

Curriculum Vitae

Personal information Anna-Karin MALTAIS

Work experience

Nov 2024 - present: Group manager for Biotechnology 2 (quality assessors) at the Swedish MPA

2022-2024: Chief Scientific Officer, XNK Therapeutics, Huddinge, Sweden

XNK Therapeutics was a clinical-stage biotechnology company developing natural killer (NK) cell-based cancer therapies. • Responsible for the Research and Innovation (R&I) including a pipeline comprising four oncology indications, including one phase II study. • Development of XNK's cell therapy platform and process.

2019-2022: Head of CMC, Biotech Research and Product Development (BRPD), Global Rare Diseases (GRD), Chiesi Farmaceutici S.p.A., Italy

Chiesi researches, develops and markets drugs in three areas: AIR (respiratory), RARE (rare diseases) and CARE (specialist & personal care). • Developed and implemented the Chemistry, Manufacturing and Control (CMC) strategy, contributing to the overall R&D strategy of BRPD and GRD. • Managed a pipeline of nine projects in various indications (rare diseases, respiratory, neonatology) at different development stages (pre-clinical to postmarketing). • Development of biologic drug substance, drug product, and analytical methods

2012-2019: Chief Scientific Officer & Vice President of Research and Development, Eurocine Vaccines AB, Solna,

Eurocine Vaccines was a public company focused on preclinical and clinical vaccine development. • Led the R&D strategy and all R&D activities at Eurocine Vaccines. • Focused on the development of a nasal influenza vaccine, overseeing preclinical studies and phase I/II trials. • Evaluated new pre-clinical opportunities to combine with Eurocine's adjuvant system. • Established and managed collaborations with academic and industrial partners. • Managed outsourced CMC activities, including formulation development and GMP manufacturing.

2011-2012: Business Development Manager, Eurocine Vaccines AB, Sweden

Developed presentations, press releases, and facilitated interactions with potential partners • Conducted analysis of the competitive landscape and IP strategies • Actively engaged in research and development activities, contributing to the advancement of company projects.

2010-2010: Vice President, Corporate Development, Cyto Pulse Sciences, Inc., MD, US

Cyto Pulse Sciences was acquired by Cellectis in 2010. Cyto Pulse was a clinical-stage medical device and treatment development company dedicated to advancing quality of life through novel electric field based technologies for oncology, gene therapy and infectious disease applications. • Involved in business activities, including interactions with investors and potential partners. • Initiated and managed license agreements for Cyto Pulse's DNA delivery systems. • Explored new commercial and academic collaborators and clinical trial opportunities. • Managed all ongoing academic collaborations and clinical phase I/II studies. • Based in Solna, Sweden at Karolinska Institute Science Park.

2008-2010: Manager EU Operations, Cyto Pulse Sciences, Inc.

• Lead on the Derma Vax system, overseeing all European preclinical studies and clinical trials. • Provided scientific support to DNA vaccine collaborators and facilitated installation and training for Cyto Pulse commercial systems in Europe. • Represented Cyto Pulse and presented data at vaccine conferences worldwide, building relationships and promoting company products.

2007-2008: Consultant, Cyto Pulse Sciences

• Provided scientific advice on genetic vaccines, adjuvants, and delivery systems, contributing to the development of innovative immunotherapy solutions. • Conducted analysis of preclinical research data and prepared scientific presentations, supporting clients in decision-making processes. • Provided guidance on regulatory aspects of DNA vaccines and in vivo electroporation protocols, ensuring compliance and efficacy in clinical trials.

2006-2008: Post-doctoral fellow, Immune and Gene Therapy Lab, Cancer Center Karolinska, Department of Oncology and Pathology, Karolinska Institute, Stockholm

• Stand-in group leader for Prof. Pisa's research group, overseeing activities & budget management. Organized/planned toxicity studies and put together ethical and regulatory applications for a Phase I/II study of DNA vaccination with electroporation. • Project leader for a Phase I/II study investigating a cancer vaccine in patients with prostate cancer. • Published four original articles and co-supervised a Ph.D. student

2002-2006: Ph.D. student, Immune and Gene Therapy Lab, Cancer Center Karolinska, Department of Oncology and Pathology, Karolinska Institute

· Published five original articles and one book chapter, contributing to the field of DNA vaccination and cancer immunotherapy. • Developed in vivo electroporation protocols for intradermal DNA vaccination, utilized in clinical studies. • Designed and developed a prostate cancer vaccine demonstrating efficacy and safety in preclinical models. Later investigated in a phase I/II study. • Evaluated vaccine adjuvants & delivery systems, contributing to better vaccine efficacy. • Presented data at multiple international conferences.

Education and training

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Publications

Projects

Memberships

Other Relevant Information