

DAVID CALDARONE

1910 Arden Creek Pl, Apt 2201, Charlottesville, VA
(804) 931-4822 – caldardn@gmail.com

CAREER OBJECTIVE

I am a reliable and detail-oriented QA Auditor II seeking to advance my career with Pharpoint. I possess a diverse background of clinical laboratory and QA auditing experiences through which I have gained several valuable skills in GCP audits, managing complex relationships, and juggling priorities. I am a motivated team player that excels in communication, problem solving, and time management.

TECHNICAL SKILLS

- Creating and maintaining documents in the Quality Management System and document control system
- Expertise in the interpretation of regulations, guidelines, policies, and procedures and in global regulatory and compliance requirements for clinical research
- Nucleic acid quantitation (Tapestation, Nanodrop technology)
- Data analysis: SigmaPlot and Microsoft Excel
- Experience with BSL-3 laboratory safety
- Extensive experience with the following equipment: QuantStudio, Nanodrop Reader, Stratagene Mx3000, Luminex LX200, QX200 Droplet digital PCR system, and Automated droplet generator
- qPCR and ddPCR
- Nucleic acid extractions (DNA/RNA)
Data analysis: SigmaPlot and Microsoft Excel

WORK EXPERIENCE

10/2021 to Present

QA Auditor II

PPD – Richmond, VA

- Conducts complex internal and external audits and inspections to ensure compliance with established quality assurance processes, standards, global regulatory guidelines, and client contractual obligations
- Identifies issues impacting the quality and integrity of clinical research programs
- Determines root causes of non-conformance and develops strategies to address issues
- Performs technical document review and other GxP practice activities in support of clinical development programs
- Efficiently provides audit reports to management
- Plans and delivers quality services for contracted quality assurance audits, internal site audits, and laboratory and file audits for clients and projects
- Proficient with GCP studies, knowledgeable of GLP studies, and GxP trained
- Responsible for organizing and coordinating all facility audits for the molecular genomics department

02/2020 to 10/2021

Scientist

PPD – Richmond, VA

- Independently performed a variety of highly complex laboratory procedures for several clinical studies
- Reliably conducted complex data analysis for multiple clients
- Reviewed analyst documentation to ensure proper execution of methods and protocols
- Entered and compiled data to produce well-organized interim and final reports to be sent to clients

- Utilized leadership and communication skills to help the team complete heavy workloads and achieve demanding deadlines
- Created guides and training aids for instrument maintenance and performing assays

10/2018 to 01/2020

Associate Scientist

PPD – Richmond, VA

- Independently performed a variety of complex sample preparation and analysis procedures
- Lead trainer for new analysts to ensure quality performance and efficiency across multiple assays
- Created helpful guides and training aids for multiple procedures to uphold accuracy and efficacy across all laboratory analysts
- Independently performed validation testing for multiple clinical studies
- Held an essential role in a project in which the processing, testing, and data analysis of 3,000 clinical samples were successfully completed within one month
- Maintained efficient managing and tracking of thousands of clinical samples through the use of Excel, PPD's LIMS, and TrackWise

01/2017 to 09/2018

Assistant Scientist

PPD – Richmond, VA

- Performed a variety of complex sample preparation and analysis procedures to quantitatively measure pharmaceutical and biopharmaceutical compounds in a variety of formulations and/or biological matrices
- Successfully conducted the review and compilation of results and data comparison against SOP acceptance criteria, methodology, protocol and product specifications
- Effectively trained analysts on routine operation, maintenance and theory of analytical instrumentation, SOPs and regulatory guidelines

EDUCATION

05/2016

Bachelor of Science in Biology

Virginia Commonwealth University – Richmond, VA