

BECKY LIEN

blien@srcconsultants.com

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

2019 - Present

Consultant (2019 – Present)

- Responsible for antimicrobial test method design, testing strategy, placement and management of studies
- Maintain GLP efficacy testing files
- Utilize NPIRS and EPA databases for competitive surveillance
- Provide technical support
- Technical writing and speaking

Analytical Lab Group, Eagan, MN

2006 - 2019

Executive Account Manager and Regulatory Specialist (2018-2019)

- Responsible for the sale of services within the antimicrobial industry
- Project managed accounts for the top antimicrobial clients
- Supported marketing campaigns, forecasted revenue, and qualified leads
- Participated in numerous associations (HCPA, ASTM, ASM, AOAC)

Site Operations Manager and Continuous Improvement Coordinator (2018)

- Responsible for the organization, supervision, and execution of testing of the microbiology, virology, chemistry, and medical device laboratories
- Acted as test facility management
- Served as a technical and regulatory resource to the operations and commercial departments

Technical Manager and Continuous Improvement Trainer/Facilitator (2017-2018)

- Responsible for training managers in problem-solving methods such as DMAIC and causal mapping
- Assisted senior management team with the implementation and use of a scorecard to assess the overall health of the organization
- Implemented and executed MDI boards for each department
- Implemented and executed bi-weekly Gemba walks
- Performed all the tasks detailed under the Technical Manager role

Technical Manager (2017)

- Participated in numerous associations (HCPA, ASTM, ASM, AOAC)
- Responsible for maintaining accurate SOPs and protocols for the company
- Responsible for training study directors and lab technicians on new methodology and regulations
- Provides manager approval on GLP reports and standard operating procedures

Manager of Study Director Operations (2013-2016)

- Developed protocols and standard operating procedures
- Represented study directors in conflict resolution with Quality Assurance unit
- Provided manager approval on GLP reports and standard operating procedures
- Managed Microbiology, Chemistry, Medical Device, Viral study directors, which included providing day to day guidance and direction, assigning studies and managing individual development
- Performed study director functions on occasion, as outlined in EPA & FDA Good Laboratory Practices Regulations (40 CFR Part 160 & 21 CFR Part 58) and was responsible for the data analysis, report generation and ensuring technical integrity of studies

Research Scientist I / Study Director (2006-2012)

- Executed study director functions as outlined in EPA & FDA Good Laboratory Practices Regulations (40 CFR Part 160 & 21 CFR Part 58)
- Technically reviewed antimicrobial efficacy raw data
- Wrote and updated standard operating procedures and protocols
- Responsible for report generation and ensured data integrity
- Provided customer service to clientele

Wuxi/AppTec, St. Paul, MN

2004 - 2006

In Vitro Study Director / Research Assistant II

- Performed bacterial endotoxin testing using Kinetic Chromogenic method
- Conducted biocompatibility assays, including cytotoxicity, hemolysis and cell growth inhibition; conducted hemocompatibility assays, including partial thromoplastin time, platelet and leukocyte
- Performed aseptic technique, bacterial and mammalian cell culture, light and fluorescent microscopy, spectrophotometer and small animal manipulation
- Aided in releasing GLP/GMP studies

University of Minnesota Veterinary Diagnostic Laboratory, St. Paul, MN

2001 - 2004

Bacteriologist

- Conducted bacterial identification and antimicrobial susceptibility testing
- Cultured necropsy and clinic samples
- Provided test results to UofM veterinary teaching hospital, pathologist and veterinary clinics statewide

EDUCATION

B.S. in Biology, Southwest Minnesota State University, Marshall, MN; 2001

PROFESSIONAL AFFILIATIONS & CERTIFICATIONS

American Association of Textile Chemists & Colorists (AATCC)
American Society of Testing and Materials (ASTM)
American Society of Microbiology (ASM)
Society of Quality Assurance (SQA)
Henrici Society of Microbiologist
Certified Professional Project Manager (CPPM)
Six Sigma Yellow Belt Certification

CORPORATE PROFESSIONAL AFFILIATIONS

British Association of Chemical Specialties (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)

Label Review Training; 12/19
Good Laboratory Practice Workshop; 02/16

American Association of Textile Chemists and Colorists

Going Green in Greenville meeting; 03/20

American Society for Testing & Materials (ASTM)

ASTM E35.15 Fall Meeting; 10/18
ASTM E35.15 Spring Meeting; 04/19, 04/18, 03/17

Center for Biofilm Engineering (CBE)

Montana Biofilm Science & Technology Meeting; 07/19, 02/19, 07/18

Household & Commercial Products Association (HCPA)

Mid Year Meeting; 05/19, 05/18, 5/17
Annual Meeting; 12/18, 12/17

ISSA

Prepare, Respond, Recover: The 2019 Novel Coronavirus (2019-NCOV); 02/20

Smith & Co. Consulting, Inc.

cGMP Training; 10/19

Society of Quality Assurance (SQA)

Welcome to Quality; 02/20