Martha Elena Leal, Ph.D.

SENIOR CONSULTANT

CONTACT INFORMATION

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PROFESSIONAL PROFILE

Dr. Martha Leal is a senior toxicologist and regulatory scientist in ToxStrategies' Health Sciences practice. She has over 30 years of experience supporting product safety, regulatory compliance, toxicology, and post-market surveillance programs, having led scientific organizations across cosmetic, consumer product, tobacco, pharmaceutical, and emerging technology domains. With a proven record of building product safety organizations, developing product safety strategies, advancing regulatory science, supporting regulatory submissions, integrating post-market surveillance, and enabling innovation through evidence-based toxicology and strategic leadership, Dr. Leal brings a wealth of expertise to complex regulatory and consumer safety projects.

Before joining ToxStrategies, Dr. Leal served in leadership positions within major global cosmetic and consumer product corporations, providing strategic oversight of product safety, regulatory sciences, and risk management programs. She established and transformed scientific functions, led global teams, and guided, safety, regulatory and post-market initiatives across multiple regions. Her expertise includes organizational development, stakeholder engagement, scientific governance, executive-level decision support, and commercialization strategies supporting product innovation and market access. She also brings extensive experience supporting regulatory and commercialization strategies across Latin America.

EDUCATION

2025 & 2009	Postdoctoral Fellowship, University of Florida
1997	Ph.D., Cellular Biology, Universidad Simón Bolívar, Sartenejas, Venezuela
1996	Ph.D. coursework, Université de Montpellier, France
1988	B.S., Bioanalysis, Universidad de Carabobo, Venezuela

HONORS/AWARDS

2016	Brilliance Beauty Award—Innovation, Kao USA
2015	Recognition Award, Americas Beauty-Care R&D Poster Symposium

SELECTED PROFESSIONAL EXPERIENCE

Consumer Product Safety

Led the safety evaluation, regulatory compliance, and commercialization of consumer products across cosmetics, personal care, fragrances, OTC products, health care products (respiratory and gastrointestinal), natural health care products, beauty devices, tobacco products, and household consumer goods.

Led product safety and regulatory programs for multinational organizations.

Supported global product portfolios spanning skin care, personal cleansing, hair care, color cosmetics, fragrances, wellness products, OTC products, health care and natural health care products, and emerging technologies.

Partnered with R&D, regulatory affairs, quality, medical, legal, and marketing teams and executive leadership to enable innovation while ensuring product safety and compliance throughout the product lifecycle.

Regulatory Toxicology

Developed and implemented toxicological safety assessment programs for substances, raw materials, finished products, and novel technologies.

Conducted safety evaluations and regulatory risk assessments supporting product registrations and commercialization across North America, Latin America, Europe, and Asia.

Provided scientific leadership on global regulatory compliance, emerging toxicology issues, ingredient safety substantiation, alternative methods (NAMs), and post-market safety monitoring.

Represented companies before regulatory authorities, industry associations, scientific consortia, and trade organizations, including support for Health Canada, FDA-related activities, and international regulatory initiatives.

Developed scientific safety dossiers, ingredient substantiation packages, product registration strategies, and regulatory submissions supporting innovation, commercialization, and interactions with regulatory authorities, including FDA and Health Canada.

Project Management

Directed multidisciplinary scientific teams and managed complex global portfolios exceeding 200 projects annually, balancing scientific rigor, regulatory requirements, timelines, and business objectives.

Led strategic planning, resource allocation, budget forecasting, cross-functional governance, and execution of product safety, surveillance, and regulatory initiatives.

Successfully implemented organizational transformations, process improvements, and automation solutions that improved operational efficiency and accelerated regulatory deliverables.

Managed internal teams, external consultants, contract research organizations (CROs), and global stakeholders to deliver business-critical programs and commercialization objectives.

Risk Assessment

Conducted toxicological hazard identification, exposure assessment, safety characterization, and risk assessments for ingredients, formulations, fragrances, medical products, and consumer products.

Developed risk management strategies addressing product safety, regulatory compliance, adverse events, consumer complaints, emerging hazards, and evolving regulatory requirements.

Led post-market surveillance, pharmacovigilance, cosmetovigilance, and safety signal detection programs to support benefit-risk evaluations and evidence-based decision making.

Provided executive leadership with scientific recommendations supporting commercialization decisions, product stewardship, regulatory submissions, and business risk management.

Applied both traditional toxicology and new approach methodologies (NAMs) to assess safety and support regulatory acceptance of innovative products and technologies.

Latin America Regulatory Strategy and Market Access

Led regulatory and product safety strategies across Latin America for multinational consumer product companies, supporting product registrations, commercialization, and regulatory compliance.

Developed regional regulatory plans, negotiated with board of health authorities, and supported successful market entry and business expansion initiatives.

Navigated country-specific regulatory requirements, local registration processes, and regulatory agency interactions throughout the region.

Built relationships with regulatory authorities, trade associations, scientific organizations, and industry stakeholders to support strategic business objectives and market access.

PEER-REVIEWED PUBLICATIONS

Labib R, Bury D, Boisleve F, Eichenbaum G, Girard S, Naciff J, **Leal M**, Wong J. 2018. A kinetic-based safety assessment of consumer exposure to salicylic acid from cosmetic products demonstrates no evidence of a health risk from developmental toxicity. Regul Toxicol Pharmacol 94(Apr):245-251; doi: 10.1016/j.yrtph.2018.01.026. PMID: 29410076.

Renner G, Audebert F, Burfeindt J, Calvet B, Caratas-Perifan M, **Leal ME**, Gorni R, Long A, et al. 2017. Cosmetics Europe guidelines on the management of undesirable effects and reporting of serious undesirable effects from cosmetics in the European Union. Cosmetics 4(1):1; doi: 10.3390/cosmetics4010001.

Aguirre J I, **Leal ME**, Rivera MF, Vanegas SM, Jorgensen M, Wronski TJ. 2007. Effects of basic fibroblast growth factor and a prostaglandin E2 receptor subtype 4 agonist on osteoblastogenesis and adipogenesis in aged ovariectomized rats. J Bone Miner Res 22(6):877-88; doi: 10.1359/jbmr.070313. PMID: 17352655.