



Evangeline Loh, PhD, RAC

Vice President, Regulatory Affairs

EXPERIENCE:

- Regulatory Affairs Scientist, Cook Inc.
- Staff Assoc. II, Div. of Biomedical Sciences and Research, Assn. of American Medical Colleges (AAMC)
- Graduate Research Asst., Dept. of Pharmacology, UTHSCSA
- Undergraduate Research Asst., Dept. of Nutrition, Cornell University
- Undergraduate Research Assistant, Hybritech Corp.

AREA OF EXPERTISE:

Disciplines:

- Global regulatory strategy
- Global medical device vigilance
- CE Marking and CE Marking training
- Technical File/Design Dossier Preparation
- Australian device registration/submission
- 510(k)/513g submissions
- Clinical Evaluation Reports

EDUCATION:

- Clinical Research Associate course (43.2 credit hours ANA), School of Nursing, Georgetown University, Washington, D.C.
- Ph.D., Department of Pharmacology, University of Texas Health Science Center San Antonio (UTHSCSA), San Antonio, TX
- B.S., Microbiology, College Agriculture and Life Sciences, Cornell University, Ithaca, NY

TRAINING AND CERTIFICATIONS:

- RAPS Regulatory Affairs Certification (RAC, EU)
- RAPS Regulatory Affairs Certification (RAC, US)

HONORS:

- ASBMB/ASPET 2000 Graduate Student Travel Award
- Cornell Quill and Dagger Senior Honor Society
- Cornell CALS Alumni Association Senior Service Award

PUBLICATIONS:

- **Loh, E.D.**, Broussard, S.R., Liu, Q., et.al. 2000. Chromosomal localization of GPR48, a Novel Glycoprotein Hormone Receptor like GPCR, in Human and Mouse with Radiation Hybrid and Interspecific Backcross Mapping, *Cytogenet. Cell Genet.* **89**:2-5.



- **Loh, E.D.**, Broussard, S.R., Kolakowski, L.F., 2001. Molecular Characterization of a Novel Human Glycoprotein Hormone Receptor GPCR, *Biochem. Biophys. Res. Comm.* **282**:757-764.
- **Loh, E.D.**, 2003. Educating Successful Researchers, *Next Wave* February 14, 2003
- << <http://nextwave.sciencemag.org/cgi/content/full/2003/02/12/2>>>.
- **Loh, E.D.** Meyer, R.E., 2004. Medical Schools' Attitudes and Perceptions Towards Using a Central Institutional Review Board, *Acad. Med.* **79**:644-651.
- **Loh, E.** 2007. The Newest Vigilance Guidance Explained, *Medical Product Outsourcing.* May 2007:32-34.
- **Loh, E.** 2007. Is Software a Medical Device, *Medical Product Outsourcing.* June 2007:34-36.
- **Loh, E.** 2007. What's Your Level of Risk, *Medical Product Outsourcing.* July/August 2007:30-31.
- **Loh, E.** 2007. Are You Really a Medical Device Manufacturer, *Medical Product Outsourcing.* September 2007:26-28.
- **Loh, E.** 2007. How Do Combination Products Translate in Europe, *Medical Product Outsourcing.* October 2007: 34-36.
- **Loh, E.** 2007. How Will Europe's Amended Device Directives Change Your Approach, *Medical Product Outsourcing.* November/December 2007: 34-35.
- **Loh, E.** 2008. Are You Clinically Prepared, *Medical Product Outsourcing.* January/February 2008: 34-37.
- **Loh, E.** 2008. The European Union in 2008 and a Review of CE Marking, *Medical Product Outsourcing.* March 2008: 30-31.
- **Loh, E.** 2008. The European Union Goes "Green" With Environmental Directives, *Medical Product Outsourcing.* April 2008: 26-27.
- **Loh, E.** 2008. The Many Roads of Conformity Assessment, *Medical Product Outsourcing.* May 2008: 32-35.
- **Loh, E.** 2008. Documenting the Justification for CE Marking, *Medical Product Outsourcing.* June 2008: 34-36.
- **Loh, E.** 2008. The Recast of Directives-Not Your Typical Fishing Expedition, *Medical Product Outsourcing.* July/August 2008: 36-38.
- **Loh, E.** 2008. The New New Approach Directives Bring Noteworthy Clarifications, *Medical Product Outsourcing.* September 2008: 32-34.
- Laufer, J, and **Loh, E.** 2008. EU clinical evaluation rules: a risk to regulatory framework? *Clinica* September 19, 2008, 1323: 11-13.
- **Loh, E.** 2008. Classification Borderline: What Constitutes a Medical Device? *Medical Product Outsourcing.* October 2008:34-37.
- **Loh, E.** 2008. Classification Borderline: Why Consult the Manual? *Medical Product Outsourcing.* November/December 2008:26-28.
- **Loh, E.** 2009. An Overview of Medical Device Labeling in 2009, *Medical Product Outsourcing.* January/February 2009:32-35.
- **Loh, E.** 2009. Europe Continues e-Labeling Efforts, *Medical Product Outsourcing.* March 2009:36-37.
- **Loh, E.** 2009. What About Medical Device Kits? *Medical Product Outsourcing.* April 2009:34-35.
- **Loh, E.** 2009. Switching Notified Bodies Part 1. *Medical Product Outsourcing.* May 2009:44-46.
- **Loh, E.** 2009. Switching Notified Bodies Part 11. *Medical Product Outsourcing.* June 2009:22-24.
- **Loh, E.** 2009. Chinese Regulators Revise Medtech Advertising Rules. *Clinica* July 24, 2009.
- **Loh, E.** 2009. What is the Status of Directive 2007/47/EC? *Medical Product Outsourcing.* July/August 2009:26-27.
- **Loh, E.** 2009. Medical Device Registration in Mexico. *RAJ Devices* Sept/Oct 2009: 1-5.
- **Loh, E.** 2009. Capitalize on Post-Marketing Surveillance Data. *Medical Product Outsourcing.* September 2009:18-20.
- **Loh, E and Farrar S.** 2009. Room to Grow. *Medical Product Outsourcing.* October 2009:69-74.
- **Loh, E and Farrar S.** 2009. CE Marking for Europe. *Infomedix* 2/09:26-27.
- **Loh, E and Farrar S.** 2009. The Great Phthalate Debate. *Medical Product Outsourcing.* November/December 2009:18-20.
- **Loh, E and Farrar S.** 2010. Busy December Yields New Regulatory Documents. *Medical Product Outsourcing.* January/February 2010:30-32.
- **Loh, E and Farrar S.** 2010. The (New) Medical Device Directive-What's Changing, *Medical Device Summit* Web site, March 15, 2010. <http://www.medicaldevicesummit.com/RegulatoryCompliance/Features1/The-New-Medical-Device-Directive-Whats-Changing--93.aspx>



