Sven McKinney

(516)531-3311 - Sven@svenmckinney.com

Summary

As a highly skilled and experienced Analytical Development Scientist, I possess extensive knowledge and expertise in pharmaceutical/biopharmaceutical cGMP Quality Control (QC) assays. I am a recognized Subject Matter Expert (SME) and technical leader with a proven ability to develop new techniques and troubleshoot complex issues. I have a track record of leading scientific investigations, designing and executing complex experiments to test hypotheses, analyzing intricate data, and drawing sound conclusions. I am dedicated to enhancing analytical strategies and technical capabilities by staying up-to-date with the latest industry trends and practices. As a team player, I am able to identify priorities within multiple tasks and quickly transition to reprioritize when needed by the business. I am proactive in sharing knowledge and training others in multiple areas of expertise. My goal is to provide exceptional leadership, collaborate with cross-functional teams, and achieve organizational goals.

Experience

Regeneron - Rensselaer, NY September 2019 – May 2023

- Evaluated candidate medicines using multiple Waters Acquity UPLC test methods including purity by Size Exclusion Chromatography (SEC) and doxycycline (dox) impurity by fluorescence detection using Empower 3 (FR2/FR4), performing troubleshooting activities or method development, for example qualifying new dox testing to BioAccord LC-MS using UNIFI, for assay transfer to release testing.
- Executed qualification protocols for reference standard characterization as the site lead SME performing diverse assays in Multi-Angle Laser Light Scattering (SEC-MALLS) using Wyatt Astra, liquid flow through Bruker AquaSpec FTIR using Opus, conformational analysis by tryptophan intrinsic fluorescence using PTI Felix, reduced and non-reduced peptide mapping using trypsin digests, etc.
- Developed analytical methods for measuring Amino Acids, N-Linked Glycans, Antifoam, dox, Puromycin, Hygromycin, Polysorbates, Poloxamer, Total Protein, Titer, Bi-specific purity by Mixed-Mode Chromatography (MMC), Hydrophobic Interaction Chromatography (HIC), Evaporative Light Scattering Detection (ELSD), SEC-MALLS, FFF-MALLS, peptide mapping, etc.
- Developed and validated testing methods for new analyte modalities, such as Polyvinylpyrrolidone (PVP), to ensure compatibility with our equipment.
- Performed investigational testing to troubleshoot manufacturing issues and gather data for problem analysis and improvement strategies.
- Utilized automation and information technology to exponentially increase efficiency including Waters NuGenesis ELN and ValGenesis SDMS, OneLab Andrew+, LabMinds Revo, Prism 8 and JMP 17 statistical analysis, HoloLens for point-of-view data integrity assessment, Microsoft PowerApps, etc.
- Directed projects that optimize resources for diverse experiments and foster open and collaborative environments for sharing ideas and knowledge such as the organization of a buffer library. Utilized technical expertise to implement new and innovative technologies, improving laboratory operations and enhancing performance. Proven capabilities include installing, qualifying, and validating equipment, as well as performing critically time-sensitive repairs, while maintaining compliance by documenting all activities in Blue Mountain Regulatory Asset Manager or logbooks.
- Authored and reviewed hundreds of Standard Operating Procedures, Technical Documents, Work Instructions, Job Aids, white papers, scientific memos, etc. Updated training curricula and notified members of emergency releases. Coordinated updates with other authors while adhering to change control windows and ensured the inclusion of previously non-traceable documents in QUMAS EDMS. Maintains quality assurance to ensure compliance with regulatory standards and requirements.
- Initiated collaborative cross functional review working with Formulations Development Group and Protein Biochemistry lab in Tarrytown, New York, manufacturing operations in Raheen, Ireland, and vendors such as in Santa Barbara, California, frequently all together over video conferencing.
- Conducted training sessions for new staff, mentors peers, and provides support to senior scientists.
- Ensured timely completion of assignments to meet project deadlines, reporting to multiple managers.
- Maintained cGMP documentation using ALCOA guidelines to safeguard SISPQ.

