Deborah Ann Cenci

Vice President of Regulatory Affairs, Compliance and Quality at DIVA Pharmaceuticals - Deborah.Cenci@DIVApharma.com

deborah.cenci@divapharma.com

Summary

Deborah has over 19 years of regulatory affairs and compliance experience in the pharmaceutical and medical devices industry in providing International R&D and Regulatory Strategies for development for over 320 Rx Drugs and 48 Medical Devices. She is presently the Vice President of Regulatory Affairs, Compliance and Quality at DIVA, where she is responsible for international regulatory departments such as; regulatory affairs, drug safety, compliance, audits, pre-clinical, post-marketing, Drug Discovery ,regulatory strategy,resource allocation, global project and portfolio management for all phases of life sciences. Deborah manages CRO relationships and all outsourced projects, and is QA advisor; She interfaces with Health Authorities, Regulatory Agencies, and is the U.S Agent for multiple Foreign Firms. She has established effective working relationships with the FDA, established SOPs for effective operation of the Regulatory Affairs departments, and prepared regulatory submissions for domestic and international product development and registration. She managed and implemented the submission of the first Chinese Rx Product to the FDA in the world. She served as Regulatory Delivery Leader assigned to multiple FDA regulated customer accounts. She was in charge of validating all applications including iCloud, providing documentation and training for all regulatory activities. She interfaces and conducts vendor audits and builds global regulatory strategies for Medical Devices and Rx Drugs in relationship to new guidelines and market expansion . She has authored and contributed to two well respected books on CSV within Life Sciences. She has also served as an Expert Witness for various Fraud, Compliance Civil and Criminal Cases. She has served on various CEO and CIO forums and boards to assist leaders in developing new approaches to avoid risk, develop stronger compliance practices and assisting in resolving 3rd party compliance issues worldwide.

Experience

Chief Compliance Officer - Vice President of Regulatory Affairs, Compliance and Quality. at DIVA Pharmaceuticals, Inc.

March 2000 - Present

DIVA Pharmaceuticals, Inc. is a dynamic pharmaceutical firm that specializes in Rx Drugs,Over the Counter Products, Animal Health, Medical Supplies and Medical Devices.

DIVA Pharmaceuticals, Inc. has just launched a new division that provides healthcare services and medical supplies. DIVA has increased it's presence in the last 6 months and is presently selling their products in over 66 countries.

DIVA Pharmaceuticals, Inc. is one of the Key Sponsors for the Medical Device Industry Council - International and Domestic Association. DIVA Pharmaceuticals, Inc. is proud to sponsor such an organization. The organization basis is to help Medical Device Firms and Innovators - Connect, Make Contacts and Communicate - Medical Device Industry Standards and New & Improve Devices Worldwide. Deborah Cenci, is the Volunteer Executive Director of the organization worldwide.

2009 - Expert Witness and Advisor for Global Regulatory Compliance Issues pertaining to Federal and State Regulations. Expert in Powerful, Persuasive, "Bulletproof" Reporting and direct testimony.

DIVA Pharmaceuticals, Inc. has since closed down their New Jersey and New York offices last quarter 2014. The firm was acquired by an International Firm with over 27 offices world-wide.

Please feel free to contact me on my reach number: 201-961-4928 for further information.

Third Party Compliance Officer
2010 - 2015 (5 years)

Director - New Jersey Office
1998 - 2004 (6 years)

Director at Coopers & Lybrand
1997 - 1998 (1 year)

Business Analyst at PSEG
1991 - 1992 (1 year)

Education

Fairleigh Dickinson University
BA and MBA Program, 1990 - 1994

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Contact Deborah Ann on LinkedIn