

SAMANTHA KAPPEL, M.S.

skappel@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 2021 - Present

Consulting Specialist II

- Specialize in scientific and regulatory consulting services for antimicrobial products from inception to commercialization
- Audit microbiology studies and raw data for GLP compliance
- Manage protocol and report revisions, and correspondence with labs

Carnegie Mellon University, Pittsburgh, PA 2020 - 2021

Testing Diagnostic Associate

- Performed high complexity diagnostic testing for Covid-19 on approximately 1,000 saliva samples per day; included, sample evaluation, sample preparation, reagent preparation, and sample analysis via RT-qPCR.
- Operated, maintained, and validated laboratory instruments including RT-qPCR units (Applied Biosciences QuantStudio 7) and Automated Liquid Handling Units (CyBio Felix by Analytik Jena).
- Assisted in development of Laboratory Developed Test; included performing validations, protocol improvements, and writing SOP's
- Maintained sample traceability and patient confidentiality throughout testing process

XBiotech, Austin, TX 2020

Quality Assurance Associate II

- Reviewed batch records, logbooks, and all documentation pertaining to drug product manufacturing
- Ensured compliance with internal Standard Operating Procedures (SOP) and Regulatory guidelines
- Edited, reviewed, and released SOP's following internal document change control procedure
- Participated in aseptic drug product fills and media fill validations
- Performed labeling, packaging, and shipping of drug products to distribution centers or clinical sites
- Assisted with quality control assays and validations as needed

Team Lead: Medical Device Efficacy Testing (2018 – 2020)

- Managed team of 3-6 analysts by overseeing orientation, evaluation, and training of employees
- Performed and supervised GLP compliant antimicrobial efficacy testing of medical devices, wound dressings, hand sanitizers, and custom sanitization devices
- Acted as project manager on multiple studies simultaneously, spanning a wide scope of microbiological and scientific methods
- Developed and wrote Standard Operating Procedures based on standardized test methods and accepted industry practices
- Provided excellent customer service by assisting clients in navigating regulatory pathways, ensuring deadlines are established and met, and providing technical expertise and guidance on study design

Analyst: Disinfectant, Sanitizer, and Custom Efficacy Testing (2017 – 2018)

- Acted as study director and sole point of control for GLP-compliant antimicrobial efficacy testing
- Designed custom scientific projects from beginning to end, including writing price quotes and protocols, creating datasheets, performing laboratory experiments, aseptically analyzing test samples and results, and writing study reports
- Safely maintained and handled microbial cultures in a biosafety level 2 facility
- Provided excellent customer service by interacting directly with clients to answer questions, provide study results, and organize receipt of payment

EDUCATION

M.S. in Microbiology, University of Florida, Gainesville, FL; 2022
B.S. in Biology, University of Texas at San Antonio, San Antonio, TX; 2016

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

American Society for Testing & Materials (ASTM)

ASTM E35.15 Spring Meeting; 04/22

Fred Pryor Seminars

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

Lewis Way Leadership Development

Communication and Public Speaking; 09/21

Smith & Co. Consulting, Inc.

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

GMP Beyond the Basics; 12/22

Advanced GLP Training; 10/22

GLP Data Integrity; 09/22

GLP Refresher Training; 09/22

Society of Quality Assurance (SQA)

2021 PRCSQA Annual Meeting; 11/21

University of Texas Center for Professional Education

Overcoming Five Dysfunctions of a Team; 11/19

Making the Transition from Employee to Manager; 04/19

Delegation and Accountability; 05/18