**
2007 – 2008	**Contura International A/S**	**Specialist, Regulatory Affairs**
2002 – 2007	**Akzo Nobel A/S**	**Team lead, Microbiology Laboratory**

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