



(58 Jahre, verheiratet, 3 Kinder)

Objectives

- Obtain leadership position with emphasis on commercialization of innovative products with an organization where experience in the marketplace is valued
- Emphasis on international-oriented company with a promising pipeline

Profile

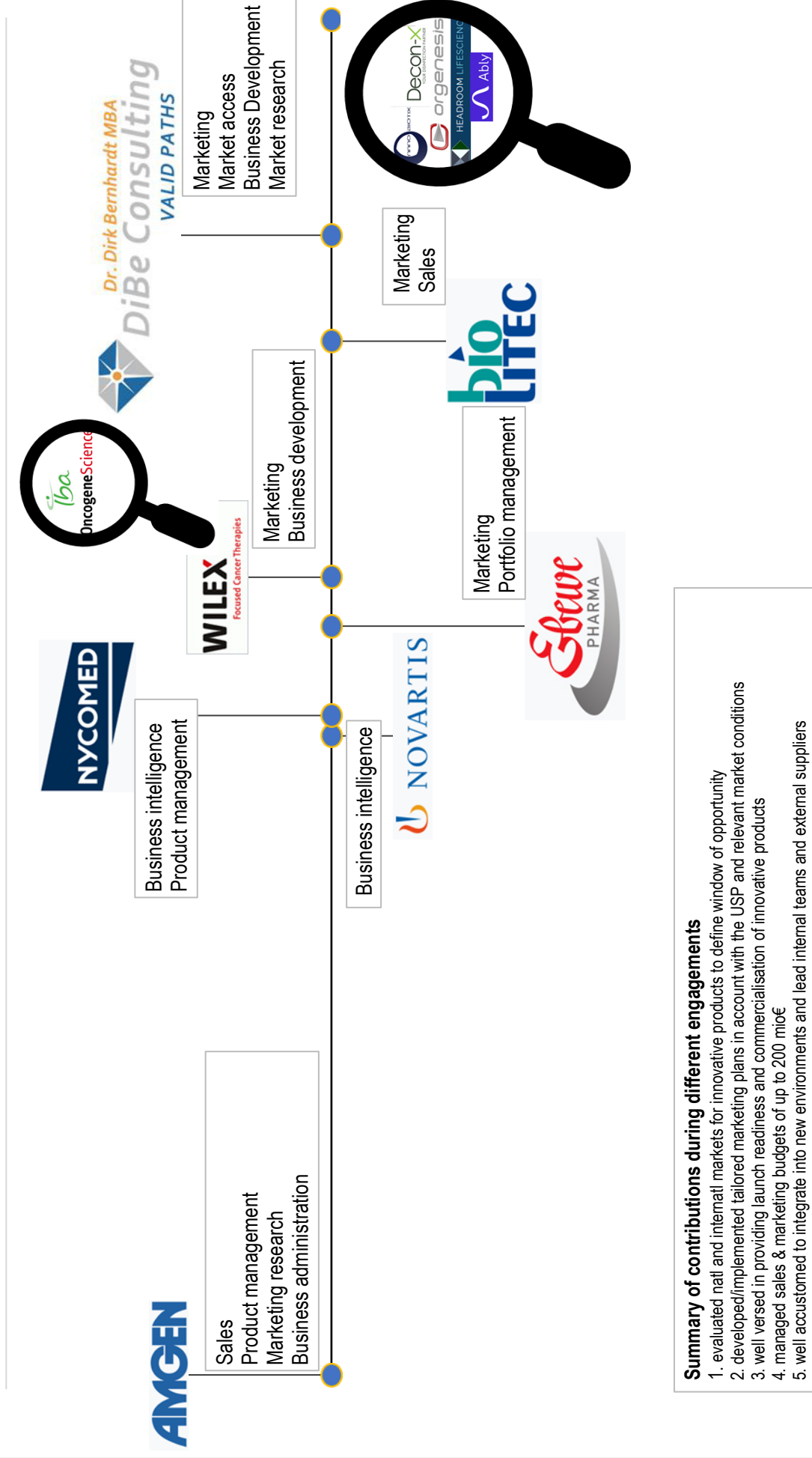
Senior marketing and business development leader with over 25 years of experience in the pharmaceutical and biotech industry, possessing executive experience and comprehensive insights into the complex environment of pharmaceuticals including sale of specialty pharmaceuticals into competitive markets. Skilled in identifying business opportunities, providing market access knowledge, creating strategic and tactical directions and possessing the ability to implement result-oriented marketing operations.

