

Robert A Paarlberg

189 Aspen Drive
Daleville, VA 24083

Cell: +1 404.345.2804
RPaarlberg@comcast.net

Summary of Qualifications

- More than 45 years of pharmaceutical industry experience in US and international regulatory affairs
- Expert knowledge and expertise in global regulatory policy and intelligence
- Recognized expert in global clinical trial disclosure/transparency strategy and operations
- Proven track record in advancing corporate regulatory policy/strategy
- Expert in US and non-US (Europe) regulatory systems
- Experienced liaison with senior staff in FDA and key non-US agencies
- Accomplished at monitoring and assessing US federal legislation impacting the pharmaceutical industry

Work Experience

Principal, Paarlberg & Associates, LLC

2010 - present

- Consultancy specializing in global regulatory policy/intelligence and global clinical trial disclosure/transparency strategy and operations
- Issue weekly Government & Policy newsletter on key global regulatory policy and intelligence topics impacting the pharma industry
- Provide clients with insight and expert opinion on global clinical trial disclosure/transparency strategy and operations
- Actively engaged in current and evolving clinical trial disclosure/transparency landscape in the US and Europe

UCB, Inc., Smyrna, GA

2010 - 2002

Director, Government Affairs & Policy (2010 – 2009)

- Monitor and assess key policy issues at the US federal level (e.g. healthcare reform)
- Prepare policy briefs on key US federal legislation for senior management
- Provide global oversight of the Clinical Trial Disclosure environment

Director, Global Regulatory Policy & Intelligence (2009 – 2004)

- Created and managed the company's first global regulatory policy and intelligence function
- Identified key legislative (e.g. FDA Amendments Act of 2007 – FDAAA) and regulatory initiatives (e.g. clinical trials registry, REMS) and prepared timely policy briefs for senior management
- Established and chaired a corporate multi-disciplinary Team tasked with interpretation of and compliance with FDAAA
- Supported development of corporate positions/strategies targeting key regulatory,

- legislative and guidance policy developments
- Leveraged corporate policy/strategy into industry positions through leadership on key committees in national/regional associations (e.g. BIO, EFPIA, EBE)
- Advanced corporate regulatory and marketing approval policies/strategies by liaising with senior staff in key regulatory agencies such as FDA and EMA
- Organized and managed the company's first Clinical Trial Registry and Results Disclosure process on a global basis

Director, Regulatory Affairs (2004-2002)

- Advanced corporate regulatory strategy concerning development and timely approval of new drug therapies and indications for North America in the CNS and Allergy therapeutic areas
- Led a staff of four managers, two associates and one support staff
- Participated on multi-disciplinary drug development teams
- Led Japan Medical/Regulatory Liaison Team tasked with achieving regulatory approval in Japan for a key product

**Pharmacia Corporation, Kalamazoo, Michigan
(formerly The Upjohn Company)**

2002-1974

Senior Director, Global Regulatory Policy & Intelligence (2002-1998)

- Established and organized the first corporate global regulatory policy and intelligence function
- Led a global staff of three directors, one senior manager and two support staff
- Initiated multi-disciplinary task force to assess implications/propose amendments to European pharmaceutical legislation
- Established a European Regulatory Intelligence Council
- Charter member in the Washington Regulatory Liaison Group since 1990
- Liaised with senior health officials in Japan, China, Taiwan, Singapore, Malaysia and Thailand

Director, Global Regulatory Intelligence (1998-1996)

- Responsible for bringing Dr. Murray Lumpkin, Deputy Center Director, FDA, to Kalamazoo for an educational seminar on regulatory issues
- Supervised five regulatory managers and eight associates
- Managed preparation of all IND amendments and NDA/IND annual reports
- Collaborated with Washington Government Affairs staff in drafting favorable legislation on Exports (1996 Export Act)

Director, Worldwide Regulatory Operations (1996-1995)

- Managed the compilation and submission of INDs, NDAs and international dossiers
- Supervised eight regulatory managers and ten support staff

Senior Regulatory Manager, Washington Regulatory Liaison (1995-1990)

- Established Upjohn's FDA Liaison Office in Washington, DC

Regulatory Manager (1990-1979)

