

SAMANTHA KAPPEL

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

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

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

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