Experienced in combining business driven objectives with in-depth health care market insights to inform business decisions, such as product-related preconditions for the integration of innovative products into standard-of-care treatment algorithms. More than ten years of experience in supervising day-to-day operations of cross-functional teams in marketing and business development.

Recognized by management as well as peers as a mindful leader, strategic thinker and trusted partner, who also inspires and motivates coworkers to reach ambitious goals.

Quickly adapts to increased responsibility and new business environments and demonstrates hands-on abilities and outstanding interpersonal skills.

Milestones of Professional Development, Roles and Contributions



1992 1993 1994 1995 1996 1997 1998 1999 2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020

Key Achievements

- **Marketing** - Demonstrated ability to successfully identify strategic marketing goals, developed thorough and reliable marketing plans, tailored positioning and branding of products in need of explanation with accompanying medical-scientific communication
 - In pre-approval, product launch and mature brand settings
 - Balancing business needs and market access requirements such as innovative pricing concepts
- **Business Development** - Accustomed to defining target markets, identifying business opportunities, and develop effective access strategies to reach bottom-line profitability; conversant with establishing and maintaining of professional networks in various national and international contexts; proficient in working at the junction of science, clinical development, medical, and regulatory affairs
- **Market Access** – Guided product commercialization with consideration of market access conditions for registration and reimbursement of medicinal products and medical devices; well versed in the evaluation of data from clinical studies and comparative effectiveness; knowledge of international health policies and measures of evidence-based medicine

Experienced at building powerful and long-term working relationships with various of clientele such as professionals in health care, responsible authorities for reimbursement and pharmaceutical industry

Professional Experience

Business consultancy (interim management & freelance projects)

Germany
08/2015 - today

Decon-X International SA (Norway)

Hospital hygiene/infectious diseases

- Assessed competitive market as to inform USP and the value added of the innovation
- Initiated KOL mapping and subsequent customer acquisition activities
- Compiled dossier including recommendations for launch and product roll out

Orgenesis Inc. (USA)

Hematology (CAR-T cells)

- Evaluated preliminary clinical added value vs. existing therapies in hematology and oncology
- Assessed market potential for CAR-T cell-based therapies in DACH countries
- Provided guidance regarding reimbursement by the German SHI

Nanobiotix SA (France)

Oncology (immune oncology)

- Led launch readiness preparation including brand development and positioning for three cancer conditions such as inoperable Head & Neck Cancer, Liver Cancer and Sarcoma, based on
 - primary market research with providers in EU5 countries
 - examination and feedback from patient journey and advocacy groups' input
 - systematic literature review and retrospective clinical data assessments in EU5 countries
- Provided business plan for NBTX3 and product-forecast based on EU5 market analysis of provider potentials
- Implemented medical affairs strategy and various activities with major KOLs in the US and EU

Headroom Life Science (Norway)

AI for Emergency Care

- Conducted market research to inform application for EU funding
- Mentor of enterprise to provide guidance for way into the German market

Ably SA (Norway)

SMART hospital bed technology

- Assessed added value of technology for decubitus prevention
- Determined market potential based on incidence by ICD-10 and OPS

Biolitec Pharma Ltd.**Jena/Dublin****Director Marketing & Sales**

07/2013 – 07/2015

Development, coordination, and implementation of marketing & sales related activities to achieve commercial turn-around of Foscan®-based photodynamic therapy for rare Cholangiocarcinoma and Head and Neck Cancer; identification, evaluation, and selection of commercial opportunities for a third-generation photosensitizer worldwide.