- Cardiovascular, Oncology, Anti-Inflammatory, Anti-Infective, Dermatology and Metabolic therapeutic areas

Laboratory Analyst/Group Leader/QA Professional (1979-1974)

Education

- Master of Science in Analytical Chemistry, Purdue University at West Lafayette, Indiana
- Bachelor of Science in Chemistry, Purdue University at Hammond, Indiana

Publications

- Zaninelli M, **Paarlberg R**. [Clinical Trial Disclosure and Data Transparency: Obligation or Opportunity?](#) *Applied Clinical Trials*. Online. January 8, 2021
- Thomas KB, **Paarlberg R**. International Committee of Medical Journal Editors' Requirements for Sharing Individual Participant Data from Interventional Clinical Trials. *European Medical Writers Association Journal*. 2019; 32: 66-73
- Forst HT, **Paarlberg R**. Outcome Measures in Study Registries: The Need for a Consistent Approach. *Drug Information Journal*. 2012; 46: 485-492
- Forst HT, **Paarlberg R**, Roberts E. FDAAA Basic Results Reporting: First Experience and Challenges. *Drug Information Journal*. 2011; 45:245-252
- **Paarlberg, R**. Preparing the New Drug Application. In: Drug Development. 2nd Edition. Boca Raton, FL: CRC Press; 1990:191-220

Achievements/Awards

- Drug Information Association (DIA) Inspire Award (2019)
- Drug Information Association (DIA) Inspire Award (2015)
- Drug Information Association (DIA) Outstanding Service Award (1994)
- W.E. Upjohn Award in recognition of excellence achieved in Regulatory Affairs (1987)

Professional Organizations

- Drug Information Association (DIA) – Chair, Clinical Trial Disclosure Community (2013 – 2016)
- Drug Information Association (DIA) - Advisory Council of North America (2009-2015)
- Regulatory Affairs Professionals Society (RAPS)

Advisory Board

- Advisory Board Member of RegLink Associates (<http://www.reglinkassociates.com/>) (2010 – present)

Presentations

- DIA Conference, Program and Session Chair, “Global Clinical Trial Disclosure and Data Transparency”, Amsterdam, The Netherlands, October 17–19, 2022
- DIA Conference, Program and Session Chair, “EU Clinical Trial Disclosure & Transparency” (virtual), December 1-3, 2021
- DIA 2021 Annual Meeting, Session Chair, “Harmonization of Regulatory Documents for Disclosing Clinical Trial Information” (virtual), June 27 – July 1, 2021
- DIA Conference, Program Committee and Session Chair, “Clinical Trial Disclosure & Data Transparency” (virtual), November 16-18, 2020
- DIA 2020 Annual Meeting, Session Chair, “Balancing Clinical Trial Disclosure & Transparency with Global Data Protection Regulations” (virtual), June 16, 2020
- DIA Conference, Program Chair, “Clinical Trial Disclosure & Data Transparency”, Amsterdam, The Netherlands, December 4-5, 2019
- DIA Conference, Program Chair, “Global Clinical Trial Disclosure and Data Transparency Conference”, Bethesda, MD, September 19-20, 2019
- DIA 2019 Annual Meeting, Session Chair, “Clinical Trial Disclosure and Transparency: Intersection of Regulators, Industry, and Patients”, San Diego, CA, June 25, 2019
- DIA Conference, Program Committee, “Clinical Trial Disclosure and Data Transparency”, Rockville, MD, September 14-15, 2018
- DIA 2018 Annual Meeting, Session Chair, “Clinical Trial Disclosure: Learnings from EMA Policy 0070, NIH Final Rule and FDA’s Clinical Data Summary Pilot Program”, Boston, MA, June 27, 2018
- DIA Conference, Program Committee, “EMA Policy 0070 Evolution”, London, UK, December 6-7, 2017
- DIA 2017 Annual Meeting, Session Chair, “EMA Policy 0070: A Game Changer for Industry”, Chicago, IL, June 21, 2017
- DIA Conference, Program Committee, “Clinical Trial Regulation Conference”, London, UK, December 6-7, 2016
- DIA 2016 Annual Meeting, Session Chair, “Clinical Data Disclosure and Transparency: ClinicalTrials.gov Final Rule, EU Requirements and Other Key Updates”, June 27, 2016
- DIA Conference, Program Chair, “Clinical Trial Disclosure & Data Transparency – The Expanding Global Environment”, Bethesda, MD, September 17-18, 2015
- DIA 2015 Annual Meeting, Session Chair, “Opening the Door to Data Transparency: What’s the Verdict?”, Washington, DC, June 17, 2015
- RegLink News Webinar, “Global Clinical Trial Disclosure – Are You Prepared?”, May 6, 2015
- DIA Clinical Trials Workshop, Program Committee and Session Chair, “Translating the New Transparency Requirements into Practice”, London, UK, September 24-25, 2014
- DIA Annual Meeting, Session Chair, “Fact or Fiction: Patient Engagement in the Drug Development Process”, San Diego, CA, June 16, 2014
- CBI Forum, Session Chair, “Compare and Contrast Benefits of Multi-sponsor and Single Sponsor Websites”, Philadelphia, PA, January 29, 2014
- DIA Conference, Program Co-Chair, “Clinical Trial Disclosure: Towards a More

