Scientific & Regulatory Consultants, Inc.

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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.srcconsultants.com

PROFESSIONAL EXPERIENCE

Scientific & Regulatory Consultants, Inc., Columbia City, IN 2016 - Present

Senior Consultant (2021 – present); promotion
Consultant (2018 – 2021); promotion
Consulting Associate (2018); promotion
Consulting Specialist (2016 – 2017)

Responsible for antimicrobial test method design, testing strategy, placement and management of studies; technical writing and speaking, author materials for SRC blogs and website, as needed; product development; technical support, marketing, regulatory affairs, quality control, manufacturing; and conduct competitive surveillance research.

- Presented ASTM E35.15 Meeting "New U.S. EPA Efficacy Guidance Documents and Test Methods". 2023
- Presented ASTM E35.15 Meeting: "Implementation of EPA's New 810 Efficacy Testing Guidelines ". 2019
- Burnside, D. M., Cianciotto, N.P. Analysis of Iron Requirements and Siderophore Production. Methods in Molecular Biology. Legionella Methods and Protocols. 2nd edition. 2019
- Presented ASTM E35.15 Meeting: "2018 Update on EPA 810 Efficacy Guidelines", 2018

Northwestern University, Chicago, IL 2008 - 2015

Graduate Student (Microbiology)

- Developed and tested scientific hypotheses regarding siderophore-mediated iron acquisition in *Legionella pneumophila*
- Developed and introduced new laboratory protocols
- Collected, analyzed, and interpreted data
- Published research findings in peer-reviewed journals
- Presented research findings at professional meetings
- Handled Biological Safety Level 2 organisms and ensured compliance to laboratory safety protocols

- Utilized microbiology and molecular biology techniques
- Mentored and trained new laboratory members
- Teaching assistant for graduate-level molecular biology and genetics course

Indiana University-Purdue University Fort Wayne, Fort Wayne, IN 2004 - 2008

Research Technician (Virology) (2007-2008)

- Designed experiments to test hypotheses regarding interactions among Varicella-zoster virus encapsidation proteins
- Employed virology, molecular biology and biochemistry techniques
- Collected, analyzed, and interpreted data
- Presented research findings at professional meetings
- Published research findings in peer-reviewed journals

Student Research Assistant (2004-2007)

- Developed and tested scientific hypotheses
- Collected, analyzed, and interpreted data
- Prepared written grants and fellowships

EDUCATION

Ph.D. in Microbiology, Northwestern University, Chicago, IL; 2015
B.S. in Biology, Indiana University-Purdue University Fort Wayne, Fort Wayne, IN; 2007
A.S. in Chemical Methods, Indiana University-Purdue University Fort Wayne, Fort Wayne, IN; 2007

PROFESSIONAL AFFILIATIONS & CERTIFICATIONS

American Society of Testing and Materials (ASTM)
Award of Appreciation; Committee E-35 on Pesticides; 10/26
American Society of Microbiology (ASM)

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)

Research and Regulation of Pesticidal Air Treatment Devices; 09/23
COVID-19: Evaluating Aerosol Treatment Technologies; 02/22
COVID-19: Aerosol Treatment Devices & Ozone Disinfection - Emergency Response; 08/21
COVID-19: Electrostatic Sprayers and Foggers for Disinfectant Application; 07/21

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
EPA Expands Research on COVID-19 in the Environment; 05/20
Legionella Management and Treatment; 01/20
Twelfth Antimicrobial workshop; 06/18
Listening Session on ATP; 06/18
Introduction to Down-the-Drain Assessment for Antimicrobial Pesticides; 10/16
Antimicrobial Data Requirements 40 CFR Part 158, Subpart W:
Introduction and Overview; 07/16
Mammalian Toxicology Data Requirements for Antimicrobial Pesticides; 07/16
Environmental Fate & Transport; 08/16
Antimicrobials Used in Cooling Water Systems; 08/16
Pesticide Label Review Training (Certified 04/16)

U.S. Food and Drug Administration (FDA)

FDA Study Data Technical Conformance Guide; 11/18
Dietary Supplements: How to Deal with New Criminal, Civil Enforcements; 05/17
How to Conduct Effective Quality Audits; 04/17
CDER Microbiology Issues: A Deeper Dive; 03/17
Medical Device Reporting; 01/17

Canadian Consumer Specialty Products Association (CCSPA)

