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SUMMARY

A senior experienced executive leader from within the multi-national pharmaceutical, medical device and consumer products industries, with strong marketing instinct and a commitment to R&D excellence from concept to market. True results oriented professional with thirty years of experience in regulatory affairs, innovation, business development, medical affairs, clinical development, and quality compliance.

Career Highlights:

Board of Directors / Board Advisor – Public and private Board Positions with key committee leadership.

Research & Development Management – Timely and successful global R&D implementation, with cultivation of key internal and external stakeholder relationships in order to optimize R&D output for business growth.

Medical Affairs Management – Founder of Medical Affairs Departments for three companies (Allergan, Ipsen and BBraun), with a focus of proactively establishing and maintaining professional working relationships with KOLs and Scientific Advisors to execute clinical studies, communication/publication strategy, ISTs, and promotional and safety materials.

Phase I-IV Clinical Trial Management - Technically skilled manager and researcher with strong project management capabilities and a proactive approach to successful endpoints. Able to analyze and interpret data to best support business objectives. Proven successful management of global clinical trials across multiple therapeutic areas from 100 to12,000 patients.

FDA /EU Regulations/ Submissions/ Health Authority interactions – Managed and directed global Health Authority submissions and negotiations for product approvals, inspections, promotional material, license renewals, and variations. Regulatory Leadership and success in all major markets.

Business Development Evaluation – Key internal consultant to business development for licensing and acquisitions. Senior member of Due Diligence Teams. Experience spans greater than 40 M&A/Due Diligence assignments.

Medical Marketing Communication – Senior Medical Advisor to the commercial side of the business on marketing strategy for promotional material, product literature, sales training, global communications, and potential partner capabilities presentations.

Regulatory and Quality Assurance Strategy – Established strategy and standards for approval and compliance pathways of medical devices, pharma products, new product ingredients, de-novo technology, dose forms, claims and packaging.

WORK HISTORY

2014-present — *Senior Vice President Scientific Affairs, Chief Medical Officer, BBraun Medical Inc., Bethlehem PA.*

Board of Directors, BBraun Medical Inc., Bethlehem PA.

Responsible for providing strategic direction and leadership for Quality Assurance, Medical Affairs, Clinical Development, Publication and Information Services, Drug Safety, Regulatory Affairs, and Biostatistics across Medical Device, Nutritionals and Injectable drug Divisions. Deliver near and long term strategies and tactics to protect and optimize company products. Senior physician in the US and member of the Board of Directors.

- Redesigned Operations across device and drug franchises to deliver focused, value add registration activities, investigator-initiated studies, regulatory, clinical development and publications.
- Initiated Quality and Compliance activities and monitoring systems to ensure protection and validity of engineering, manufacturing, and scientific activities across all franchises.
- Delivered novel KOL interaction and services programs to optimize product advocacy and share of scientific voice.
- Created innovation platform for continual updating and improvement of product labeling to support claims.

2013 - 2014 — *Chief Medical Officer, Ipsen Biopharmaceuticals Inc., Basking Ridge, NJ*

- Key member of the executive team with accountability for providing strategic leadership as well as operational prioritization and oversight for all scientific aspects of product development, registration, and post-marketing activities in Neurology (Dysport botulinum neurotoxin) and Endocrinology (Increlex).
- Worked directly with the Chief Executive Officer and other members of senior management team to identify and prioritize product opportunities and align development activities with corporate strategy.
- Direct responsibility in all aspects of R&D, Medical Affairs, Clinical Development, Regulatory Affairs, Drug Safety and Clinical Operations.

2006 - 2013 *Senior Vice President, Global Research & Development. Bayer HealthCare, Specialty Pharma, Medical Device & Consumer Care, Morristown, NJ*

Responsible for full scope of research and development activities globally consisting of design, formulation, analytical, pre-clinical, clinical development and medical affairs, regulatory affairs, drug safety, project management and innovation departments. Responsible for annual budget of greater than 320MM through 9 direct and 400 indirect reports globally.

