

Heather Keith

Executive Management

Medical Device Industry

CONTACT DETAILS

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HIGHLIGHTS

- Experience in Neurotech areas of stroke, FES, TCD, neuroplasticity, bioelectronic medicine
- Successful experience managing engineering, manufacturing, sales/marketing, and RA/QA/QC teams to execute large-scale projects, product development, and clinical trials
- Founded a medical device company, raised \$1.2M seed funding, hired/directed engineering team to build product (hardware + disposable), conducted 2 clinical trials, and achieved FDA 510(k) clearance
- Successful sales launch of a start-up company, new company divisions, and product lines
- Former MassMEDIC Board of Director, MIT D-Lab Scale-Up Mentor, Springboard Advisor

WORK EXPERIENCE

2018 – March 2020

Gemstone Biotherapeutics, Director, Marketing & Sales

- Prepare company for marketing and sales launch of Briagen flagship product
- Develop relationships with KOLs, manage clinical trials, establish branding, pricing and sales model, and participate in company fundraising

2015 – 2018

Battelle Memorial Institute, Sr. Director, Business and Market Development

- Responsible for commercialization and IP out-licensing of NeuroLife™ program assets
- Co-managed NeuroLife budget (\$2M) and team of 12 engineers to achieve clinical study and product development goals

2011 – 2015

Strohl Medical Technologies Inc., CEO, Founder, and President

Created a company to develop and commercialize the NeuroEPG™ System for rapid detection of stroke in the Emergency Department

- Raised \$1M from individual investors and secured \$245K loan from MLSC
- Patent to Product in 3 years – Directed the development of hardware, software and disposable product, vendor contract negotiations (components, packaging, testing, etc.), creation of company cGMP Quality System, 510(k) submission, transfer to manufacturing, and multiple manufacturing runs
- Achieved successful 510(k) clearance, managed 2 clinical trials, hired and managed engineering staff

2008 – 2011

Contract Sales Director Positions

New Health Sciences, Director of Sales & Marketing

- Prepared company for product launch, hired and trained initial sales staff, and developed marketing plan for a TCD ultrasound device

Soluble Systems, National Sales Director

- Managed a team of direct sales reps and independent reps
- Overhauled the sales process and revenue structure for TheraGauze smart wound dressing

2004 – 2008

TEI Biosciences, Director of Sales & Marketing

TEI Biosciences manufactures a biologic mesh for surgical repair

- Grew SurgiMend sales from zero to >\$13M annual revenue
- Hired and managed a team of 9 direct sales reps and 30 distributor sales reps
- Exceeded quota for 4 consecutive years
- Developed partnerships with KOLs and top surgeon users
- Developed marketing strategy and all marketing materials
- Initiated and managed all case studies and clinical trials

2002 – 2004

Strohl Marketing Strategies – Independent Consultant

Strategic marketing and sales consulting to medical device companies

- Provided an overview of several therapeutic areas, market trends, market assessments for niche markets, identification of clinical issues, product requirements, and sales channel options for client considering entry into new market
- Determined the viability of new product line claims regarding clinical need, sales projections, market acceptance and penetration for acquisition decision
- Developed multiple revenue models for the launch of a physician website
- Determined stage of development, competitive landscape, and evaluation of future trends for a surgical software program

2000 – 2002

eXcelon (now Progress Software)

Worldwide Product Marketing Manager

- Managed a \$1.2M annual marketing budget to drive sales across 4 products
- Launched new products including sales training and lead generation programs

1996 – 2000

SonaMed

Marketing Manager (Full time 1996 – 1998, Part time 1998 – 2000)

- Developed product pricing structure to meet corporate financial goals
- Developed the marketing and sales product launch program
- Initiated and managed a 1,000-patient clinical study on newborns

1996 – 2000

Medical Device Consultants, Inc. (now ICON)

Marketing Manager (Part time 1996 – 1998, Full time 1998 – 2000)

- Prepared and delivered a 4-part sales training program for the staff consultants
- Developed and implemented a marketing plan of advertising, website development, tradeshows and PR
- Positioned corporate branding to differentiate MDCl from competition

1993 – 1996

Level 1 Technologies (now Smiths Medical)

Product Manager and Clinical Coordinator for HotLine Fluid Warmer

- Annual product sales for grew from \$500K to > \$16M for disposable tubing sets during my tenure as Product Manager
- Managed all HotLine clinical studies
- Managed regional sales trainings, national sales meetings, and 20 annual trade shows

1991 – 1993

Hemagen Diagnostics,

Operations Associate, Regulatory Affairs/QA/QC Associate :

- Manufactured *in vitro* diagnostic test kits and produced QC test matrices
- Assisted in PMA and 510(k) filings
- Revised entire DMR/DHR and labelling procedures and updated documentation for FDA cGMP requirements

EDUCATION

Boston University Metropolitan College

Masters of Science in Business Administration (MSA) in Technology and Innovation

Gordon College, Double Degree

BS – Biology (PreMed)

BS – Business Administration

Minor – Chemistry

Emergency Medical Technician Certification