Marc Meijer

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datbos.com

Project Lead

I am a hands on BS Electrical/MS optical engineer with a PhD in molecular biology with over 8 years experience leading the development of regulatory compliant micro-fluidic optical and image based 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 Highlights

Scientific Advisor and Technical Lead, Proximie Tele-Surgery, MA 2016 - 2017

Deliver the technical strategic vision for the development of novel 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.

Medical Development Scientist, Bedford Stem Cell Research Foundation, MA 2013- 2016

Brought innovative startup enthusiasm and "get it done" attitude in a cost sensitive academic foundation. Set project direction and performed hands-on CDx (companion 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 CRISPR CAS genome editing project of parthenotes and embryonic stem cells.
- QPCR, digital PCR and fluorescent probe assay design for genome editing diagnostics.
- NAT assay development under design control process for IVD process.
- Supervise junior scientists and/or technicians, where applicable

Molecular Senior Scientist, Experimed Biosciences, CA 2011-2012

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 Device Development Manager, W.L. Gore and Associates, CA 2007-2010

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.

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- Worked 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 (primarily 510K).

Device Development Engineer, Bay Glass Research Inc. Berkeley, CA 2007

Contract lead engineer in a fast paced environment in the electrical and optical design, development and testing of ophthalmic instrumentation to characterize, quantitate 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, Tencor Instruments, California, Netherlands, Germany, France 1997-1999

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.

Medical Product Engineer, Laserscope Surgical Systems,CA
1991-1997

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. Managing project activities including client communication, managing internal communications, creating project plans based on written proposals, meeting 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 tissue effects and optical system and delivery device design.
- Prepared and presented field product capability/validation reports to 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 and oversee the completion of those studies to assess clinical results.
- Responsible for the preparation of clinical sections of FDA Premarket submissions (primarily 510K)
- Provided scientific support to the global sales and marketing organization in the areas of laser dentistry, dermatology, urology, and clinical trials.

Education

Ph.D. Molecular Biology, University of California, California 2000-2007

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2008 Nobel Prize research Laboratory of Roger Tsien

Conducted fundamental research in molecular tool design, protein structural biology and biochemistry including advanced micro fluidic microscope cell sorter design and development.

- Designed high throughput fluorescent-FRET based assays and FACS sorting as applied to mutation library , small molecule, peptide and phage display assays.
- Expert in Microscopy (FRET, Confocal, TIRF, 2 Photon)

M.S. in Optical Engineering, Tufts University, Massachusetts.
B.S. in Electrical Engineering (**Cum Laude**)**,** University of Massachusetts, Massachusetts.

Skills

ISO 13485 Microfluidics Risk management Design Control LabView optical/sensor design CAD Signal processing Mammalian cell culture protein expression Matlab R Python SPR CRISPR/CAS Parthenote Stem Cell Protein Engineering DNA Evolution Library FACS-FRET TIRF 2-photon/Fluorescent microscopy