Supervised a team of 4 key account managers in charge to increase market penetration in the different territories of Europe.

- Increased sales by 15% over last year
- Accomplished filing of applications for reimbursement by the German statutory health insure (NUB application), benefit assessment and prolongation of product registration in France and Belgium
- Established sustainable medical liaison with European decision makers in the relevant disease area

Wilex AG**Munich****Director Marketing**

08/2008 – 06/2013

In cooperation with Wilex' licensees provided direction for the commercial development of Wilex' leading therapeutic product candidates Rencarex®, Redectane®, and Mesupron® in their respective indications worldwide (kidney-, breast cancer), i.e. definition of USP and implementation of tailored (pre-) marketing strategies across different customer segments. As member of the Wilex steering committee established interface management of the Wilex business partners and as an assigned member of the Global Brand Team at IBA Molecular North America provided input for the preparation of US launch of Redectane®.

- Supervised authoring of medical information of the Wilex product portfolio, i.e. product monograph, promotional material
- Implemented activities to raise awareness and interest in the Wilex product portfolio in the context of personalized medicine in urologic-oncology, pancreatic and breast cancer
- Led business development activities regarding licensee acquisition and due diligence preparation
- Provided marketing plan and launch readiness for EU5 roll-out of Rencarex®

Oncogene Science Inc., a fully owned subsidiary of Wilex AG**Cambridge / USA**

Coordinated relaunch and actively participated in marketing and sales activities of HER2/neu ELISA companion diagnostic kit

12/2011 – 06/2013

- Developed relaunch strategy with increasing sales targets
- Expanded market coverage by contracting with new distributors and label expansion
- Supervised preparation, presentations of 4 scientific posters at 4 major conferences within 6 months

IBA Molecular North America Inc.**Washington D.C. / USA**

For Wilex' prime licensee initiated organizational build-up, USA-based medical affairs and start of pre-approval marketing of Redectane®

10/2009 – 12/2010

- Provided training on product and disease environment to the US marketing & sales organization
- Coordinated market access strategy incl. coding, coverage, and reimbursement path for product
- Presented at CMS and private payer organizations to set stage for future negotiations with regulators
- Served as consultant for 7 local project-associated marketers and specialists

Ebewe (a subsidiary of SANDOZ)

Salzburg / Austria

***Head of Portfolio Management &
Product Management Special Pharmaceuticals***

08/07 - 07/08

Led marketing department and supervised annual oncology sales budget of 200 million Euro. Shaped internal processes to accommodate further product launches in the context of the portfolio strategy:

- Developed/implemented dosage and route of administration based USP and marketing messages for generic parenteral cytostatic drugs
- Introduced principles of portfolio management for evaluation of new product candidates, managed interface with pharmaceutical-, process-, and regulatory development
- Supervised a team of 5 members to manage worldwide marketing services for sales force, including definition of USP of branded generics and decrease of go-to-market time
- Supervised timely launch of two generic products prior to the originator's patent expiration

Nycomed GmbH (member of the Takeda group)

Munich

Head of Business Intelligence

08/05 - 08/07

Assisted in the implementation of marketing & sales processes established by best-in-class pharmaceutical companies, such as launch strategies for highly competitive markets:

- Applied methods of primary market research to inform product branding and product USPs
- Concept/implementation of systematic competitive intelligence reporting's tailored to product-needs
- Initiated market research studies for product branding and determination of brand end user prices
- Internal counsel for product managers to prepare for and conduct three launches in highly competitive markets of antithrombotic therapy, osteoporosis, and break-through pain treatment

Novartis GmbH

Nürnberg

Internal Consultant Marketing & Sales Information Management

06/05 - 07/05

Amgen GmbH

Munich

Sales/Business Administration Manager

04/00 - 10/04

Marketing Research Manager

04/96 - 03/00

Sales Representative

04/92 - 03/96

Dirk Bernhardt, PhD MBA

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Education

MBA-program, FOM University of Applied Sciences for Economics and Management, Munich

