EXAMPLE CLIENT

12345 Any Ave, Anytown, USA 12345 • 123.456.7890 • Email@email.com

EXPERIENCED QUALITY ASSURANCE/CONTROL PROFESSIONAL

Quality expert with background of progressive responsibility and extensive experience in regulatory compliance, process improvement, and data integrity. Known for demonstrating a unique blend of talents, combining scientific expertise and attention-to-detail with a sophisticated understanding of methodologies. Proven record of proactively resolving quality problems and utilizing a collaborative approach to achieve measurable improvements in efficiency, accuracy, and results.

AREAS OF EXCELLENCE

- COMPLIANCE AUDITING
- DATA INTEGRITY
- PROBLEM RESOLUTION
- PROCESS IMPROVEMENT
- PROTOCOL DEVELOPMENT
- QUALITY ASSURANCE (QA)
- QUALITY CONTROL (QC)
- REGULATORY AFFAIRS
- SOP DEVELOPMENT

PROFESSIONAL EXPERIENCE

TEAM LAULIMA, USAMRIID, FT. DETRICK, MD 2014 to present
Quality Control Specialist, Contractor

Successfully performed Quality Control audit of study files to ensure compliance with 21 CFR Part 58, SOPs and protocol. Reviewed raw data to verify accuracy, completeness, and compliance to Good Documentation Practices.

- Developed new process and reporting SOPs to improve regulatory compliance and enhance clarity of the department's role, resulting in improved tracking and documentation of findings
- Established timekeeping database for measuring QC activities, resulting in improved scheduling, budgeting, and tracking of data integrity
- Performed final quality review and prepared audit reports summarizing omissions, errors, and regulatory issues ensuring satisfactory compliance with FDA audits
- Identified gaps and trends in data integrity for development of corrective and preventative action plans (CAPA) significantly improving reliability of results
- Reduced repeated errors amongst staff by developing and conducting internal training
- Built productive relationships with labs and scientists, communicating useful feedback to enhance collaboration and reduce inter-departmental tension

NCI/LEIDOS BIOMEDICAL RESEARCH INC., FREDERICK, MD 2009 to 2014
Research Associate II, Contractor
Center for Advanced Preclinical Research

Successfully spearheaded establishment of pathology lab in support of preclinical research. Developed and performed all sample processes including scanning, specialized staining, and quantification in compliance with Good Laboratory Practices (GLP) regulations.

- Developed new SOPs, methods, and protocols and validated processes to ensure viability of results
- Established and managed biorepository to catalog paraffin blocks and slides, resulting in improved ability to compare studies and share data collaboratively
- Measurably improved indexing and retrieval times by creating and maintaining digital archive of all slides using Aperio

- Implemented and managed Microsoft Access database for tracking requests and generating reports, resulting in improved status communication and ability to accommodate rush orders

- Consistently met high-pressure deadlines to generate supporting data for presentations, resulting in enhanced lab reputation in the field

ALIZEE, THURMONT, MD 2007 to 2009
Scientist
Contract for Research Organization

Produced immunohistochemical results for clients per request or protocol and generated data using optimal or image analysis tools such as ImagePro.

- Supported QA by generating, reviewing and revising SOPs and protocols to meet new client demands
- Consistently met quality standards and ensured GLP compliance of data generation and image management processes

CHARLES RIVER LABORATORIES, FREDERICK, MD 2005 to 2007
Technician II, Molecular and Immunopathology Laboratory
Contract Research Organization, Nonclinical Services

Performed immunohistochemical staining with sponsor test and control articles and prepared frozen tissue blocks, paraffin blocks, and microtomy/cryotomy. Conducted all processes in compliance with Good Laboratory practices (GLP) regulations.

- Identified and utilized appropriate controls, tissue fixations, staining procedures and solution preparation to successfully meet all quality standards
- Established improved methods for paraffin work resulting in cleaner, sharper, and more quantifiable images

EDUCATION

HOOD COLLEGE, GRADUATE CERTIFICATE IN REGULATORY COMPLIANCE (4.0 GPA)
Masters level courses include:
Product Development: Prepared pre-IND package for FDA
Good Clinical Practices: Assembled Trial Master File document
Good Laboratory Practices: Prepared FDA 483 response, GLP inspection checklist
Regulation of Medical Devices: Prepared 501(k) for Class II device
Good Manufacturing Practices: Prepared CMC per eCTD format

LEHIGH UNIVERSITY, B.A. BIOLOGY
Leigh University Scholarship, Ruth Keith Scholarship

AFFILIATIONS

Regulatory Affairs Professional Society (RAPS)
Society of Quality Assurance (SQA)
American Society for Quality (ASQ)