

CRYSTAL A. MAIRA

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Scientific & Regulatory Consultants, Inc. provides a full range of regulatory services for the antimicrobial industry. Our consultants' insight provides scientifically-sound, cost-effective, and timely solutions to routine and complex issues facing our clients. Our collective knowledge base includes experience in industry, laboratories and with government entities. For more information about Scientific & Regulatory Consultants, Inc. visit our website at www.sriconsultants.com

PROFESSIONAL EXPERIENCE

Scientific & Regulatory Consultants, Inc., Columbia City, IN 2020 - Present

Senior Consultant (2022 – Present); promotion

Consultant (2020 – 2022)

- Specializing in scientific and regulatory consulting services for antimicrobial products from inception to commercialization
- Study testing strategy, placement, and management
- SDS authoring
- Monitoring regulatory changes and inspection trends
- Competitive surveillance
- EPA submission strategy
- Complete registrations and amendments for California Dept. of Pesticide Regulation (DPR), including Cleaning Product Right to Know Act (CPRKA or SB-258) compliance
- Address Data-Call-In (DCI) requirements for clients
- Audit product labels prior to federal and state submission
- FIFRA 6(a)(2) reports
- Provide on-site and remote technical support of peroxygens and other antimicrobial technologies

SciTech Consulting, LLC, Webster, NY 2011 - 2020

Owner/Principal Consultant

- Subject Matter Expert for Peracetic Acid
- FDA registration of OTC hand hygiene products
- Placed efficacy studies to support claims registration with EPA and FDA
Provided on-site and remote technical support related to microbiological issues in food production facilities, peroxygens and other antimicrobial technologies
- Assisted clients with Cleaning Product Right to Know Act (CPRKA or SB-258) compliance
- Developed OSHA/GHS-compliant chemical Safety Data Sheets (SDS) and production labels
- Management consultation – reviewed business practices and policies; regulatory compliance review; business strategy development and implementation; project management

- Developed documentation – written hazard communications programs; corporate policies; standard operating procedures; technical data sheets; technical and commercial marketing materials
- Developed presentation materials for clients – management training; sales training; GHS implementation and training; new product launch; microbiological concepts; technical trade association presentations

Lonza, Inc., Allendale, NJ 2004 - 2009

Associate Director, Global Microbiology & Analytical Technology 2009 – 2009

- Responsible for setting strategic and tactical direction for the Life Science Ingredients – Microbial Control global microbiology and analytical laboratories (New Jersey, Switzerland, Japan, and China).
- Harmonized best practices and coordinated workflow between laboratories
- Managed international cost centers totaling over \$5M in regular costs and over \$0.5M in CAPEX
- Strong collaboration with Regulatory Affairs, Applications Technology, and Sales & Marketing for base business support and new product development globally

Manager, Microbiology & Analytical Technology 2006 – 2009

- Responsible for operations of the microbiology and analytical chemistry labs in the Allendale, NJ location.
- Initiated and managed the \$1.1M expansion of the microbiology labs.
- Developed LEAD program for Lonza – novel product stewardship program for Lonza with US EPA
- Successfully managed multiple, simultaneous projects with cross-functional teams

Senior Microbiologist 2004 – 2006

- Lonza technical lead for joint Ecolab-Lonza project to evaluate principal deficiencies in the Use-Dilution Test (UDT).
- Managed numerous Hygiene and Personal Care projects simultaneously

FMC Corporation, Princeton, NJ 2000 - 2004

Senior Microbiologist 2002 – 2004

- Supervised laboratory and technicians; prepared technical protocols, reports and SDSs
- Assisted Regulatory Affairs with sanitizer/disinfectant registrations (Federal and State), including conducting and/or placing efficacy testing for both EPA and FDA registrations
- Served as Product Steward for Active Oxidants Division
- Planned, coordinated, and conducted cross-functional teams for customer field trials of prototype products
- Provided technical service and field troubleshooting to the food processing and environmental markets
- Presented to internal and external customers and governmental agencies
- Led internal and external sales training and active participant in promotional campaign
- Managed new product from conception through product launch

Microbiologist 2000 – 2002

- Conducted microbiological efficacy studies for new products/applications
- Placed efficacy studies at GLP laboratories for product EPA registrations

- Coordinated and worked on new application and EPA registration activities leading to successful product commercialization resulting in \$750,000 in annual sales
- Reduced laboratory supply costs by 29%

