PAUL M. KIRSCH

pkirsch@harmonybiosciences.com

PROFESSIONAL SUMMARY:

I have over 40 years of industry experience in both Pharma and Biotech organizations with over 30 years in Regulatory Affairs. I currently serve as the VP of Regulatory Affairs in a small pharma company. My regulatory expertise spans early- and late-stage development, marketing applications, and post-approval activities. Specifically, I have led teams for submission of over ten original NDAs/MAAs, and label-expansion supplements, over 30 INDs, as well as five FDA Advisory Committee meetings. Over the years, I have gained expertise in neurology, psychology, pain, and orphan products along with direct FDA liaison interactions. My regulatory experience also includes International regulatory activities covering, the EU, UK, Asia-Pacific, Middle East, Canada, Mexico, and South America.

EXPERIENCE:

Harmony Biosciences, LLC – Plymouth Meeting, PA

Vice President – Regulatory Affairs ***Oct 2023 – Present***

Zynerba Pharmaceuticals, Inc. – Devon, PA

Vice President – Regulatory Affairs & Quality Assurance ***Jan 2020 – Oct 2023***

- Leading the regulatory strategy for the phase 3 development of lead candidate in the treatment of behavioral symptoms in pediatric patients with Fragile X syndrome (orphan), 22q11.2 deletion syndrome (orphan), and autism spectrum disorder
- Serve as primary contact to FDA on all assigned products

Trevena, Inc. – Chesterbrook, PA

Vice President – Regulatory Affairs ***May 2017 – Jan 2020***

- Led the preparation, completion, and submission of the company's first NDA for an NCE
- Led internal team in preparation for FDA Advisory Committee Meeting
- Served as primary contact for FDA (DAAAP)

Iroko Pharmaceuticals, LLC – Philadelphia, PA

Vice President – Regulatory Affairs ***July 2014 – May 2017***
Exec. Director – Regulatory Affairs – US ***May 2013 – June 2014***

- Developed global regulatory strategies for all marketed and investigational products
- Served as FDA liaison and regulatory lead for 3 NDAs, negotiated final approval of 2 NDAs and 1 efficacy sNDA, and directly involved in 3 product launches (DAAAP)
- Responsible for maintaining current labeling and the review and approval of all promotional materials
- Provided regulatory due diligence for all potential acquisition candidates

TEVA Global Branded Products (formerly Cephalon, Inc.) - Frazer, PA

Sr. Dir. and Group Leader – Regulatory Affairs ***January 2007 – April 2012***
Senior Director – Regulatory Affairs ***January 2001 – December 2006***
Director – Regulatory Operations ***March 1998 – December 2000***
Associate Director – Regulatory Affairs ***July 1995 – February 1998***
Manager – Regulatory Affairs ***July 1994 - July 1995***
Senior Associate – Regulatory Affairs ***July 1993 - July 1994***

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- Responsible for company's CNS therapeutic area, including products in narcolepsy (orphan), OSA, circadian misalignment, ADHD, epilepsy, and ALS (orphan)
- Responsible for the International RA activities for all Global products in Asia-Pacific, Canada, Mexico, and South America
- Developed registration strategies for entry of our products in targeted markets
- Led the preparation of 6 INDs, 3 original NDAs and an efficacy supplement
- Key participant in numerous FDA meetings and four FDA Advisory Committee Meetings
- Responsible for maintaining current labeling and the review and approval of promotional materials for assigned products
- FDA Divisional contacts: Neurology, Psychiatry, Oncology, Pain and Rare Diseases

Wyeth-Ayerst Research - Radnor, PA
Regulatory Coordinator - US Regulatory Affairs ***June 1990 - July 1993***

- Coordinated the scheduling, preparation, and submission of Supplemental NDAs and Amendments, NDA Annual Reports, ADE Periodic Reports, 15-day Adverse Drug Experience Reports, DMF Annual Updates, Drug Listing Updates to FDA
- Reviewed labeling revisions and promotional materials for assigned products
- Responsible for coordinating activities for compliance with User Fee legislation
- Review of product change requests for conformance to the NDA
- Member of systems design team for various computer applications
- FDA Divisional contacts: CDER: Anti-Infective, Anti-Viral, Pilot Drug, GI; OGD; and CDRH

Wyeth-Ayerst Research - Radnor, PA
Coordinator - Clinical Data Management ***March 1987 - May 1990***
Clinical Research Assistant - Clinical R & D ***August 1985 - February 1987***
Medical Data Assistant - Biostatistics ***October 1983 - July 1985***

EDUCATION:

Bachelor of Science - Biology, May 1983
University of Scranton, Scranton, PA

PROFESSIONAL AFFILIATIONS/ACTIVITIES:

BIO –Representative to Regulatory Affairs Steering Committee (RASC)
Member on FDA Meetings and ICH Taskforces
Regulatory Affairs Professional Society – Current Member
Drug Information Association – Current Member
Presentations:
ACI - Advertising and Promotion, Jan. 2016
BIOTECH 2002 – Navigating Drug Development in Small Pharma

LinkedIn public profile: www.linkedin.com/in/paul-m-kirsch-22626216