Regulated Products Committee (RPC) Meeting; 11/22

Alston & Bird

EPA requirements for Antimicrobials and Treated Articles; 06/20

American Chemistry Council

EPA Research & Efficacy Testing Methods for Antimicrobial Public Health Devices; 04/26
Biocides Panel Legionella Work Group member, 2016 - Present
Biocides Panel Meeting; 01/18

American College of Toxicology

The Introduction and Application of GLP Regulations; 05/19

American Society for Testing & Materials (ASTM)

ASTM E35.15 Fall Meeting; 11/23, 10/21, 10/19, 10/18, 10/17
ASTM E35.15 Spring Meeting; 03/26, 04/25, 04/24, 04/23, 04/22, 04/19, 04/18, 04/17

Bergeson & Campbell, P.C.

FIFRA Hot Topics in Pesticide, Biocides, and Other Agricultural Chemicals Regulation and Litigation; 04/19
Emerging Ingredient Disclosure Requirements and Confidential Business Information; 10/18

Citrix ShareFile

Everything You Need to Stay Connected from the Cloud; 04/17

Center for Biofilm Engineering (CBE)
Anti-Biofilm Technologies: Pathways to Product Development; 02/24, 02/18
Biofilm Technologies: Pathways to Product Development; 02/21, 02/19

Center for Disease Control (CDC)
When to Clean, When to Disinfect, and What Science Says about SARS-CoV-2 on surfaces; 04/21

Chemical Watch
Biocides The Americas 2024; 11/24

Compliance4All
Validation and Use of Excel Spreadsheets in FDA Regulated Environments; 02/19
Excel Spreadsheets – Step by Step Instructions for Compliance; 05/17
21 CFR Part 11 – Compliance for Electronic Records and Signatures; 04/17

ECG, Inc.
Convince Me: Persuasion and Negotiation Training; 08/18

FDA News
Writing Effective SOPs; 04/17
Promotion of Drugs, Devices and Biologics Using Social Media; 02/17
Form 483 and Warning Letter Responses; 12/16
Preparing for an FDA Preapproval Inspection: 11/16
Spreadsheet Validation 2016; Tools and techniques to Meet FDA Requirements

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

Gladieux Consulting
Better Business Writing; Add Power to Your Words at Work; 05/18

Global Leadership Network
Global Leadership Summit; 08/22, 08/20

Green Mountain Quality Assurance
Reviewing Electronic Data and Audit Trails; 03/18

Household & Commercial Products Association (HCPA)
Are you asking what ingredients need to be shared online and on your label, and when?; 03/19
Changes to the Notice of Decision to Register Pesticide Products; 01/19
IMPACT Meeting; 04/18
Discover the New Consumer Product Ingredients Dictionary; 11/17
Mid-Year Meeting; 05/22, 05/21, 05/19, 05/18, 05/17
Annual Meeting; 12/23, 12/20, 12/18, 12/17

Infection Control Today (ICT)
Balancing Surface Disinfecting & Compatibility in Healthcare Today; 05/19

Indiana University – Purdue University – Fort Wayne (IPFW)
Professionalism and Etiquette for Business; 10/17
The Building Blocks of Effective Messages; 08/17

Integrity of Data
GLP Refresher and Advanced Training; 06/25

International Association for Food Protection
Practical Applications of Microbial Modeling; 11/17

International Sanitary Supply Association, Inc (ISSA)
Antimicrobial Workshop; 08/25, 04/21, 03/21

The Jackson Laboratory
Understanding the Landscape of the Skim Microbiome and Potential Applications for Personal Care Products; 06/17

Keller & Heckman
A Practical Primer on Pesticides; 10/16

Lewis Way Leadership Development
Communication and Public Speaking; 09/21
Diversity Training; 11/24, 07/23, 07/20

Montana State University, The Center for Biofilm Engineering
Anti-Biofilm Technologies: Pathways to Product Development; 02/22

National Academies Press
Management of Legionella in Water Systems; 08/19

Q Laboratories
GMP Training; 08/26
FDA Microbiology Enforcement Trends: What Non-Sterile Pharma Must Know; 10/25

Regulatory Affairs Professionals Society (RAPS)
Raising the Regulatory voice – Persuasive Framing; 01/18

Scientific & Regulatory Consultants, Inc.
GLP Electronic Signature; 10/25
Anti-Bribery; 10/24, 08/23, 08/22, 09/20