Xechem, Inc., New Brunswick, NJ

1997 - 1999

Associate Analytical Chemistry Analyst – Quality Control and R&D

- Responsible for the development and validation of analytical methods for nutraceutical and pharmaceutical raw, in-process, and finished materials
- Wrote and edited SOPs, protocols, specifications, and test methods

SmithKline Beecham Clinical Laboratories, Dallas, TX

1994 - 1997

Senior Technical Support Technician – Microbiology/Virology

- Responsible for culturing clinical microbiology and virology specimens using aseptic techniques
- Conducted identification and susceptibility testing
- Trained new staff in culturing procedures

EDUCATION

B.A. in Biological Sciences, Rutgers University, New Brunswick, NJ; 2000

Master’s Degree in Microbiology, 12 hours completed, Seton Hall University, South Orange, NJ; 2006-2008

Certificate in Strategic Marketing, Cornell University Samuel Curtis Johnson Graduate School of Management, Ithaca, NY; 2015

PROFESSIONAL AFFILIATIONS & CERTIFICATIONS

American Society for Microbiology (ASM)

AOAC International (AOAC)

International Association for Food Protection (IAFP)

Society for Chemical Hazard Communication (SCHC)

Society of Quality Assurance (SQA)

CORPORATE PROFESSIONAL AFFILIATIONS

British Chemicals Association (BCA) (Formerly BACS)

Center for Biocide Chemistries (CBC)

Household & Commercial Products Association (HCPA)

International Sanitary Supply Association (ISSA)

Personal Care Products Council (PCPC)

PROFESSIONAL DEVELOPMENT

U.S. Environmental Protection Agency (EPA)

COVID-19: Aerosol Treatment Devices & Ozone Disinfection - Emergency Response; 08/21

Reducing Environmental Exposure to SARS-CoV-2: An Overview of Findings; 06/21

COVID-19: UV-C Devices and Methods for Surface Disinfection; 01/21

U.S. Food and Drug Administration (FDA)

CDER Small Business and Industry Assistance (SBIA) - Reporting Drug Amount
Under Section 510(j)(3) of the FD&C Act; 09/22
OTC Monograph Reform: OTC Sunscreen Drugs; 12/21
OTC Monograph Reform: Deemed Final Orders; 12/21
OTC Monograph Reform in the CARES Act: Safety Orders; 01/21

Alchemy Systems

Effective Metrics to Advance Your Food Safety Training; 10/17

Association of Home Appliance Manufacturers (AHAM)

Clearing the Air on Microbiologicals: a Technical Review of AHAM-AC-5; 04/22

California League of Food Processors

Taking Cleaning & Sanitation to the Next Level; 02/15
Bringing Sanitation Procedures in Line with the New FSMA Requirements; 02/14

Center for Professional Advancement

Preserving Water Based Formulations; 10/05

Covington & Burling LLP

Unpacking the Modernization of Cosmetics Regulation Act of 2022; 01/23

Decagon Devices

Understanding Water Activity; 01/06

FDA News

Communicating Directly with Consumers on Social Media: What You Must Know About FDA and FTC
Ad and Promo Rules; 04/22

Fred Pryor Seminars

Workplace Life Jacket: 7 Tips to Improve Your Work-Life Balance; 05/22

Global Leadership Network

Global Leadership Summit; 08/22

Household & Commercial Products Association (HCPA)

CPSC A-Z Workshop; 09/22
Mid-Year Meeting; 05/22, 05/21
Annual Meeting; 12/22, 12/20
FIFRA 25(b) Pesticides; 10/20
Importing Pesticides under FIFRA; 10/20

Exporting Pesticides under FIFRA; 10/20
25(b) Challenges; 10/20
Opportunities and Challenges of 25(b) Products Industry Perspective; 10/20
Advertising and Claims & Supplemental Distribution; 10/20
Lonza representative on CSPA Antimicrobial Efficacy Group, 2007 - 2009

International Association for Food Protection (IAFP)

Eliminate Harborage Sites and Growth Niches with Chlorine Dioxide Gas; 06/17
Draft *Listeria monocytogenes* Guidance and Legal Implications; 02/17

International Sanitary Supply Association (ISSA)

Antimicrobial Workshop; 03/21, 04/21
Hand Sanitizers and the FDA; 08/20

Intertek

Considerations in Bringing a Germicidal Product to Market; 11/22

Keller & Heckman

FSMA Fundamentals: A Guide to the Final Rules Implementing HARPC Provisions for Human and Animal Food; 10/15

