

MIKKEL NOERHOLM

Mikkel Noerholm
Greater Munich Area
Germany

BIOTECH R&D EXECUTIVE & ENTREPRENEUR

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SUMMARY



I am an International Life Science R&D executive, scientist, and entrepreneur, with 20+ years of experience from biotech start-ups, industry, and academia. I am good at building, structuring, organizing, and translating multi-disciplinary research and development activities into products and milestones.

I have experience hiring, leading, and mentoring teams of PhD, MSc, and Lab Techs in Molecular Biology, Bioinformatics and QA/RA.

I have lead development of life science products sold by Qiagen, Roche, Thermo and Bio-Techne, as well as numerous clinical and molecular biology assays. Most recently, I lead the team to launch the first exosome biomarker *in-vitro* diagnostic CE-marked IVD product, meeting regulatory requirements for in-vitro diagnostics.

Through an international career, I have gained an excellent cross-cultural understanding. Born and raised in Denmark where I received my PhD, I have spent several years in the US, including as Research Scholar at Harvard Medical School and Massachusetts General Hospital, and I received an MBA in Entrepreneurship from Babson College, MA, US. I now live in Munich, Germany with my wife and teenage daughter, where I am coming to terms with the end of the ski season.

I am an easy-going optimist, a team builder, a good motivator, and a relentless, analytical, data-driven trouble-shooter. I enjoy mentoring team members to develop new skills and I love to be part of a team on a mission.

WORK EXPERIENCES

Aug 2018 – Jan 2022

Head of European Operations, Director of Product Development
Bio-Techne, Munich, Germany (US company acquiring Exosome Dx.
Based in Minnesota, US, ca. US\$ 1B revenue, 2700 employees).

Responsible for Site Management and IVD product development.

Main achievements:

- 1 CE-marked, in-vitro diagnostic (IVD) product developed and launched ("EPI-CE", exosome RNA for prostate cancer prediction)
- 14 clinical site international prospective clinical study planned and completed (according to ICH/ISO 20916)
- IVD development including design-control, IVD software development, IVD manufacturing and supplier control
- 20+ R&D projects organized into a global project management framework across Exosome Dx sites in US and Germany
- 10+ biomarker/CDx/pharma service projects executed locally
- Integration of Exosome Dx into Bio-Techne's annual corporate business cadence of Strategy Development → Project Prioritization → Annual Operating Plan

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WORK EXPERIENCES (Continued)

Jul 2010 – Jul 2018

VP of Product Development, Head of European Operations

Exosome Diagnostics GmbH, Munich, Germany (Biotech startup spun out of Mass General Hospital, Boston to develop the exosome technology).

Responsible for building Exosome Dx' GmbH laboratory. Relocated the family to Munich, Germany.

Main achievements:

- \$250M acquisition of Exosome Dx by Bio-Techne
- 1 European clinical & development lab established
- 14-person team hired, managed, & mentored, incl. PhD/MSc R&D-scientists, bioinformatics, RA/QA, Lab Techs & project managers
- €1.7M non-dilutive grant funding secured
- \$110M VC funding secured
- 1 Quality Management System (QMS) implemented
- 2 QMS certification/accreditations obtained (ISO13485/ISO15189)
- 3 products launched via Qiagen (licensee) exoEasy/exoRNeasy
- 4 clinical laboratory oncology biomarker assays launched
- 3-gene biomarker signature successfully developed (EPI test)
- 14 scientific publications / 10 patent applications
- 10+ oral presentations at international scientific conferences

Jun 2009 – Jun 2010

Research Scholar

Harvard Medical School/Massachusetts General Hospital, Boston, US (MGH is the largest university hospital at Harvard Med School).

Joined the founder team at MGH to develop the exosome diagnostics technology to achieve venture capital funding:

- 2 technology patents / 2 published scientific manuscripts
- \$20M Series A funding for Exosome Diagnostics

May 2006 – May 2009

Director, Technical Support

Exiqon, Inc., Woburn, US (new US sales subsidiary of Exiqon A/S)

Responsible for technical representation of Exiqon's products and technology in US. Relocated family to Boston, US to join Exiqon, Inc.:

- 3 Tech Support staff hired, trained for North America
- 8 US sales reps trained
- 20+ oral presentations at scientific conferences/meetings
- >50% year-over-year revenue growth for 3 consecutive years

Feb 1998 – May 2005

Senior Scientist/Project Manager, R&D

Exiqon A/S, Denmark (Startup biotech focused on Locked Nucleic Acids and UV-mediated biomolecule coating of polymer surfaces).

Responsible for R&D/Product development:

- 3 Life Science tools products developed and launched

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EDUCATION

- May 2008 – May 2010 **MBA, Entrepreneurship**
F.W. Olin Graduate School of Business, Babson College, MA, USA
Two-year Fast Track Master of Business Administration program in entrepreneurship.
- Dec 2000 – Sept 2004 **Ph.D. Micro/Biotechnology**
Technical University of Denmark (DTU)
Multiplex detection of Single Nucleotide Polymorphisms (SNPs) on a polymer- based bio-array platform with integrated microfluidics.
- Sept 1991 – Oct 1997 **MSc, Chemical Engineering**
Technical University of Denmark (DTU)
Wheat identification by Neural Network recognition of MALDI-TOF spectra. Polymer modification of dipeptidyl aminopeptidase I (DAP I)

PERSONAL INFORMATION

Civil status:

Married, one teenage daughter

Hobbies:

I enjoy spending time with family and friends running, skiing, hiking (especially in the mountains), diving, foosball (table soccer), and good food & wine

Languages:

Danish (mother tongue), English (excellent), German (good)

EXPERTISE

Hiring good people Extensive knowledge	Venture Capital Good knowledge	Biotech startup Extensive knowledge	Grant funding Extensive knowledge	Liquid Biopsy Extensive knowledge
Product Development Extensive knowledge	R&D Extensive knowledge	Life Sciences Extensive knowledge	Patenting Extensive knowledge	Exosomes/EVs Extensive knowledge
General Management Extensive knowledge	Nucleic Acids Extensive knowledge	Biomarkers Extensive knowledge	Diagnostics/CDx Extensive knowledge	Reimbursement Some knowledge
Project Management Good knowledge	RT-qPCR / NGS Extensive knowledge	Publication Extensive knowledge	Sample Prep Extensive knowledge	Bioinformatics Good knowledge
Operations Good knowledge	GMP/GCP/GLP Good knowledge	Clinical Lab Good knowledge	Design Control Extensive knowledge	Prostate Cancer Extensive knowledge
IVD Manufacturing Good knowledge	IVDD/IVDR Some knowledge	ISO13485/15189 Extensive knowledge	Clinical Studies Extensive knowledge	QA/RA Good knowledge
Running Extensive knowledge	Skiing Extensive knowledge	Diving Extensive knowledge	Foosball Extensive knowledge	Food & Wine Extensive Appreciation

PUBLICATIONS & PATENTS

Complete list of 19 scientific publications and 16 patents available on request