MARY ELLEN COSENZA, Ph.D., DABT, ATS, RAC

530 Los Angeles Ave #115-179 Moorpark, CA 93021 C: (805) 469-9555 mecosenza@gmail.com

MEC Regulatory & Toxicology Consulting, LLC Moorpark, CA 2015 - Present
President
Consultant specializing in early and late stage product development and regulatory strategy and advice to Biopharmaceutical developers. Help clients with respect to their investments in clinical and non-clinical development programs that will lead to safer and more effective products, and help to achieve optimal global market access. Expertise in Toxicology, Agency Advice and Meeting Preparation.

AMGEN Global Regulatory Affairs and Safety (GRAAS) Thousand Oaks, CA 2011– 2015
Executive Director US Regulatory Affairs (Regional Head)
Provide management and leadership by overseeing the execution of and by providing advice on the development of regulatory strategy and plans for the FDA across all therapeutic areas (40+ programs).

Executive Director Emerging Markets London, UK 2009 – 2011
Directed Emerging Market Staff and worked with the team to develop processes and organizational alignment in Regulatory and Safety to support Commercial, Development and Clinical Trial Support. Staff included local Regulatory and Safety personnel and core Regulatory support functions. Region covered Latin America, Asia Pacific, Middle East, Africa, Eastern European (non EU), Russia and CIS countries.

Executive Director and Therapeutic Area Head Thousand Oaks, CA 2005 – 2009
Oversaw Medical Sciences and Inflammation Therapeutic Areas of Regulatory Affairs and Safety. Managed the Global Regulatory Leaders (GRLs) for Early Development and the Inflammation TAs.

AMGEN Senior Director /Director Thousand Oaks, CA 2000 – 2005
Directed Toxicology staff of over 80 at 3 sites in support of the development of novel therapeutics. Set policy concerning study type, study design, approval of contract laboratories and interacted with FDA and other Boards of Health. Provided toxicology expertise to ensure appropriate and complaint pre-clinical studies are performed to establish safety profile of new therapeutics.

AMGEN Associate Director Thousand Oaks, CA 1997 – 2000
In addition to the duties as a Research Scientist III noted below, added is the small molecule screening program for Toxicology. Set up the corresponding in vitro and in vivo lab capabilities. Supervised additional Toxicology Staff. Conducted all licensing reviews for the Toxicology Department.

AMGEN Research Scientist III Thousand Oaks, CA 1995 – 1997
Oversaw preclinical safety evaluation that includes *in vivo* toxicity, safety pharmacology, and *in vitro* screening of various biologics and small molecules; design, evaluate, monitor, and interpret contracted preclinical toxicology studies; ensure compliance with Good Laboratory Practice (GLP) US and international regulations.

American Home Products/Wyeth-Ayerst Research, Pearl River, NY. 1987 - 1995
Principal Scientist Toxicology, Manager QAU, Group Leader Regulatory Toxicology and Bioresearch Monitoring Specialist.

Ayerst International Inc., New York, NY. 1986 - 1987
Assistant Manager International Regulatory Affairs

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Revlon Health Care Group (USV Pharmaceuticals) **Tuckahoe, NY. 1984 - 1987**
Quality Assurance Regulatory Associate.

EDUCATION

M.S. Regulatory Science 2008
University of Southern California, Los Angeles, CA
School of Pharmacy

Ph.D. Toxicology 1994
M.S. Toxicology 1986
St. John's University, Queens, NY
Dissertation: Lipid Peroxidation as a Mechanism of Developmental Toxicity in a Micromass Assay System

B.A. Biology (minor in Chemistry) 1981
Queens College, CUNY
Vice President of the Biology Honor Society

ACCREDITATIONS

Board Certified by the American Board of Toxicology in General Toxicology, 1992.
Re-certified in 1997, 2002, 2007, 2012 and 2017.
Regulatory Affairs Certified – United States, 2006 and Europe, 2008. Recertified in 2011, 2014 and 2017.
The Academy of Toxicological Sciences Fellow, 2014.

PROFESSIONAL MEMBERSHIPS

Society of Toxicology (1990-Present)
American College of Toxicology (1987-Present): Current Past-President
Previous leadership positions: Councilor, Co-chair of the Education Committee, Treasurer, President
Regulatory Affairs Professional Society (1995-current)
BioSafe (Preclinical Expert Group for BIO) (1995-current)
Drug Information Association

TEACHING

2008 – Present: Adjunct Professor - Regulatory Science Graduate Program at University of Southern California (USC).

ICH

Member of the Expert Working group for ICH M3 (R2); Advisor for ICH S6 Addendum

PUBLICATIONS

Available upon request.