MICHAEL D. BUI, DDS, MPH, JD

Pyxis Oncology
Cambridge, MA 02139
mbui@pyxisoncology.com

EXPERIENCE

- **Senior Vice-President, Head of Global Regulatory Affairs,** Pyxis Oncology *(1/2022 – Present)*
- **Senior Vice-President, Regulatory Affairs,** Kadmon Pharmaceuticals, a Sanofi Company *(3/2020 – 12/2021)*
- **Vice-President, Regulatory Affairs**, Surface Oncology (*4/2019 – 2/2020*)
- **Vice-President, Immuno-Oncology, Regulatory Affairs**, Idera Pharmaceuticals, Inc. (*7/2017 – 3/2019*)
- **Director, Global Regulatory Lead, Immuno-Oncology, Global Regulatory Affairs,** EMD Serono (*6/2016 – 7/2017*)
- **Director, Internal Medicine Group, Global Regulatory Affairs**, Teva Pharmaceuticals Inc. (*3/2014 – 6/2016*)
- **Associate Director, Global Regulatory Strategist**, **Specialty Medicine, Oncology, Global Regulatory Affairs,** Bayer HealthCare Pharmaceuticals Inc. (*6/2010 – 3/2014*)
- **Drug Regulatory Affairs Specialist, Pharma Development Regulatory**, Hoffmann-La Roche (*7/2007 - 6/2010*)
- **Global Labeling Strategist, Global Labeling and Promotion Compliance, Regulatory Science,** Bristol-Myers Squibb Company (*9/2006 – 7/2007*)
- **Medical Writer (Consultant)**, Keryx Biopharmaceuticals, Oncology Clinical Development Group (*6/2006 – 8/2006*)
- **Regulatory Intelligence Analyst (Consultant)**, Regulatory Affairs, Genentech, Inc. (*4/2005 – 4/2006*)

EDUCATION

- **Juris Doctor**, State University of New York at Buffalo, School of Law, NY (*2003*)
- **General Practice Residency Certification**, Veterans Affairs Medical Center, Brooklyn, NY (*2000*)
- **Doctor of Dental Surgery**, Columbia University, College of Dental Medicine, NY (*1999*)
- **Master of Public Health**, Columbia University, School of Public Health, NY (*1999*)
- **Bachelor of Arts**, Molecular Cell Biology, University of California at Berkeley, CA (*1992*)

ACADEMIC APPOINTMENTS AND PROFESSIONAL AFFILIATIONS

- **Adjunct Lecturer, Regulatory Affairs and Health Policy**, Massachusetts College of Pharmacy and Health Sciences University (*2019 – Present*)
- **Regulatory Science Forum Member**, Harvard-MIT Center for Regulatory Science (*2018 – Present*)
- **Adjunct Lecturer, Master of Science in Regulatory Affairs Program**, Northeastern University (*2011 – 2020*)
- **Adjunct Assistant Professor, Epidemiology**, Rutgers University, School of Public Health (*2011 -2016*)
- **Editorial Advisory Board Member**, Food and Drug Law Journal (*2013 – 2016*)
- **Member**, Food and Drug Law Institute's Global Committee *(2013 – 2015)*

FDA ADVISORY COMMITTEE MEMBERSHIP

- **Industry Representative,** CDER Pharmacy Compounding Advisory Committee (PCAC) *(2019 – Present)*
- **Industry Representative**, CDRH Dental Products Panel (*2010 – 2014*)

PRESENTATIONS

- Workshop Leader, "Best Practices Seminar – Key Skills to Optimize Presentation Approaches," CBI's 5th Annual Summit on FDA Advisory Committee Preparation, Washington, DC (February 6, 2014)
- Panelist, "Ascertaining the Type and Volume of Clinical Data Necessary to Establish Biosimilarity," American Conference Institute 2nd National Conference on Biosimilars, New York, NY (June 8, 2011)
- Panel Speaker, "Managing Legal Risks in Structuring and Conducting Clinical Trials in the United States and Abroad," American Conference Institute 13th Advanced Forum on Clinical Trials, Philadelphia, Pennsylvania (January 26, 2011)
- Speaker, "Tackling Social Media and Advertising Compliance in the Absence of Formal Regulations," Pharmaceutical Compliance: Off-Label Promotion Conference sponsored by Q1 Productions, Philadelphia, PA (November 8, 2010)
- Panel Speaker, "Rules for Good Clinical Practice/GCP Audits," 2010 Regulatory Affairs Professionals Society (RAPS) Annual Conference & Exhibition, San Jose, CA (October 26, 2010)
- Panelist, Fourth Annual Student Health Law Conference, American Society of Law, Medicine, and Ethics and Center for Health & Pharmaceutical Law & Policy, Seton Hall School of Law, Newark, New Jersey (October 22, 2010)

- Panel Speaker, "Clinical Trial Compliance: Meeting Quality and Safety Obligations While Keeping Oversight Agencies Happy," New York Biotechnology Association 19th Annual Meeting, New York, NY (April 19, 2010)

- Panelist, "Corporate Counsel Guide to Advertising, eMarketing and Promotions for the Pharmaceutical Industry," American Conference Institute's 8th Annual Program, Philadelphia, Pennsylvania (April 14-15, 2010)