Simin Shamsfallah
19614 110th Place NE
Bothell, WA, 98011
Cellphone: 508-818-2424
Email: simin.shf@gmail.com

EXPERIENCE

Regulatory Affairs Specialist
Earlens Corporation, Menlo Park, CA   November 2017-Present

The Earlens Light-Driven Hearing Aid is an FDA-approved medical device that directly activates the natural hearing system, delivering the full spectrum of sound. The Earlens hearing aid provides the broadest audible frequency range on the market, delivering significant output from 125-10,000Hz.

- Drafted and documented multiple US and OUS Letters to File
- Developed and maintained EU technical file
- Involved in preparation and submission of premarket notification (510(k)) to FDA for Earlens Hearing Aid
- Performed collaborative work through cross-functional meetings with the R&D team to ensure compliance with the regulations
- Reviewed and approved proposed design changes and ECOs to assess regulatory impact
- Reviewed and approved labeling and Instruction For Use (IFU) for domestic and international compliance including meeting US and EU UDI requirements
- Participated on project and product development teams to provide early guidance, design control reviews, and regulatory strategy
- Participated in internal and external audits
- Reviewed, and approved risk management files

Software Validation Engineer   February 2017 – October 2017
Earlens Corporation, Menlo Park, CA

- Defined and drafted software Test Protocol (TP), Software Requirements Specification (SRS), Operational Qualification (OQ), and Performance Qualification (PQ)
- Validated Salesforce and its integration with QAD to be in compliance with FDA guidelines
- Drafted and released software validation protocols and test reports
- Worked with clients to define and implement validation requirements
- Created and tracked issues/features using Atlassian Jira
- Wrote, updated, reviewed and approved Standard Operating Procedures (SOPs) and QA procedures

- Worked with Operations Process Management (OPM) software Solumina that manages work and quality processes for the manufacturing and MRO (Maintenance, Repair, and Overhaul) of highly engineered products
- Validated 3D design software including MeshLab, Geomagic Control, Rhino3D, and EarMould Designer to be consistence with FDA guidelines

Accountant   December 2009 – September 2011
Tehran University of Medical Sciences, Tehran, Iran

- Performed and managed all monthly payroll activities
- Calculated salaries, rate changes, bonus, vacation, and termination
- Processed accounts payable invoices assuring proper approvals and receipt of goods/service
- Processed payment of payable invoices, attaching correct documentation and obtaining check signatures
- Controlled and managed employees' Paid Time Off (PTO)
- Provided assistance to human resources department staff on an as needed basis.

TECHNICAL SKILLS
- **Programming:** Proficient in Java (Eclipse, NetBeans IDE), JavaScript, CSS, HTML
- **Version Control System**: Git
- **Operating Systems:** Windows and Linux (Ubuntu)
- **Network Analyzing and Troubleshooting:** Wireshark
- **Design Software:** Meshlab, Geomagic Control, Rhino 3D, Earmould Designer
- **Customer Relationship Management (CRM) Software:** Salesforce
- **Microsoft Office:** Word, Excel, PowerPoint, MS Project, Outlook
- **Adobe Software:** Photoshop, Illustrator

SELECTED ACADEMIC PROJECTS

- **Simulated Automatic Teller Machine**: Developed a simulated ATM to maintain information of all accounts. It records the customer's information such as customer number, customer PIN, accounts types, and all transactions done by the customer, using Java Graphical User Interface (GUI).
- **Restaurant Management System**: Developed a system for restaurants to records items that are being purchased by the customers, and keep track of sold items using Java Graphical User Interface.
- **Desktop Calculator**: Developed a desktop calculator application using Java JFrame.

Awards & Honors
- The Robin L. Kaplan and TJX Companies Memorial Scholarship, 2015
- Outstanding Academic Achievement Certificate, Dean's List, Worcester State University, 2014

EDUCATION

- **B.Sc., Computer Science**   May 2013 - Aug. 2016
  Worcester State University, Worcester, MA
  GPA: 3.84 /4.0

- **B.Sc., Accounting (Minor in Finance)**   Sep. 2002 - Sep. 2007
  Technical College of Dr. Shariaty, Tehran, IR

PERSONAL SKILLS

- Able to analyze technical documentation for inconsistencies, ambiguities, and incomplete / contradictory requirements
- Able to collect and analyze data to solve complex problems in a timely manner
- Well versed in Functionality, Usability, Security, Load, Localization and Regression testing
- Highly motivated and detail oriented with an exceptional ability to work independently as well as part of a team while demonstrating excellent analytical, technical and problem solving skills
- Can get things done on tight schedules prioritizing the tasks and using the resources effectively
- Knowledge of SQA methodologies and practices
- Accurate, thorough, and committed to excellence
- Quick and motivated learner
- Diligent, hard working with a strong work ethic
- Great communication skills
- Committed to product quality and excellence
- Fluent in Persian and English languages

OTHER ACTIVITIES

- Member of Cultural Exchange Group at WSU   2015-2016
- Member of International Student Organization   2014-2016
- Member of Association for Computing Machinery (ACM)   2014-2016