



## Yvette Lloyd, Attorney-at-Law

*Senior Consultant, Regulatory Affairs*

### EXPERIENCE:

- Attorney – Law Office of Yvette R. Lloyd
- University Instructor, University of California, Irvine-extension and Argosy University
- Staff Regulatory Affairs Consultant, Beckman Coulter, Inc.
- Senior Advisor, Regulatory Management – Cardinal Health, 207.
- Regulatory Affairs Manager, SensorMedics Corporation (renamed Cardinal Health, 207)

### AREAS OF EXPERTISE:

Including, but not limited to

#### *Products:*

- In Vitro Diagnostic
- Cardiovascular
- Respiratory
- Physical Medicine
- Anesthesiology
- Neurological

#### *Disciplines:*

- FDA Regulations – 21 CFR Part 801, 803, 806, 812, 820
- US FDA 513(g), 510(k), PMA submissions
- Canadian Medical Device Regulations
- Canadian Medical Device submissions
- European Union Medical Directives
- CE Marking - Technical Files and Design Dossiers
- International Regulatory Affairs
- Domestic and international environmental management

### EDUCATION:

- J.D., Concord University School of Law, Los Angeles, CA USA
- Graduate studies in Molecular Biology, California State University, Hayward, Hayward, CA USA
- B.Sc., Biological Sciences, University of California, Irvine, Irvine, CA USA

### PROFESSIONAL AFFILIATIONS:

- Member, State Bar of California
- Member, American Bar Association (ABA)
- Member, ABA Health Law Section, ABA Administrative Law and Regulatory Practice Section, General Practice, Solo and Small Firm Division, Legal Education Committee (General Practice, Solo and Small Firm Division)
- Member, Orange County Bar Association (OCBA)



- Member, OCBA Product Liability Section, OCBA Environmental Law Section, OCBA Solo Practitioner/Small Firm Section

#### **TRAINING AND CERTIFICATIONS:**

- California licensed attorney

#### **PUBLICATIONS AND PRESENTATIONS:**

- Calling All Attorneys in Practice Four Years or Less: The Orange County Bar Association Wants to Hear From You. (Orange County Lawyer, January 2008 Vol. 50 No.1., co-authored with Katrina Robson)
- Citizen's Petition, Permit manufacturers to remove intended use statement from box label. ([http://www.fda.gov/ohrms/dockets/dailys/01/Jun01/061801/cp00001\\_01.pdf](http://www.fda.gov/ohrms/dockets/dailys/01/Jun01/061801/cp00001_01.pdf), last accessed February 6, 2009)
- Comments on FDA Docket, 02N-0209: Governing First Amendment Case Law , (<http://www.fda.gov/ohrms/dockets/dailys/02/Sep02/091602/80027d3b.pdf>, last accessed September 9, 2008)
- Citizen's Petition to FDA, Use of Symbols for IVD Labeling ([http://www.fda.gov/ohrms/dockets/dailys/01/Jul01/071001/cp00001\\_01.pdf](http://www.fda.gov/ohrms/dockets/dailys/01/Jul01/071001/cp00001_01.pdf), [http://www.fda.gov/ohrms/dockets/dailys/04/jan04/010704/03D-0383\\_emc-000003-01.doc](http://www.fda.gov/ohrms/dockets/dailys/04/jan04/010704/03D-0383_emc-000003-01.doc), last accessed September 9, 2008)
- ACCA-SOCAL FOOD, DRUG & HEALTHCARE MCLE EVENT (May 12, 2010)
- Panel member, "Foreign Component Part Suppliers - What Can We Do To Avoid Holding the Bag?"
- Panel member, "We Said That? Navigating the Risks of a Robust Advertising, eMarketing& Promotions Program for Medical Products."
- FDA Regulations and the impact to Orange County Medical Device Manufacturers (Presentation to the Orange County Medical Device Network, July 15, 2009)
- Dangerous Documents (Presentation to the Orange County Regulatory Affairs Discussion Group, May 5, 2009, co-authored presentation with Nancy Singer)