SCIENTIST I - STUDY DIRECTOR

Professional Overview

Quality Control Scientist with 17 years in Quality Control experience including supervising and managing ALCM remediation teams comprised of scientists and analysts working to remediate analytical methods. Excel in organizing, writing, reviewing, and editing Qualification and Validation plans, protocols, and reports. Proficient in Microsoft programs. Expert in analytical instrumentation Microbiological techniques with extensive Qualification and Western blotting Validation experience Automated equipment Expert in data analysis Leader in data presentation Experimental design

Education

MBA University of Maryland University College - City , State Master of Business Administration
Bachelor of Science Salem State University - City , State BSc. Biology

Professional Experience

Scientist I - Study Director Jan 2012 to Current
Batteries Plus, Llc - Decatur , AL

- Analytical Lifecycle Management (ALCM) Study Director for ELISA remediation projects Design, author, review, and approve qualification and validation protocols and reports, SOPs, transfer reports, and IOPQ reports in accordance to cGMP guidelines and ACH requirements Assay validation/co-validation Document, review, and approve Change Control requests and deviations Technical method transfer to Quality Control departments and CMO/CRO Assay development and troubleshooting Subject Matter Expert (SME) for Quality Control molecular imaging systems Perform analytical assays for qualification, validation, and method transfer including Biacore, cIEF, ELISA, and SDS-PAGE.

Principal Quality Control Analyst Jul 2006 to Jan 2012
Marquette University - Milwaukee , WI

- Responsible for the testing of in-process and bulk drug products for stability and release Identification and evaluation of molecular imaging systems (Kodak/Bio-Rad/Fuji) for gel and dot blot assays and the training and transfer of imaging capabilities to CMO Write, revise, and review SOPs, transfer reports, IOPQ reports in accordance to cGMP guidelines and ACH requirements Support global Quality Control departments by troubleshooting assays and the preparation of controls and standards Assay technical transfer to Quality Control departments Analytical assays include: RP-HPLC, cIEF, Phastgel IEF, ELISA, and Biacore Monoclonal antibody purification and biotinylation.

Quality Control Supervisor Sep 2005 to May 2006
Danaher - Fremont , CA

- Supervision of Quality Control analysts in the Protein Production Laboratory (PPL) Generate testing schedules for bulk drug products, in-process, and stability samples for the Microbiology, Analytical and Raw Materials departments Primary Quality Control liaison between QC and Purification, Cell Culture, R&D and QA Departments cGMP review of Microbiology, Analytical and Raw Material data for product and component release Write, revise and review SOPs, qualification protocols and qualification reports in accordance to cGMP guidelines and ACH requirements Perform OOT/OOS/OOL investigations Perform Alert/Action investigations Responsible for year-end employee reviews and establishing annual goals for all QC employees.

Adjunct Professor Sep 2002 to Jul 2004
Cake Enterprise - Newport Beach , CA

- Lecture and laboratory, 50 students.
- Immunology: Lecture and laboratory, 19 students.

Lead Quality Control Analyst Jul 2002 to Sep 2005
Waters Corporation - Unavailable , MI

- Responsible for the testing of in-process and bulk drug products.
- Write, revise and review SOPs in accordance to cGMP guidelines.
- Assay development, troubleshooting, technical transfer from the Protein Chemistry and Analytical Development departments Analytical assay transfer to project CMO FDA/EP pharmaceutical regulations Analytical assays include: ELISAs (Host Cell Protein/Protein A/Immunoreactivity), residual DNA, IEF, HPLC(rPA/SEC), BCA and Bradford Total Protein Assays.

Technical Support Associate Dec 1999 to Sep 2000
Endogen-Pierce, Inc - City , STATE

- Responsible for the production and testing of monoclonal and polyclonal antibodies.
- Performed biotinylation of monoclonal antibodies.
- Preparation of Fluoroscein-5-Isothiocyanate (FITC) labeled antibodies.
- Small scale protein purification Initiated and participated in projects aimed at the replacement of mercury-based preservatives from assay kit components.

Manufacturing Technician Sep 1998 to Dec 1999
Endogen - City , STATE

- Responsible for the formulation of antibody dilution buffers, HRP concentrates and microplate coating, blocking and stabilizing solutions.
- Large scale production of 96-well ELISA microtiter plates.
- Operated and maintained an Oyster Bay Microplate Coating System (M.P.C.S - 10) in class 100/100,000 clean-room.
- Filled, labeled and packaged finished products for Quality Control approval and release.

Memberships and Affiliations
American Society for Quality (ASQ) - 2015 Member of the North East Quality Council
Skills
BCA, Cell Culture, Chemistry, DNA, ELISA, HPLC, IEF, imaging, Immunology, Director, Materials, PAGE, P.C., protocols, QA, Quality Control, Rad, Supervision, troubleshooting, validation, author, year-end