- Transparent World”, October 1-2, 2013, Bethesda, MD
- DIA 2013 Annual Meeting, Session Chair, “The Evolving Clinical Trial Disclosure Global Landscape”, Boston, MA, June 25, 2013
 - DIA 2012 Annual Meeting, Session Chair, “Hot Topics in Clinical Trial Disclosure”, Philadelphia, PA, June 26, 2012
 - CBI Forum, Session Chair, “Clinical Trial Registries and Results Databases”, Philadelphia, PA, April 24-25, 2012
 - RAPS 2011 Regulatory Convergence Conference, Session Chair, “Conducting Clinical Trials Outside the US and EU”, Indianapolis, IN, October 24, 2011
 - DIA Conference, Program Chair, “Clinical Trial Disclosure”, Bethesda, MD, September 14-15, 2011
 - DIA 2011 Annual Meeting, Session Chair, “Clinical Trial Disclosure Requirements: Coping with Multiple Governmental Registries”, Chicago, IL, June 21, 2011
 - CBI Forum, Session Moderator & Presenter, “Clinical Trial Registries and Results Databases”, Philadelphia, PA, April 27-28, 2011
 - Exl Pharma, Session Moderator & Presenter, “Clinical Data Disclosure Summit”, Philadelphia, PA, March 1-2, 2011
 - DIA Workshop, Presenter, “Sustaining Clinical Trial Disclosure”, Bethesda, MD, November 9-10, 2010
 - CBI Forum, Presenter, “Clinical Trial Registries and Results Databases”, London, UK, February 3-4, 2009
 - Exl Pharma, Presenter, “Clinical Data Disclosure Summit”, Washington, DC, January 12-13, 2009
 - CBI Forum, Roundtable Moderator, “Strategic Publication Planning”, Philadelphia, PA, December 9-10, 2008
 - DIA Workshop, Session Moderator & Presenter, “Current Advancements in Clinical Trial Disclosure: The Changing Tide”, Chicago, IL, October 15-16, 2008
 - DIA Annual Meeting - Program Committee/Regulatory Affairs Track, 2009/2008/2007/2006
 - CBI Forum, Panelist, “Clinical Trial Registries and Results Databases”, Arlington, VA, April 28, 2008
 - Exl Pharma, Moderator, “Clinical Data Disclosure Summit”, Arlington, VA, January 14, 2008
 - Emory-GT CCNE Workshop on Commercialization & Entrepreneurship, Presenter, “Regulatory Process for Diagnostics & Therapeutics in Nanotechnology”, Atlanta, GA, December 4, 2007
 - DIA Workshop, Presenter, “Clinical Trial Disclosure”, Westin, FL, November 13, 2007
 - DIA 2007 Annual Meeting, Session Chair, “Nanomedicine: The Way Forward”, Atlanta, GA, June 18, 2007
 - DIA Webinar, Presenter, “Navigating the Course for Public Registration of Clinical Trials”, May 22, 2007
 - CBI Forum, Panelist, “Clinical Trial Registries and Results Databases”, Arlington, VA, April 24, 2006

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