



International Union of Toxicology

**PROPOSAL TO THE NOMINATING COMMITTEE:
MEMBERS SUITABLE FOR NOMINATION TO THE IUTOX EXECUTIVE
COMMITTEE FOR THE PERIOD 2019-2022**

Proposal due to Barbara Hales at the [IUTOX Secretariat](#) by: **November 19, 2018**
Please include a short CV for the nominee

PROPOSAL SUBMITTED BY

Member Society: [American College of Toxicology](#)

IUTOX Member Society representative submitting nomination:

Name: [Tracey Zoetis, M.S.](#)


Position: [Past President \(2017\), American College of Toxicology](#)

Signature:

Date: [November 13, 2018](#)

BIOGRAPHICAL DETAILS OF PROPOSED CANDIDATE

Name of proposed candidate: [Mary Ellen Cosenza, MS PhD DABT ATS RAC](#)

Signature of proposed candidate: 

Nomination for officer or director may be indicated: [Officer \(Secretary-General\)](#)

Date of Birth: [August 29, 1959](#)

Current Position: [Consultant](#)

Address: 6936 Shadow Wood Dr. Moorpark CA 93021

Nationality: [United States of America](#)

Scientific Field: Toxicology

Education: [Ph.D. Toxicology St. John's University, NY](#)
[MS Regulatory Science, University of Southern California](#)

Professional positions held (with dates):

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

2015-2018 **Owner/President** MEC Regulatory & Toxicology Consulting, LLC

2005-2015 Amgen Inc., Global Regulatory Affairs and Safety, Thousand Oaks, CA

Executive Director, Head US Regulatory, Head Emerging Markets, Immunology Therapeutic Area Head, Early Development Therapeutic Area Head

1995 – 2005 Amgen Inc., Toxicology Department, Thousand Oaks, CA

Senior Director, Director, Associate Director, Research Scientist

1987-1995 American Home Products/Wyeth-Ayerst Research formally American Cyanamid Company/Medical Research Division Lederle Laboratories, Pearl River, NY.

Principal Scientist Toxicology, Manager QAU, Group Leader Regulatory Toxicology and Bioresearch Monitoring Specialist.

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

1984-1986 Revlon Health Care Group (USV Pharmaceuticals) Tuckahoe, NY. **Quality Assurance Regulatory Associate.**

1982-1984 Diagnostic Technology Inc. Hauppauge, NY. **Research Associate**

1981-1982 Sloan Kettering Institute New York, NY. **Research Technician**

IUTOX positions held (with dates):

Program Planning Committee for ICT Meeting in Serbia (2016-2018)

Other ad hoc committees as requested and as part of my role as President of ACT

Member Society positions held (with dates):

Society of Toxicology: Past-President Women in Toxicology (WIT)

American College of Toxicology: Councillor, Co-Chair Education Committee, Treasurer, VP, President and Past-President

Regulatory Affairs Professional Society (1995-current)

BioSafe (Preclinical Expert Group for BIO) (1995-current)

Professional memberships and/or awards:

Member SOT 1990 to present

Member ACT 1987 to present

Lifetime Achievement Award 2012

Regulatory Affairs Professional Society 1995 to present

BioSafe Leadership Committee 1995 to present

Fellow Academy of Toxicology 2014 to present

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

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.

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PROPOSAL SUBMITTED BY

Member Society: [American College of Toxicology](#)

IUTOX Member Society representative submitting nomination:

Name: Tracey Zoetis, M.S.

Position: Past President (2017), American College of Toxicology

Signature: *Tracey Zoetis*

Date: November 13, 2018

BIOGRAPHICAL DETAILS OF PROPOSED CANDIDATE

Name of proposed candidate: Mary Ellen Cosenza, MS PhD DABT ATS RAC

Signature of proposed candidate: *Mary Ellen Cosenza*

Nomination for officer or director may be indicated: Officer (Secretary-General)

Date of Birth: August 29, 1959

Current Position: Consultant

Address: 6936 Shadow Wood Dr. Moorpark CA 93021

Nationality: United States of America

Scientific Field: Toxicology

Education: Ph.D. Toxicology St. John's University, NY
MS Regulatory Science, University of Southern California

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

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

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

Revlon Health Care Group (USV Pharmaceuticals)
Quality Assurance Regulatory Associate.

Tuckahoe, NY. 1984 - 1987

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.