Doctoral thesis at the Institute of Microbiology at the University of Hannover

Scholarship at Northeastern University in Boston

Academic studies in Biology at the Universities of Braunschweig and Hannover

Professional Development

Health Technology Training Program, *International Society for Pharmacoeconomic and Outcomes Research*

Licensing and Business Development, *PLC Deutschland* (Society of Pharmaceutical License Managers)

“Systemic Coaching in the Organizational Area”; *Institute for Systemic Consulting*

Compact training course Project Manager, *LearnAct! Corporate Development*

Corporate Controlling Planning and Controlling, *Chamber of Industry & Commerce*

Ethical Pharma Marketing and Pharma Product Management, *Forum Institute*

Distance learning course for diploma as Marketing Specialist, *AFW Business Academy Bad Harzburg GmbH*

Publications and Presentations

Neumann, R., D. Bernhardt and W. Carney. “Clinical Relevance of Circulating HER-2 in HER-2 Negative Breast Cancer patients.” In *13th St. Gallen Breast Cancer Conference Primary Therapy of Early Breast Cancer*. St. Gallen, Switzerland, March 14-16, 2013.

Neumann, R., D. Bernhardt and W. Carney. “Serum HER-2 Levels as a Predictor of Prognosis and Clinical Outcome in Metastatic Breast Cancer (MBC) Patients Treated with Trastuzumab-based Therapies.” (#215) In *5th IMPACT Breast Cancer Conference*. Brussels, Belgium, May 02-04, 2013.

Carney, W., R. Thiel and D. Bernhardt. “A Bayesian Meta-analysis of the Prognostic Value of Circulating HER-2/neu Levels in Breast Cancer (BC) Patients.” (#643) In *American Society of Clinical Oncology 2013 Conference*. Chicago, IL, May 31-June 4, 2013.

Neumann, R., D. Bernhardt and W. Carney. “Klinische Bedeutung des HER-2 Nachweises im Serum von Brustkrebspatienten: eine aktuelle Literaturübersicht.” (#PO44) In *33. Jahrestagung der Deutschen Gesellschaft für Senologie e.V.* Munich, Germany, June 27-27, 2013.

Carney, Walter P., Dirk Bernhardt and Bharat Jasani. “Circulating HER2 Extracellular Domain: A Specific and Quantitative Biomarker of Prognostic Value in All Breast Cancer Patients?” *Biomarkers in Cancer* 12 (August 2013): 31-39.

BIO-Europe 2017, (Berlin, 6-8 November 2017), moderation of two events, i.e. Therapeutic Track “Immuno-Oncology” and “Company Presentations”

BIO-Europe 2019, (Hamburg, 11-13 November 2019), moderation of three events, i.e. Therapeutic Track “Immuno-Oncology” and “Company Presentations”

“Product benefit assessment in the context of economic efficiency and regulation in the healthcare market,” *PLCD Spring Meeting*, Hamburg 17. - 18.05.2018.

“Introduction of innovative health care technologies in the statutory health services in Germany”, In *Erstattung von Medizinprodukten im deutschen Gesundheitssystem*, Fachtagung *Forum Medtech & Pharma*, Berlin 18.09.2018

“Basics of refinancing and reimbursement in German health care services,” In *Start-Ups in der Medizintechnik: Besonderheiten und Fallbeispiele*, Fachtagung *Forum Medtech & Pharma*, München 17.07.2019

Affiliation

Alumni *Institut für systemische Beratung*, Wiesloch

Health Care Bayern e.V., Munich

BIO Deutschland e.V., Berlin

Deutsche Fachgesellschaft für Market Access e.V., Berlin

Forum MedTech Pharma e.V., Nürnberg

Pharma Lizenz Club Deutschland e.V., Bonn