EPA 101 Part 1 and 2; 02/19
Child Resistant Packaging; 01/19
EPA Regulatory Update; 11/18
Exempt vs. Non-Exempt Treated Articles; 01/18
6(a)(2) Training; 07/16
EPA 101: Submission Review, Training, and Overview; 06/16

Smith & Co. Consulting, Inc.
GMP: FDA Regulatory Action and Enforcement Trends; 12/22
GMP Beyond the Basics; 12/22
Advanced GLP Training; 10/22, 09/20
GLP Data Integrity; 09/22, 09/20
GLP Refresher Training; 09/22, 09/20
cGMP Training; 10/22, 10/19

Society of Corporate Compliance and Ethics (SCCE) & Health Care Compliance Association (HCCA)
Navigating the Antitrust Arena: A Compliance Playbook; 09/26

Society of Quality Assurance (SQA)
Auditing Software and Data Providers with a Focus on Cloud Services; 09/18
Auditing Techniques; 09/18
Management Culture & Data Integrity Governance Programs; 02/18
Method Validation and ILV (Independent Lab Verification); 12/16
Basic Training: Good Laboratory Practices; 09/16

Steptoe & Johnson
Threshold of Toxicological Concern; 01/19
What's on the Food Contact Horizon; 11/18

Waters Corporation
Why is Electronic CDS Data a Major Data Integrity Concern for Regulators?; 04/17

Water Science and Technology Board
NASEM Legionella Meeting 1; 02/18

WEAS Engineering
Legionella Seminar; 11/19

Webber Training
New Developments in Environmental Cleaning and Disinfection; 12/24
Chlorhexidine Use and Bacterial Resistance; 09/18
Using Expert Process to Combat Clostridium Difficile Infections; 02/17

The Role of Dry Surface Contamination in Healthcare Infection Transmission; 02/17
Antimicrobial Environmental Surfaces in Healthcare Settings – Can They Really Be Beneficial?; 10/16

PUBLICATIONS AND PRESENTATIONS

PUBLICATIONS

Fernandez, D. M., Data generation and development of non-public health or public health disinfectant biofilm claims. 2022 Feb 01.

Burnside, D. M., Cianciotto, N.P. Analysis of Iron Requirements and Siderophore Production. Methods in Molecular Biology. Legionella Methods and Protocols. 2nd edition. 2019

Burnside, D. M., Wu, Y., Shafaie, S., Cianciotto, N.P. The *Legionella pneumophila* siderophore legiobactin is a polycarboxylate that is identical in structure to Rhizoferrin. Infection and Immunity. 2015 Oct:83(10): 3937-3945.

Portier, E., Zheng, H., Sahr, T., **Burnside, D.M.**, Mallama, C., Buchrieser, C., Cianciotto, N.P., Hechard, Y. IroT/mavN, a new iron-regulated gene involved in *Legionella pneumophila* virulence against amoebae and macrophages. Environmental Microbiology. 2014 Aug 20.

Howard, A.J., Sherman, D.M., Visalli, M.A., **Burnside, D.M.**, Visalli, R.J. The Varicella-zoster virus ORF54 gene product encodes the capsid portal protein, pORF54. Virus Research. 2012 July: 167(1): 102-105.

Stewart, C.R., **Burnside, D.M.**, Cianciotto, N.P. The surfactant of *Legionella pneumophila* is Secreted in a TolC-dependent manner and is antagonistic of other *Legionella* species. Journal of Bacteriology. 2011 Nov: 193(21): 5971-5984.

Chatfield C.H., Mulhern B.J., **Burnside, D.M.,** Cianciotto, N.P. *Legionella pneumophila* LbtU acts as a novel, TonB-independent receptor for the legiobactin siderophore. Journal of Bacteriology. 2011 Apr: 193(7):1563-1575.

Yip, E. S., **Burnside, D.M.**, Cianciotto, N.P. Cytochrome c4 is required for siderophore expression by *Legionella pneumophila*, whereas cytochromes c1 and c5 promote intracellular infection. Microbiology. 2011 Mar: 157: 868-878.

Visalli, R.J., Knepper, J., Goshorn, B., Vanover, K., **Burnside, D.M.**, Irven, K., McGauley, R., Visalli, M. Characterization of the Varicella-zoster virus ORF25 gene product: pORF25 interacts with multiple DNA encapsidation proteins. Virus Research. 2009: 144(1-2): 58-64.

