

**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](http://www.sriconsultants.com)

**PROFESSIONAL EXPERIENCE**

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

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**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
- Author materials for SRC blogs and website, as needed

**SciTech Consulting, LLC, Webster, NY** 2011 - 2020

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**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

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**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

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**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)**

Manufacturers and Distributors: Get Ready for MoCRA!; 06/23  
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**

Diversity Training; 07/23  
Communication and Public Speaking; 09/21

#### **Montana State University, The Center for Biofilm Engineering**

Anti-Biofilm Technologies: Pathways to Product Development; 02/22, 02/23

#### **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)**

Get Ready for MoCRA; 03/23

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)**

EPA GLP Inspection Program Under FIFRA & TCSA; 03/23

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

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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

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**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*- guggulesterones in *Commiphora mukul* resin and its products." J Chromat B. 1998; (720): 189-196.

#### PRESENTATIONS

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