

Robert Sandberg

Background Summary

Experienced biotechnology quality professional with thorough knowledge of development and testing of drug products in a regulated environment. Managed multiple concurrent drug quality programs and submitted data for inclusion in regulatory applications to the FDA for inflammation and oncology products. Dedicated team player responsible for transferring methods, executing them on analytical equipment, and reviewing data for quality assurance purposes.

Professional Skills

- ICH, GLP, and cGMP guidelines
- 21CFR part 11 compliance
- Validation of analytical instrumentation
- UV-vis, GC, and HPLC with LIMS
- MS Excel and GraphPad statistical software
- Quality systems management

Volunteer Accomplishments

Immanuel Lutheran School, Loveland, CO

School Volunteer (*Aug 2013 – Present*)

Providing volunteer services for student recess, library cataloging, and tutoring for an elementary school.

Employment History

Array BioPharma Corporation, Boulder - Longmont, CO

2003 – 2013

Research Associate III (*Oct 2011 – Aug 2013*)

Quality and analytical development associate supporting Phase I and II inflammation and oncology drug products in a GMP and GLP environment. Worked on multiple drug product and API stability programs while providing peer review for analytical data and stability reports to support IND and annual report submissions to the FDA.

- Provided input for CMC development strategy and established timelines for in-house and outsourced material analyses.
- Led and motivated junior staff members and cross functional teams which increased productivity and allowed for effective knowledge transfer.
- Contributed to the development and transfer of analytical methods used in the laboratory for solid dosage and sterile injectable (IV) drug formulations.
- Developed working relationships with contract analytical laboratories used to perform microbial testing, as well as drug product and API stability analyses.
- Maintained analytical equipment and IQ/OQ/PQ schedules within operating budgets.
- Established a database system for tracking expiration and retest dates of APIs, intermediates, and drug products for inclusion in each certificate of analysis.
- Investigated out of specification events (OOS) on raw materials and initiated corrective and preventative actions (CAPA) to insure future compliance.

Research Associate II (*Oct 2008 – Oct 2011*)

Lead QC analyst on an oral dosage asthma medication which achieved phase II clinical success. Collaborated with analytical development chemists to create and transfer release and stability testing methods to the QC department.

- Established maximum allowable drug carryover limits on process equipment by matrixing the therapeutic threshold of multiple clinical drug products manufactured in the GMP suites.
- Managed the dose formulation analysis of a drug formulation for 3 toxicology studies.
- Drafted SOPs for laboratory and documentation procedures to ensure regulatory compliance.
- Audited and approved manufacturing sites for active pharmaceutical ingredient and sterile drug product campaigns.
- Attended conferences, seminars, and training to keep up to date on analytical instrumentation and on the latest trends and regulations in GMP.

Research Associate I (*Jan 2006 – Oct 2008*)

Lead QC analyst on a sterile drug formulation for oncology. Performed analytical laboratory tests for product release and stability studies.

- Developed a UPLC method to reduce impurity analysis times and led dose formulation analyses for acute toxicology studies.
- Established cleaning validation protocols for bulk API process and oral drug product manufacturing equipment.
- Audited and qualified a contract testing laboratory for microbiological analyses of a high purity water system used by process chemistry.
- Created an Access database system for preparing and tracking monthly water samples submitted to a contract testing laboratory.

Laboratory Technician I/II (temporary to permanent) (*Jun 2003 – Jan 2006*)

Managed and distributed fine chemical inventory in support of the lead generation chemistry department. Used Access database management software and lab automation equipment to accurately track and prep samples for the analytical chemistry department and external customers.

- Updated compound processing procedures as a result of changes in business requirements and addition of new laboratory equipment.
- Participated in and managed clinical drug manufacturing and batch recording in a GMP environment.

Langham Partnership International, Menlo Park, CA

Feb 2002 – Apr 2003

Computer and Administrative Consultant

Provided volunteer services for office administration and computer equipment maintenance for a non-profit organization.

Archway Digital Solutions, Mountain View, CA

May 2001 – Jan 2002

Peakstone Corporation, Sunnyvale, CA

Apr 2000 – Mar 2001

Mainssoft Corporation, San Jose, CA

Sep 1997 – Apr 2000

Quality Assurance Engineer

Worked with engineers in developing UNIX based software systems for mathematical and web-based applications. Provided quality assurance, generated test scripts, and created user documentation for the software front ends.

Raychem Corporation, Menlo Park, CA

Nov 1996 – Sep 1997

Associate Product Development Engineer

Developed experiments and maintained laboratory equipment for chemical and mechanical testing of polymer materials produced by a company specializing in electrical insulation products in an ISO environment.

Education and Certifications

M.S., Pharmaceutical Sciences, University of Florida, 2013

B.S., Chemistry, University of California, Davis, 1996

Certificate in Software Quality Engineering and Management
University of California, Santa Cruz Extension, 2001