Marc Meijer

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Summary

Program Manager
I am a hands-on PhD with a BS Electrical & MS optical engineering with a with over 9 years experience providing customer facing data solutions and leading the development of regulatory compliant molecular diagnostic tools, imaging & medical devices, systems and algorithms from concept, product requirements, risk management, feasibility studies, development, verification and validation to final product launch. Responsible for ensuring regulatory compliance (ISO 13485), design control documentation and prototyping and testing. Strong teamwork and communication skills to effectively manage and guide cross-functional teams.

Experience

Data Science Fellowship
Insight Data Science
Sep 2019 - Present (2 years 1 month +)
• Developed a web app that predicts the likelihood of hospital pharmacy drug shortages
• Built data processing pipeline in Jupyter Python and trained regressive predictive models on FDA drug shortage reports using features including prior shortages, manufacturers, and reason
• Deployed a Flask-based web app on AWS to increase hospital drug shortage mitigation time

Co-Founder
Cambridge Innovation
2017 - Present (4 years 9 months +)
Specialized in applying data science, sensor/imaging and engineering to various disciplines including biotechnology, molecular biology, medical devices, semiconductors, telehealth and pharmacy systems
• Initial developmental stages of a pharmaceutical management platform company to help prevent errors and control inventory.
• US market assessment of applied machine learning to next generation biomarker development.

Technical Advisor
Proximie Telehealth
Jan 2016 - Jan 2017 (1 year 1 month)
Deliver the technical strategic vision for the development of novel 3D Augmented Reality (AR) digital health platform technologies designed to transform surgical protocols and education in less served populations.
• Build and support a development team of cross discipline specialists for effective collaboration research agreements.
• Facilitate the partnering and licensure of advanced lead programs for clinical development.

Product Development Scientist
Bedford Stem Cell Research
Jan 2013 - Jan 2016 (3 years 1 month)

Brought innovative startup enthusiasm and hans-on “get it done” attitude in a cost sensitive academic foundation. Set project direction and performed Diagnostic assay development, cell based biology and fluorescent assay development and cell sorting.
• Designed and built fluorescent/luminescent lab for microscope diagnostics and cell sorting.
• Digital image processing of time lapse cellular fluorescent images for cell tracking and counting.
• Initiated genome editing project of parthenotes and embryonic stem cells.
• Digital PCR and fluorescent probe assay design for genome editing diagnostics.
• Assay development under design control process.
• Supervise junior scientists and/or technicians, where applicable

Senior Scientist

Experimed

Jan 2011 - Jan 2012 (1 year 1 month)

Directed and performed experimentation in a fast paced biotech startup in the design, development, and execution of biophysical, biochemical & cell-based assays in the development of molecular imaging tools.
• Provided technical and budgetary management in therapeutic ligand complex development.
• Introduced new functional assay concepts to project to improve ligand efficacy.
• Managed and mentored internal/external teams in assay development & sample testing
• Engaged key opinion leader relationships in brainstorming new product opportunities
• Engineered protein evolution libraries, protein expression and live cell imaging and FACS.
• Expert in molecular and cell biology in the context of physiologically relevant cell-based models

Senior Development Manager

W. L. Gore & Associates

Jan 2007 - Jan 2010 (3 years 1 month)

• Lead a large multidisciplinary teams to develop a diagnostic and therapeutic microfluidic optical based compliant medical system and associated disposable devices for treating stroke & peripheral thrombosis.
• Lead the system design, execution, and efficacy analysis of in-vivo/in-vitro blood clotting studies, ensuring compliance with class III FDA regulatory requirements, GMP and ISO13485 to bring novel class III laser product from feasibility to commercialization in less than 1 year.
• Coordinated CRO technical support between multiple international collaborative interests in defining product requirements, coordinating and executing biochemical, biophysical & cell assay design and beta testing.
• Designed and built tissue studies laboratory for feasibility investigative bench research, optimize delivery device design and pre clinical verification and validation experiments.
• Assurance test fixture creation leading to 90% increase in efficacy and reliability.
• Generated Verification & Validation documentation including assay test process protocols, SOP and acceptance criteria.
• Collaborated with physicians to define product requirements, develop medical devices and clinical efficacy test protocols, and create teaching tools.
• Provided scientific support to the global sales and marketing organization
• Worked with the customer to analyze data, develop optimal algorithms and parameters for digital image processing for improved throughput and FDA Premarket Notification submissions

Development Engineer

EnChroma, Inc.
Jan 2007 - Dec 2007 (1 year)
Lead engineer in a fast paced environment in the electrical and optical design, development and testing of ophthalmic instrumentation to characterize, quantify and treat color blindness correction.
• Reduced development cost and time to market by 80% through innovative state of the art optical and mechanical design of spectral sensitive diagnostic system.

Product Specialist
KLA
Jan 1997 - Jan 1999 (2 years 1 month)
Key account management with a strong customer focus in the areas of process optical pattern recognition algorithm development and machine vision inspection automation, imaging and data processing in the final
stages of product development and product introduction in a very competitive automation market.
• Provide on-site customer specific technical design and experimentation to initiate and validate pre-launch automation optical inspection system in a high pressure environment followed by post launch applications support, evaluation and training.
• Work with the customer and with internal sales and marketing and R&D scientists to analyze data, develop optimal control and data algorithms for digital image processing parameters for new product development and product manufacturing simplification.

Product Engineer
Laserscope Corp
Jan 1991 - Jan 1997 (6 years 1 month)
Lead a multidisciplinary team to develop optical based solid state laser ISO & FDA compliant medical devices and equipment while successfully meeting functionality, quality, safety, cost and schedule objectives.
• Managed project activities including client communication,
• Managed internal communications
• Created project plans based on written proposals and project deadlines.
• Engineered and tested prototype electro-optical subsystems for medical instrumentation used in laser tissue welding, dermatology, urology and cancer therapy (Photo Dynamic Therapy).
• Conducted fundamental research in laser optical system and delivery device design.
• Prepared and presented field product capability/validation reports for Asian, European and domestic customers.
• Worked with physicians to define product requirements, develop medical devices and clinical efficacy test protocols, and create teaching tools.
• Worked with physicians to design clinical studies in accordance with regulatory requirements.
• Responsible for the preparation of clinical sections of FDA Premarket submissions (510K)
• Provided scientific support to the global sales and marketing organization

Education

University of California
Ph.D, Molecular Biology

Tufts University

M.S, Optical Engineering

University of Massachusetts Boston
B.S, Electrical Engineering

Skills

Account Management • Product Requiremens • Risk Management • Feasibility Studies • Design Control • Verification and Validation (V&V) • sensor design • signal processing • imaging • Python (Programming Language)