

Experience

WCG Manager, Technology QA & Compliance

Durham, NC May 2022 – Present

- Engage in the continued development, maintenance, and enforcement of the Quality Management System.
 - o Manage/lead efforts with regard to the development and maintenance of quality goals, objectives, and process improvements.
 - o Establish and enforce quality department standards.
 - o Coach and train WCG staff on quality department standards and best practices.
- Engage with WCG staff to author and revise internal technology standards (i.e. IT and/or Software Development Policies, SOPs, et al).
 - o Ensure such standards are in conformity with applicable regulatory agency regulations and guidance.
 - o Ensure such standards presented to employees for training.
 - o Oversee and manage the implementation, development, and change management of systems to ensure same is performed in line with regulatory agency regulations and guidance, including but not limited to, GxP, 21 CFR Part 11/Annex 11, GDPR, and HIPAA
- Manage the integration, implementation, and/or development, of new WCG businesses and/or systems.
 - o Serve as the primary technology quality liaison for the integration of new WCG business acquisitions and systems.
 - o Serve as the subject matter expert with respect to the harmonization of processes and procedures.
- Manage/lead the investigation of Quality Events/Corrective Actions Preventative Actions (CAPA), deviations, and notes to file (NTF).
 - o Ensure proper investigation of such events is performed, and documentation maintained.
- Manage/lead the conduct of internal audits to ensure internal standards and staff performance are in compliance with applicable WCG process, regulatory agency regulation and guidance.
 - o Manage/lead the conduct of internal audits/periodic review of company policies and procedures.
 - o Manage/lead the conduct of internal audits/periodic review of WCG systems.
 - o Identify compliance gaps and provide support and suggestions for remediation. Report status of the quality levels of staff, systems and production activities to the VP, IT Compliance.
- Maintain the compliance schedule of external vendor qualification to ensure that vendors remain in compliance with applicable WCG process.



- Host external audits and inspections including communication with sponsor/agency, internal audit preparation activities, review of audit report, collection of responses, and follow-up on findings resolution.
- Maintain current knowledge with respect to quality legislation and regulatory compliance best practice.
 - o Provide training and guidance to staff regarding compliance and interpretation of regulations.
- Other duties as assigned by supervisor. These may, on occasion, be unrelated to the position described here.

WCG Durham, NC Manager of Product and Testing Validation September 2020 – May 2022

- Recommend new validation test approach, test environment, and qualification strategies
 with a comprehensive Computer System Development Life Cycle (SDLC) architecture that
 identifies and delineates Operational Qualification (OQ), Performance Qualification (PQ),
 Installation Qualification (IQ), and User Acceptance Testing (UAT) while exceeding
 regulatory standards, guidance, and expectations.
- Planning and managing Validation Test Design and Coverage of complex, strategic systems using risk based approaches to ensure systems are fit for purpose, that significant risks are identified and mitigated, and that the approach and rigor of Validation is in proportion to the risks the systems present to regulated business processes.
- Produce accurate and detailed Test Script Exports that catalyze and drive Automated
 Software Test activities that increase test coverage, accuracy, and regulatory compliance.
- Manage Agile development of Computer System Validation test strategy, accuracy and compliance performance.
- Participate in all Software Development Agile planning activities, such as user story
 creation, point estimation, and expected testing tasks while paying particular attention
 to testability, test script design and test suite architecture.
- Collaborate and provide feedback on user story details related to clarifying requirements, testability, acceptance criteria and test coverage.
- Other duties as required.

VeraSci Durham, NC Validation Supervisor August 2019 – September 2020

- Supervise and mentor validation specialists.
- Work with other team members to write, execute and document the results of validation testing that is completed for any application (e.g. system or app) that is managed by VeraSci.
- Communicate issues identified during testing to the appropriate Technology Development department staff to resolve the issue.



- Assist with identifying the requirements for new or existing VeraSci applications and convey the information gathered to the Technology Project Lead and all applicable Directors in the Technology Development Department.
- Participate in the presentation of VeraSci proprietary tools at industry conferences and booths as necessary.
- Assists with the review and correction of data captured by VeraSci applications managed by VeraSci as needed.
- Works closely with the Science team to provide feedback regarding the functionality of new and existing VeraSci applications

VeraSci Durham, NC Validation Specialist February 2019 – August 2019

- Work with other team members to write, execute and document the results of validation testing that is completed for any application (e.g. system or app) that is managed by VeraSci
- Communicate issues identified during testing to the appropriate Technology Development department staff to resolve the issue.
- Assist with identifying the requirements for new or existing VeraSci applications and convey the information gathered to the Technology Project Lead and all applicable Directors in the Technology Development Department.
- Participate in the presentation of VeraSci proprietary tools at industry conferences and booths as necessary
- Assists with the review and correction of data captured by VeraSci applications managed by VeraSci as needed
- Works closely with the Science team to provide feedback regarding the functionality of new and existing VeraSci applications

United Parcel Service Dispatch/Preload Supervisor

Chapel Hill, NC June 2018 – Feb 2019

 A Dispatch supervisor distributes package volume to vehicle routes depending on the number of deliveries, total miles, and driver experience. A Preload Supervisor facilitates staffing, establishes flow (packages per hour), and ensure safe work methods.

One Restaurant and Piedmont Inspired Foods Server

Durham, NC 2013-March 2018



 Delivered an orchestrated dining experience to restaurant guests. Quickly identifying needs, gaining trust, and resolving problems with maximum efficiency. Practicing advanced sales techniques while also enhancing the guests dining experience.

Education

North Carolina Central University Bachelor of Science, Physics Durham, NC 2015