- **Loh, E and Farrar S.** 2010. Regulatory “Changes” to Device Registration in Italy. Medical Product Outsourcing. March 2010:36-37.
- **Loh, E and Farrar S.** 2010. Are European Bar Code Requirements on the Horizon? Medical Product Outsourcing. April 2010:22-24.
- **Loh, E and Farrar S.** 2010. Label Them Right, Medical Device Summit Web site, May 3, 2010.
- <http://www.medicaldevicesummit.com/Main/Features1/Label-Them-Right--121.aspx>
- **Loh, E and Farrar S.** 2010. Europe Becomes More Vigilant About Vigilance. Medical Product Outsourcing. May 2010:32-35.

AUDIOCONFERENCES AND SEMINARS:

- ForeignExchange Translations, Industry Update: Vigilance for Medical Devices, January 17, 2008.
- ForeignExchange Translations, The New MDD: 14 Things You Need to Know, April 10, 2008.
- LifeSciences British Columbia, Medical Device Seminar Series The EU Regulatory Environment-2008, June 9, 2008.
- FOI Services, The European Medical Devices Directive: Upcoming Changes, July 30, 2008.
- RAPs, EAAR Workshop, Vigilance, September 14, 2008.
- FOI Services, Revision on Guideline on Medical Device Vigilance System, November 13, 2008.
- Compliance Alliance, Implementing an Effective Postmarket Surveillance Program, March 10, 2009.
- LifeScience Alley, Demistifying STED: The “New” Global Regulatory Submission Format, May 27, 2009.
- LNE/G-MED Training Session, Clinical Evaluation of Medical Devices: Meeting the European Essential Requirements for the CE Marking, Post Market Clinical Follow-up, June 2, 2009.
- USC lecturer, graduate course in MS Regulatory Sciences, MPTX 509 International Approvals to Medical Product Regulations, CE Marking System, Device Development Path in EU, and Combination and Borderline Products-EU Framework, September 25, 2009.
- ASQ NEDG, Complaints and Beyond Program, Authorized Representation view EU complaints-Issues and trends, October 14, 2009.
- ASQ Austin, Quality and Regulatory Environment in the Medical Device Industry, November 11, 2009.
- Medical Devices Summit 2010, Workshop D: Brazil: An Overview of the Market and Steps to Obtaining Regulatory Approval, March 1, 2010.