Leah M. Jenkin

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Global Medical Affairs Strategist

20+ years' success in the pharmaceutical industry and clinical practice

Repeated success guiding Medical Affairs operations and clinical trial programs, coordinating global product launch, and establishing cross-functional teams in organizations. Experienced in developing and executing medical affairs strategies and plans, to include Launch Readiness and Lifecycle Management. Effective in administering scientific communications, handling medical publications and medical education. Talent for leading teams and forging partnerships with internal and external employees. Excellent knowledge of clinical practice in oncology, hematology, gastroenterology, and endocrinology. Versatile problem with excellent interpersonal skills. Highly adaptable within a demanding environment.

Product Expertise

- Tasigna® (Nilotinib)
- Revlimid® (Lenalidomide)
- Pomalyst® (Pomalidomide)
- Thalomid® (Thalidomide)
- Procrit® (Epoetin Alfa)
- Natpara® (Parathyroid Hormone)
- Gattex®/Revestive® (Teduglutide)
- gammaCore® (Vagus nerve stimulation device)
- NTRA-2112 (Oral recombinant human inhalation insulin)
- Arikayce® (Amikacin liposome suspension)
- Galafold™ (Migalastat)

Career Experience

Grave Technology, Inc., New Brunswick, NJ

Global biotechnology company focused on discovering, developing, and delivering high-quality medicines for people living with rare metabolic diseases.

SENIOR DIRECTOR, PUBLICATIONS (Jan 2018 to Jul 2019)

Held responsibility for development and execution of publications and scientific communication strategy and tactical plan for multiple disease areas, including chaperone therapy and gene therapies.

- Provided guidance in administering a global publication and scientific communications functions.
- Coordinated cross-functional and cross-regional efforts to generate evidence and analyze clinical trials, registry, and health economics and outcomes research (HEOR) data.
- Collaborated with the external agency in developing a scientific platform, manuscripts, medical congress abstracts and presentations to manage data and ensure its accurate presentation.
- Prepared medical affairs materials and supporting documentation for internal training and external communication.
- Conceptualized and initiated content development strategy for advisory boards and scientific symposia.
- Created a compliant publication policy and outlined the development process.

MedSave Inc., New Brunswick, NJ

Global biopharmaceutical company focused on transforming the lives of patients with serious/rare diseases. Its mission is to develop and bring to the market new therapeutic solutions to enhance the patient experience.

DIRECTOR, SCIENTIFIC PUBLICATIONS (May 2017 to Jan 2018)

Held responsibility for scientific publications and streamlined publication processes.

- Redesigned Veeva Vault Content Management System workflow to optimize streamlined publication and medical material review process.
- Developed and introduced a new publication policy and established development process.

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- Ensured full compliance with publication guidelines; educated staff members on the publication process and prepared medical affair materials.
- Planned and executed data generation and analysis plan, including HEOR data.

Natural Health Inc., New Brunswick, NJ

Privately held pharmaceutical company (headquartered in Israel) focused on developing propriety products for intestinal malabsorption and short bowel syndrome, orphan gastrointestinal indications in infants.

EXECUTIVE DIRECTOR, MEDICAL AFFAIRS (Sept 2016 to Feb 2017)
CONSULTANT (Mar 2017 to Aug 2018)

Coordinated medical affairs for product development and assisted with new clinical trials.

- Initiated, developed, and executed an integrated medical affairs strategy and tactical plan in preparation for product development and launch phases.
- Collaborated with the Executive Team to create and implement the corporate development plan.
- Authored the Pediatric Investigation Plan (PIP) for submission to the European Medicines Agency's (EMA) Pediatric Committee (PDCO) and managed responses to the Agencies.
- Assisted in executive two new Phase III clinical trials by managing discussions with potential investigators, providing tools and materials for study sites, and making site initiation visits.
- Developed protocols, created investigator brochures, and prepared disease education presentations.

Treatment Technology, LLC., New Brunswick, NJ

Medical technology company harnessing nVNS innovation and technology to develop safe and clinically backed treatments for patients suffering from pain and chronic conditions.

EXECUTIVE DIRECTOR, CLINICAL DEVELOPMENT AND MEDICAL AFFAIRS (2015 to 2016)

Oversaw strategic development of the company and medical affairs operations.

- Designed new medical affairs strategy and tactical plans to prepare for the product launch.
- Collaborated with the Chief Medical Officer and Executive Team Members to develop the corporate strategic development plan.
- Initiated launch readiness program to facilitate patient finding initiatives, field medical force sizing, and call center administration.
- Established Medical Affairs departmental standard operating procedures (SOPs).
- Developed and implemented policies for administering 50+ investigator-initiated-trials (IITs).
- Designed a scalable promotional and medical material review process complying with the guideline requirements and company needs.
- Planned and executed clinical trials in collaboration with the Chief Medical Officer.
- Assisted with the design of post-marketing patient registries.

IRT Pharmaceuticals Inc., New Brunswick, NJ

Biopharmaceutical company developing treatment options for patients with rare gastrointestinal and endocrine disorders and serious unmet medical needs.

SENIOR DIRECTOR, GLOBAL MEDICAL PUBLICATIONS (2012 to 2015)
DIRECTOR, GLOBAL MEDICAL INFORMATION (2011 to 2013), **INTERIM** (2014 to 2015)
DIRECTOR, MEDICAL EDUCATION AND PUBLICATIONS (2011 to 2012)

Oversaw global publication programs, communication strategy, and medical informational processes.

- Led a team of internal/external publication experts and cross-regional global publication planning team.
- Designed a publication development process and a Global Medical Review Board procedure.

- Introduced and integrated a new scientific communication strategy to support U.S. and global programs for products in short bowel syndrome and hypoparathyroidism.
- Developed and implemented medical information processes during the inception phase of the Medical Affairs Department.
- Oversaw the global medical information function (i.e. contracted call centers, medical writing resources, etc.)
- Managed the global medical affairs annual operating budget of $12M.

Additional Experience

Director, Global Scientific Communications (2009 to 2011) ▪ Rense Corporation, New Brunswick, NJ

Associate Director (2006 to 2009) ▪ Oncology Corporation, New Brunswick, NJ,

Clinical Trials Specialist (2004 to 2006) ▪ Biotech Health, New Brunswick, NJ

Senior Medical Information Specialist (2000 to 2004) ▪ Biotech Health, New Brunswick, NJ

Clinical Pharmacist (1998 to 2000) ▪ Medical Center, New Brunswick, NJ

Teaching and Research Experience

Adjunct Faculty (1996 to 1997) ▪ *State University, College of Pharmacy, Indianapolis, IN*

Teaching Assistant (1992 to 1994) ▪ *Purdue University, West Lafayette, IN*

Research Lab Assistant (1992 to 1993) ▪ *Purdue University, West Lafayette, IN*

Education & Training

Doctor of Pharmacy (1996)
Purdue University, School of Pharmacy, West Lafayette, IN

Residency in Pharmacy Practice (1996 to 1997)
Methodist Hospital of Indiana, Indianapolis, IN

Licensure

- Licensed Pharmacist – New Jersey, Indiana