

# Scientific & Regulatory Consultants, Inc.

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## DENISE FERNANDEZ, Ph.D.

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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](http://www.srcconsultants.com)

## PROFESSIONAL EXPERIENCE

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

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**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*. 2<sup>nd</sup> edition. 2019
- Presented ASTM E35.15 Meeting: “2018 Update on EPA 810 Efficacy Guidelines”, 2018

**Northwestern University**, Chicago, IL 2008 - 2015

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**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

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**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)

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**

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; 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

**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 Skin 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**

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 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*. 2<sup>nd</sup> 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.**, "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 pneumophila* 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." 113<sup>th</sup> 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." 32<sup>th</sup> 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." 25<sup>th</sup> 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." 25<sup>th</sup> 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." 105<sup>th</sup> General Meeting of the American Society for Microbiology. Atlanta, Georgia. 2005