Carol Pekar, RAC
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OVERVIEW: Vice President of Clinical and Regulatory Affairs with record of accomplishment in delivering successful clinical trials and obtaining key global regulatory approvals for Combination Products (Drug-Device, Biologic-Device), Class II/III Medical Devices, and Veterinarian Drugs. Clinical trial experience spans over 50 drug and device trials in cardiology, orthopedics, dermatology, and oncology. Significant experience with FDA includes 505(b)(2) NDA, PMAs, HDEs, Advisory Panels, Appeals, Combination Product Designations, IDEs, and INDs. Additional global product approvals obtained in Europe, Canada, Japan, China, and other ROW countries. At the request of AdvaMed, represented industry at FDA 'New Innovation Pathway' Panel. Credentials include Regulatory Affairs Professional Society certification (RAC), Babson MBA, Certificate in Clinical Research from Boston University School of Medicine, and Graduate Certificate in Regulatory Affairs from Northeastern University.

EXPERIENCE:

5/2016 - Present **Microchips Biotech, Inc.** **Lexington, MA**
VP Regulatory and Clinical Affairs

- Reporting to the CEO, lead regulatory and clinical affairs for a biotechnology start-up revolutionizing drug delivery with a microchip-based implantable device that can be wirelessly activated to dose on demand or per a pre-programmed schedule
- Technology platform designed to use approved APIs in areas such as diabetes and contraception so that a streamlined 505(b)(2) NDA approach may be used for product approval
- Engaged the FDA 'early and often' via Request for Designation, informational meetings, and pre-sub meetings, and interactions with Office of Digital Health.

5/2013 – 4/2016 **Anika Therapeutics, Inc.** **Bedford, MA**
VP Regulatory and Clinical Affairs (Corporate Officer)

- Developed and implemented regulatory and clinical strategies supporting business objectives
- Managed global Clinical and Regulatory Affairs staff in U.S. and Italy; five pivotal clinical trials
- Worked regulatory pathway and clinical development requirements with the FDA for a novel drug-device combination product, Cingal®, for the treatment of osteoarthritis. Obtained European and Canadian approvals as a device with ancillary medicinal substance.
- Achieved PMA approval for hyaluronic acid viscosupplement for treatment of osteoarthritis, Monovisc®, after product was declared 'not approvable' by the FDA
- Successfully obtained CE Mark for a new indication (tendinopathy) of a marketed product, Orthovisc®, without requiring a clinical trial
- Persuaded CBER to allow a novel device-biologic product, Hyalofast® for orthopedics to proceed directly to a pivotal trial without a feasibility study first

4/2009 to 5/2013 **Abiomed, Inc.** **Danvers, MA**
Sr. Director Global Regulatory and Clinical Affairs

- Reporting to the COO, responsible for development of clinical and regulatory strategies for product line of Class III active implantable electronic heart pumps including the total artificial heart, VADs, and Impella percutaneous devices
- Managed global Clinical Research and Regulatory Affairs staff
- Provided oversight for six global clinical studies including protocol development, study management, analysis of results and clinical study reports

- Primary liaison with FDA (for PMAs, HDEs, 510(k)s, and IDEs) and other global regulatory agencies (EU, Health Canada, Japan, China, Australia) to obtain global regulatory approvals
- Managed Abiomed participation in an FDA Advisory Panel for Impella® heart pump including preparation of team, conduct of a mock panel, and orchestration of advocacy statements by physicians, patients, medical associations, and industry trade associations

3/2005 – 4/2009 Palomar Medical Technologies, Inc. Burlington, MA

Director of Clinical Affairs

- Developed clinical and regulatory strategy for Palomar consumer product development; acted as Alliance Manager for strategic partnership with J&J Consumer Products Division
- Drove clinical and regulatory program to achieve first FDA 510(k) clearance of OTC consumer home-use laser device for treatment of rhytids and solar lentigines, which required a total of 13 studies under 9 different IDE's
- For professional light and laser business, managed luminary investigators, clinical sites, and external vendors to oversee successful execution of over 20 medical device clinical trials in dermatology and plastic surgery indications

4/2003 – 3/2005 Perceptive Informatics (Parexel) Waltham, MA

Project Manager II

- Provided project management for imaging component of six global clinical trials studying diverse therapeutic agents including a new drug to treat ischemic stroke, drug-coated coronary stents, and PFO-closure device

9/2002 – 4/2003 Clinical Assistance Programs Brookline, MA

Clinical Research Associate

- Responsible for monitoring 10 sites across the United States for pivotal Phase III oncology trial for major pharmaceutical firm

Summer 2002 Boston Medical Center Boston, MA

Clinical Research Coordinator Internship, Cardiology Unit

- Screened patients for enrollment in four cardiovascular clinical trials
- Prepared IRB review materials, submitted SAE reports, maintained regulatory documentation

1985-2001 Polaroid Corporation Waltham, MA

Divisional Vice President Media R&D (1996 – 2001)

- Successfully delivered seven new consumer and professional film products to market
- Responsible for 110-person group; $45M budget
- Reduced product development cycle time by 50% over two years and achieved 30% share take-back from major competitor

EDUCATION/CERTIFICATIONS:

- Regulatory Affairs Professional Society *RAC Certification*
- Northeastern University *Graduate Certificate in Regulatory Affairs*
- Boston University School of Medicine *Certificate in Clinical Research*
- Babson College *MBA*
- St. Bonaventure University, Olean, N.Y. *Bachelor of Science, Chemistry*

ASSOCIATIONS:

- AdvaMed — Member, AdvaMed Technical and Regulatory Group; FDA Strategy Group
- MDMA — Member, FDA Working Group
- RAPS — Member, Regulatory Affairs Professional Society
- St. Bonaventure University — Member, Scientific Advisory Board (1999-2002)
- Shanti Christo Foundation — Member, Board of Non-Profit Directors (2005 – 2008)

FDA PANEL MEMBER: 'New Innovation Pathway' FDA Panel (2011)