Sciarra Labs - Hicksville, NY July 2019 – August 2019

- Employed subject matter expertise using UPLC test methods for cGMP quality of aerosol drug products such as metered dose inhalers, nasal sprays, dental, and rectal foams.
- Recorded in a laboratory notebook experiments with ATR FTIR, coulometric KF, and microscopic evaluation for assay and identification.
- Resolved method discrepancies, improved reporting with custom field programming, and suggested process improvement using robotic efficiency and accuracy.

Curia - Rensselaer, NY January 2019 - June 2019

- Reviewed the quality of large scale cGMP manufacturing of bulk active pharmaceutical- ingredients (APIs), as well as process development and scale-up.
- Conducted testing of USP/EP/JP monographs according to FDA/ICH/ISO guidelines with attributable, legible, contemporaneous, original, and accurate records.
- Maintained the safety for millions of doses of over-the-counter medicine, in investigational new drug clinical trials, and in multiple stages of chemical manufacturing intermediates.
- Operated chromatography (Empower HPLC and TotalChrom Perkin Elmer GC), spectroscopy, (TopSpin Bruker NMR and Qtegra ICP-MS) and other instrumentation (Tiamo volumetric, coulometric, and potentiometric Karl Fischer titrations).

3M - Cottage Grove, MN December 2017 - December 2018

- Lead chemical analysis at the Corporate Incinerator for the entire organization's plants nationwide to meet disposal and transportation guidelines by the EPA and DOT.
- Communicated with teams for changes based on analytical test results and implications.
- Developed and implemented new information systems and equipment installations.

Medtronic - Fridley, MN April 2017 - August 2017

- Analyzed various medical device components in a cGMP setting for acceptance testing.
- Documented procedures in Waters Scientific Data Management System (SDMS) Vision Publisher as an electronic laboratory notebook (ELN) and data into Labware LIMS.

Eurofins - Mounds View, MN August 2015 - April 2017

- Measured the colloidal composition of various dairy products using AOAC methods, including testing sugar content using Empower to control an Agilent HPLC.

Cantel - Plymouth, MN May 2015 - July 2015

- Upheld cGMP quality for thousands of gallons of dialysate and sterilants shipped worldwide daily.

Pace Analytical - Minneapolis, MN July 2013 - August 2013

- Restructured lab space and developed workflow designs for water quality testing.

Education

University of Minnesota - Twin Cities August 2010 - May 2011

- Additional coursework from the college of continuing education.
- Focused on spectroscopy theory, structural analysis, and multidimensional NMR analysis.

Winona State University August 2007 - December 2009

- Earned a four year bachelors of science in chemistry degree in 2½ years with a 3.5 GPA.

Skills

- Understanding and practice in the use of common laboratory equipment including NMR, ICP, UHPLC, GC, IC, GPC, MS, FTIR with microscope ATR, UV-Vis, AA, TOC, ionograph, particle sizer, FRET, EPR, DNA sequencing, X-ray crystallography, western blotting, bomb calorimetry, wet chemistry, titrations, etc.
- Proficient in Node.js, Python, Java, android, and self-hosted deep learning projects.
- Fluent in Norwegian and German and international travel experiences.

Additional Experience

Eurofins Community Care & Outreach (ECCO) September 2019 - Current

- Co-founded a team to organize service events to spread awareness on issues that affect humans, animals, and the environment at large, such as environmental clean up days at local nature preserves.
- Created a place to share excess supplies and stories with each other and the wider community.

Burn Center Peer Support Volunteer October 2013 - December 2019

- Created a volunteer network and organized support at the hospital where I received life-saving treatment and institutions throughout the state and worldwide.

Courage Kenny Rehabilitation Institute October 2015 - December 2018

- Providing training and encouragement to children and adults with disabilities to allow them to realize their abilities to cope with any challenge.

Rust Consulting December 2011 - December 2012

- Gained legal insight in factors affecting the pharmaceutical industry.