Visalli, R.J., **Nicolosi, D.M.**, Irven, K.L., Goshorn, B., Khan, T., Visalli, M.A. The Varicella-zoster virus DNA encapsidation genes: Identification and characterization of the putative terminase subunits. Virus Research. 2007: 129(2): 200-211.

Visalli, R.J., **Nicolosi, D.M.**, Irven, K.L., Khan, T., Visalli, M.A.. Characterization of the murine cytomegalovirus m136 gene. Virus Genes. 2007: 34(2): 117-126.

PRESENTATIONS

Fernandez, D.M., "Two Regulators, One Goal: A Comparative Look at U.S. EPA and Health Canada Efficacy Testing Requirements", ASTM 35.15 Meeting. 2026

Fernandez, D.M., "U.S. EPA Efficacy Guidance Document Update", ASTM 35.15 Meeting. 2025

Fernandez, D.M., "U.S. EPA Efficacy Update: Viral Claims for Sanitizers and Planktonic *Legionella pneumophilia* Claims for Cooling Tower Water" ASTM 35.15 Meeting. 2024

Fernandez, D.M., "New U.S. EPA Efficacy Guidance Documents and Test Methods", ASTM E35.15 Meeting. 2023

Burnside, D.M., "Implementation of EPA's New 810 Efficacy Testing Guidelines ", ASTM E35.15 Meeting. 2019

Burnside, D.M., Jones, R. "2018 Update on EPA 810 Efficacy Guidelines", ASTM E35.15 Meeting. 2018

Burnside, D.M., Wu, Yuyang, Cianciotto, N.P. "Legiobactin siderophore produced by *Legionella pneumophila* is structurally similar to rhizoferrin." Midwest Microbial Pathogenesis Conference. Chicago, Illinois. 2014

Burnside, D.M., Cianciotto, N.P. "Evidence for a second *Legionella* siderophore." 113th General Meeting of the American Society for Microbiology. Denver, Colorado. 2013

Burnside, D.M. "The Evolving Role of TolC in *Legionella pneumophila*." Microbiology-Immunology Departmental Seminar Series. Chicago, IL. 2012

Burnside, D.M., Cianciotto, N.P. "A role for TolC in the export of siderophore in *Legionella pneumophila*." Midwest Microbial Pathogenesis Conference. Ann Arbor, Michigan. 2011

Burnside, D.M., Yip, E.S., Cianciotto, N.P. *"Legionella pneumophila* TolC facilitates siderophore production and amoebae infection. Midwest Microbial Pathogenesis Conference. St. Louis, Missouri. 2010

Goshorn, B., Visalli, M.A., **Nicolosi, D.M.**, Khan, T., Byers, M.A., Visalli, R.J. "Identification of the Varicella-zoster virus encapsidation proteins in infected cells." 32th International Herpesvirus Workshop. Asheville, North Carolina. 2007

Nicolosi, D.M., Visalli, R.J. "Identification of protein-protein interactions between the VZV DNA encapsidation proteins ORF30 and ORF45/42." Indiana University-Purdue University Fort Wayne Student Research and Creative Endeavor Symposium. Fort Wayne, Indiana. 2007

Visalli, R.J., **Nicolosi, D.M.**, Goshorn, B., Khan, T., Byers, M.A., Visalli, M.A. "Cloning, sequencing and expression of the seven putative Varicella-zoster virus DNA encapsidation genes." 25th American Society for Virology Meeting. Madison, Wisconsin. 2006

Nicolosi, D.M., Visalli, R.J. "Identification of protein-protein interactions between the VZV DNA encapsidation proteins ORF30 and ORF45/42." Indiana University-Purdue University Fort Wayne Student Research and Creative Endeavor Symposium. Fort Wayne, Indiana. 2006

Nicolosi, D.M., Visalli, M.A., Visalli, R.J. "Characterization of murine cytomegalovirus m136 mutants." 25th American Society for Virology Meeting. Madison, Wisconsin. 2006

Nicolosi, D.M., Visalli, M.A., Irven, K.L., Visalli, R. J**.** "Identification of protein-protein interactions between the VZV DNA encapsidation proteins ORF30 and ORF 42/45." 105th General Meeting of the American Society for Microbiology. Atlanta, Georgia. 2005