Vikas "Vik" Bhardwaj, MSc
email: vik.bhardwaj01@gmail.com cell: 224-588-2201 San Jose, CA

Education

Indiana University- Kelley School of Business
- Online MBA/MSBA Dual Degree Candidate, Expected 2024

University of Illinois at Urbana-Champaign
- Master of Science (M.S.), Plant Biotechnology, Professional Science Master's, 2014 - 2015
- Bachelor of Science (B.S.), Molecular and Cellular Biology, 2010 - 2013

Certifications/Relevant Coursework

UW-Foster School of Business and UCSD-Extension
- Biotechnology Project Management Certificate, June 2022

Scaled Agile Inc. Certified SAFe Agile Practitioner
- Date of Acceptance: Oct. 31, 2022, credential #: 38884472-6629

UCSC-Extension
- REGL.X404.(6) Regulation of Medical Devices and Diagnostics, Summer 2020
- SEQA.X403.(9) Software QA Testing, Winter 2022
- MEDD.X410.(6) Validating Software for Medical Devices and Emerging Technologies, Spring 2022

Regulatory Affairs Professional Society: Online University
- Certificate in Medical Devices, 2017-2018

Experience

Board Member/President-Elect, Healthcare Association at Indiana University - Kelley School of Business
- While pursuing my part-time MBA degree, became a leader in a student organization to facilitate/lead and curate usually one-hour long recorded guest speaking events via Microsoft Teams focusing on career highlights with senior leaders in the Healthcare Industry.

Sr. Product Quality Engineer at Clario *remote-based*
July 2022- Jan 2023
- Ensure compliance as per 21 CFR Part 11 and implementation of ERT's design control processes/standards (e.g. PLC, DLC, SDLC) in assigned (global) projects.
- Provides and reviews Development and Technical Documentation during (global) Design Projects; consideration of current standards and regulations.
- Provides regulatory expertise to assigned (development) projects throughout the life cycle.
- Ensure compliance of medical and non-medical devices/solutions with the applicable regulations (e.g. FDA, MDR, RED).
- Contribution to review of product information, labeling and/or marketing material.
- Supports Validation activities to ensure fulfills intended and indications for use requirements as per IEC 62304.
- Support UATs and resolve open issues.
- Work alongside product management in readiness meetings ahead of launch.

Design Quality Engineer (Contract) at Apple Health *in Cupertino, CA*
January 2022- May 2022
- Ensured that Design Controls are properly executed in accordance to established standard operating procedures
- Led risk management activities in relation to design changes, and issues discovered during internal testing, and in the field.
- Completed and supported design change assessments and design control documentation to support new software releases.
- Facilitated/led design review meetings.
- Identified and implemented effective systems to support products post market.
- Implementing the execution of systems which identify and resolve quality issues (CAPAs).
- Applied sound, systematic problem-solving methodologies in identifying, prioritizing, communicating, and resolving quality issues.
- Updated bug tracking lists via Radar and reported updated unresolved anomalies as per design review meetings
- Worked closely with SW QA test teams to develop test reports, protocols, and follow up on failed tests.
- Made updates to traceability matrices for Series 6 and 7 WatchOS.

Quality Engineer III (Contract) at Smith and Nephew *in Fremont, CA/ Menlo Park, CA*
October 2021-December 2021

- Investigated, dispositioned and reviewed manufacturing non-conformances reports, CAPAs, and audit findings for manufacturing related issues and recommended courses of corrective action.
- Prepared metrics for NCRs, CAPAs, suppliers performance and analyze process data and trends to drive improvement.
- Managed product complaint investigations, complaint trend analyses, and other related post market surveillance. activities.
- Supported calibration activities.
- Created inspection procedures for the inspection of incoming materials, in-process materials and finished goods.
- Supported sterilization and environmental monitoring activities.
- Interfaced with suppliers on supplier corrective action requests.

Quality Engineer III (Contract) at Abbvie *in Dublin, CA*
June 2021-October 2021

- Acted as a Quality lead to oversee day to day Manufacturing activities on Control Unit (COM3 and COM1 line).
- Worked with internal customers and suppliers to ensure that non-conformances, failure analysis reports and deviations are appropriately investigated, documented, reviewed, and approved.
- Responsible for driving continual process improvements in responsible areas of the business. Drive quality and manufacturing improvements to assure that processes are in a state of control.
- Developed and maintained effective relationships and integrated activities with other departments and suppliers (as needed).
- Design drawing analysis to confirm potential component defects.

Product Quality Engineer (Contract) at Abbott *in Santa Clara, CA*
January 2020-June 2021

- Certified CAPA trained to be able to investigate manufacturing records to uncover possible issues.
- Performed complaint investigations on US, EU, and Global areas detailing technical writing skills, project management and regulatory compliance.
- Selected by the Director and gave a well-received departmental-wide ice breaker via WebEx.
- Performed device failure analysis and risk assessment review into the returned device using failure mode effect analysis, decision trees, SOPS, and databases.
- Statistical analysis of complaint trends.
- Component failure analysis/nonconformance inspection.
- Participated in BSI recertification audit as scribe.

Quality Specialist-Post Market (Contract) at Amgen *in Thousand Oaks, CA*
January 2018- June 2019

- Supported the product complaint system (IRPC) at Amgen through; leading and managing global product customer complaint investigations.
- Supported CAPA and Root Cause processes, provided extensive day-long training sessions.
- Performed data analysis and trending of complaint information, as it pertains to electromechanical cardiologic medical devices, to proactively detect signals and take appropriate steps.
- Carefully managed patient data and cognizant of different regulatory requirements globally in terms of patient privacy.
- Managed time efficiently and effectively to meet specific quality metrics related to complaints.
- In-depth knowledge of FDA and global complaint regulatory requirements.

Product Surveillance Quality Associate 1(Contract) at Baxter Healthcare *in Round Lake, IL*
June 2017- January 2018

- Owned the full-cycle product complaint record process from after initial call-center intake until writing the complaint summary.
- Analyzed and obtained highly regulated, pertinent, US renal device complaint information well as adverse event information to ultimately determine cause codes for trending purposes.
- Tracked the return unit and followed up with the patient if the sample shipment is delayed.
- Analyzed technical documents such as batch record and device history (service) record for deviations, non-conformances or change controls.
- Evaluated return sample data to determine the most suitable As Investigated Cause Code.

Leadership Experience
Associate Project Manager (Contract) at Weiman Products, LLC *in Gurnee, IL*
September 2016 - December 2016

- In an agile consumer products environment, managed 7 projects simultaneously with budgets from $50K to above 1 M through execution, monitoring, and controlling phases.
- Assessed risk and changes to scope and updated team through appropriate communication channels.
- Built rapport with members of cross-functional teams to ensure productivity.
- Excellent communication, interpersonal and organizational skills.
- Scheduled and coordinated meetings to implement communication plans among project team.