SOFTWARE SYSTEMS QUALITY ENGINEER
Professional Overview

Skilled validation professional and l aboratory manager with extensive background in and thorough knowledge of cGMPs, ICH guidelines, GAMP5, USP and the pharmaceutical industry in general. Experienced in managing challenging projects in the quality chemistry laboratory and software development/validation areas. Expert in the use and administration of Empower 2/3 including troubleshooting issues. Experience with validation of various types of equipment in laboratory and manufacturing areas. Exceptional analytical, troubleshooting, organizational, problem solving and managerial skills.

Core Qualifications

- Problem Solving
- Root Cause Analysis
- Validation
- Empower
- Software Administration
- Laboratory Management

Accomplishments

- Administered all laboratory software programs
- Analyzed, installed and validated new software
- Applied critical thinking to determine root cause and appropriate CAPAs
- Managed laboratory and validation departments on an interim basis
- Managed all CAPAs for our department
- Served as key strategist and subject matter expert during inspections

Education
Bachelors : Biology May 2000 West Virginia University , City , State Biology
Experience
Us Oncology, Inc. Flemington , NJ Software Systems Quality Engineer 07/2012 to Current

- Served as administrator for all laboratory computer systems including Empower 2.
- Developed and instituted the process of online review and approval of chromatographic data in Empower 2 including validation of the process.
- Performed and verified laboratory computer system back-ups on a weekly basis.
- Performed audit trail assessments on a weekly basis.
- Developed a process and created methods to be used during FT-IR testing in order to reduce the chance of errors in setup during testing.
- Led projects related to upgrading and/or re-installing instrument software on new hardware including authoring and executing IOPQ protocols and final reports.
- Developed processes and wrote SOPs as required.
- Served as subject matter expert (SME) for all software quality systems validations and compliance to applicable regulatory requirements.
- Served as validation representative on the change control board.
- Served as interim validation manager for signatory purposes from October 2013 - June 2014.
- Wrote, executed and approved validation (IOPQ) protocols and reports.
- Served as key strategist during inspections.

Chemistry QC Supervisor 09/2010 to 06/2012

- Managed the day to day activities of the QC chemistry laboratory.
- Led both finished product (solutions and emulsions release and stability testing) and raw materials (active and inactive ingredients and commodities testing) laboratories during this time.
- Managed outsourced testing provided by third party CROs.
- Served as subject matter expert for Empower 2.
- Improved/Implemented processes to ensure quality data is being generated.
- Authored and updated SOPs as required.
- Managed the completion of CAPAs and other remediation activities in the laboratory.
- Led, wrote and approved laboratory investigations and event reports including root cause analysis using Trackwise.
- Provided technical support for process improvements for various emulsions and solutions made at the plant.
- Active member of validation review board and change control board.
- Helped lead implementation of LEAN initiatives for the laboratory.

NA City , STATE Laboratory Supervisor 01/2004 to 09/2010

- Managed a group of 7 Ph.D., masters and bachelors degreed analytical chemists performing analytical testing on products in all phases of development (from pre-phase 1 formulation support through commercial product release and stability), formulation development studies, method developments, method validations, and transfers.
- Developed relationships and worked closely with many different clients to ensure that their testing is completed with the highest quality and on time.
- Assisted Laboratory Director with annual budgeting.
- Performed interviews and made hiring decisions.

- Performed a quality review of the data for compliance with our SOPs and cGMPs before the report is completed and sent to the client.
- Performed and/or approved any laboratory investigations or deviations including root cause analysis as required.
- Authored and updated SOPs as required.
- Took part in several audits every year that were conducted by internal personnel, clients, and the FDA (or other regulatory agency).
- Trained chemists in various techniques such as dissolution, HPLC, GC, FTIR, Karl Fischer, and Empower 2 to name a few.
- Worked on teams to validate the functions of our acquisition software programs (Millennium and Empower 2).
- Served as the SME for all computer systems including Millennium/Empower 2 at the site.
- Power of Attorney for DEA controlled substances.
- Head of site's safety and HAZMAT teams.

Associate Scientist / Assistant Scientist II / Assistant Scientist I 10/2000 to 01/2004

- Steadily promoted through the three laboratory analyst levels throughout this time and became a lead analyst who others in the laboratory would go to with questions.
- Performed method developments, validations, and transfers; as well as, routine analytical testing on products in all phases of development (from pre-phase 1 formulation support through commercial product release and stability).
- Served as a power user for Millennium in the laboratory, helping other chemists when they had trouble with the software.
- Performed testing on many different types of dosage units including extended and immediate release tablets and capsules, injectables, creams, lotions, and API.
- Testing included HPLC, GC, dissolution, UV, Karl Fischer, Titrations, FTIR, and disintegration.
- Trained chemists in various techniques ranging from dissolution to HPLC to FTIR to Karl Fischer.

Skills

API, budgeting, CAPA, commodities, client management, DEA, HAZMAT, Waters Empower, FT-IR, GC, hiring, HPLC, Investigations, laboratory management, LEAN, KanBan, Microsoft Office, personnel, processes, protocols, quality, root cause analysis, safety, SAP, technical support, Trackwise, troubleshooting, UV, validation