- Increased pipeline NPV four-fold with the implementation of new strategy, processes, goals, and efficiencies resulting in pipeline clinical development clinical development programs in thousands of patients.
- Created best in class innovation process and group to evaluate and implement clinical development/medical affairs strategies, new device technologies, novel ingredients, dose forms, combinations, packaging, Rx-OTC switch and non medicated therapies.
- Created best in class pharma regulatory compliance system globally as a business protection measure – 1200 formulations, 134 country registrations, and greater than 200 manufacturing sites.
- Key management committee member and Chief Medical Officer for Division.

2000-2006 *Vice President Medical Affairs. Allergan, LLC. Irvine California*

Founder of Allergan Medical Affairs.

Responsible for the creation and execution of Medical Affairs Department strategies and plans for all products. Focus on neurology, dermatology and ophthalmology. Managed the department and budget to successfully support the creation of company sponsored pilot trials, investigator initiated trials, drug safety collection and analysis, product medical information, KOL development, CME programs, and publication analysis and planning.

- Successfully created and implemented a vision to build an industry- recognized best-in-class Medical Affairs/MSL Department.
- Track record of successful change management and organizational scaling.
- Directly responsible for Medical Affairs product support yielding marked product growth across all therapeutic areas.
- Acknowledged as industry leader in Medical Affairs regulatory compliance.

1992-2000 *Warner Lambert Company, Morris Plains NJ.*

- *Senior Medical Director & Global Head - Dermatology, Gastroenterology, and Complementary Medicine.*

Responsibility for Clinical Research and Medical Affairs department activities for company marketed products, NDA compounds, and Rx-to-OTC switch candidates. Senior member of R&D management and leader, global product development in personal care, dermatology, complementary medicine and GI areas, providing strategic planning and direction in those areas. Strong role in stakeholder development and continuous procurement of medical and business/competitive intelligence. Critical continuous interaction with, and medical advisor to Regulatory Affairs, Statistics, Marketing Research, Marketing, Sales, Legal, and Public Affairs departments. Accomplishments include H2RA switch, multiple SNDAs, healing and anti-scarring development, and homeopathic/botanical drug development to support business goals.

- *Medical Director, Rx-OTC compounds.*

Responsible for the planning and implementation of clinical research and FDA activities in support NDAs of a nicotine patch and an NSAID (meclofenamate sodium) for Rx-OTC switch. Pivotal studies successfully completed for both compounds prior to program discontinuations for business reasons. Instrumental in the development of label comprehension and actual-use trials through leadership within the company and also at FDA and in industry wide collaborative projects.

Pre-industry Medical Practice:

General Practice, Chicago, Illinois .Associate Director, Physicians Cooperative, Chicago, Illinois.

Family Practice attending physician with clinical and administrative responsibility for two medical facilities in partnership.

AFFILIATIONS

- Board Member – B Braun Medical Inc.
- Board Member – Medical Device Innovation Consortium (MDIC)
- Board Member - American Foundation for Pharmaceutical Education 2010-2012
- Advisory Board Member – GlaxoSmithKline (US & UK) 2012-2015
- American Academy of Family Practice
- Accreditation Council for Medical Affairs
- American College of Clinical Pharmacology
- American Society for Clinical Pharmacology and Therapeutics
- Canadian Society for Clinical Pharmacology
- Nonprescription Drug Manufacturers Association (CHPA)
- Drug Information Association
- College of Physician Executives
- Gerson Lehrman Group, Inc., Healthcare & Biomedical Council
- Reviewer - Journal of Wound Care, London England

EDUCATION

McMaster University, Hamilton, Ontario
Pre-med studies.

American University (AUC) School of Medicine, Northern Antilles
Doctor of Medicine. Preclinical, clinical training.

Canadian Foreign Equivalency Certification

ECFMG certification

University of Illinois Affiliated Hospitals, Chicago, Illinois

Rotating Internship. Training included Internal Medicine, Pediatrics, Ob/Gyn, Psychiatry, Cardiology and Emergency Medicine.

University of Illinois Affiliated Hospitals, Chicago, Illinois

Family Practice Residency. All appropriate areas of training, leading to Board Qualification in Family Practice by the American Academy of Family Practice.

Accreditation Council for Medical Affairs

Board Certified in Pharmaceutical Medical Affairs

Medical Licensure : State of Illinois #125014417 (inactive)