Lewis Way Leadership Development

Communication and Public Speaking; 09/21

Northwest Food Processors Association

Pacific Northwest *Listeria* Control Workshop; 05/16
Navigating Food Safety Certification Standards; 01/14
OSHA's Adoption of GHS: Changing the Look on Chemical Safety; 01/13

Northwest Food Processors Expo & Conference

Case Study: An Innovative Dry Lubricant Increases Sustainability Practices; 01/15
Navigating Food Safety Certification Standards; 01/14

Northwest Food Safety & Sanitation Workshop

Cleaning for Food Safety – Best Practices; 10/18
Listeria Control – The Why, The Where & What to Do; 10/16
Choosing an Effective Sanitizer; 10/15
Hand Hygiene: A Cornerstone for Food Safety; 10/15

Personal Care Products Council (PCPC)

Unpacking the Modernization of Cosmetics Regulation Act of 2022; 01/25
Lonza representative to PCPC, 2006-2009

- CTFA Microbiology Committee
- SDA/CTFA Topical Antimicrobial Coalition

- CTFA Wipes Working Group

CTFA Webinar: California Cosmetics Law (SB-484); 09/06

Preservation of Cosmetic Products: The Microbiologist's Role in Product Development; 11/05

Roka Bioscience

Game of Zones - A Practical Guide to Listeria Environmental Monitoring and Testing Programs; 08/17

Safety Chain

Zone One Testing: Do You Dare; 08/18

Scientific & Regulatory Consultants, Inc.

Anti-Bribery; 09/20

Smith & Co. Consulting, Inc.

GMP: FDA Regulatory Action and Enforcement Trends; 12/22

GMP Beyond the Basics; 12/22

cGMP; 11/22

Advanced GLP Training; 10/22, 09/20

GLP Data Integrity; 09/22, 09/20

GLP Refresher Training; 09/22, 09/20

Society for Chemical Hazard Communication

How much do you really understand in a SDS? Maybe Less than you think!; 04/22

Fall 2020 Meeting; 11/20

Society of Quality Assurance (SQA)

Knock, Knock, FDA is Here; 07/22

U.S. Poultry and Egg Association

A Practical Approach to Exposure, Assessment, and Control Strategies for Peracetic Acid (PAA); 01/20

Regulatory Update: What's ahead for 2016 and Understanding Salmonella; 01/16

Poultry; Microbial Control in Second Processing; 01/15

Environmental/Personal Safety Impact of Low Temperature Cleaning and Sanitation Processes; 01/15

Answers to Important Challenges in the Poultry Processing Industry; 01/14

Organic Acid Effectiveness: A New Alternative for Listeria Control; 01/14

Wright Alliance

Introduction to Toxicology; 10/20

PATENTS, PUBLICATIONS & PRESENTATIONS

PATENTS

Nunez, R., **Nesbitt, C.**, et al. "Synergistic Preservative Blends," U.S. Patent Number 9,060,952 (2015)

Kellar K, **Nesbitt, C.**, et al. "High Retention Sanitizer Systems," U.S. Patent Number 6,828,294 (2004)

PUBLICATIONS

Maira, C. "Considerations for Reduced Usage of Quaternary Ammonium Compounds in Food Production and Healthcare Environments." 2019 Aug. DeVere Company Inc. website:

<https://deverechemical.com/reduced-usage-of-qacs/>

Arlea, C., King S, Bennie B, Kemp K, Mertz E, Staub R. "Modifications to the AOAC use-dilution test for quaternary ammonium compound-based disinfectants that significantly improve method reliability." J AOAC Int. 2008 Jan-Feb; 91(1):152-8.

Arlea, C., Nunez R. "IPBC – A globally approved fungicide." Personal Care Magazine. 2007.

Arlea, C., Nunez R, Cappabianca C. "Alternative preservative and potentiator system for the personal care market." CTMW. 2006 Mar. 45-48.

Mesrob B, **Nesbitt, C.**, Misra R, Pandey R. "High-performance liquid chromatographic method for fingerprinting and quantitative determination of *E*- and *Z*- gugglesterones in *Commiphora mukul* resin and its products." J Chromat B. 1998; (720): 189-196.

PRESENTATIONS

Numerous oral and poster presentations given at national and international conferences, to governmental agencies, to internal stakeholders and external customers