

Upasana Veturi

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OBJECTIVE

To obtain a full-time position in the Quality/Regulatory system of the medical device industry, starting June 2016.

CAPABILITIES

- Familiarity with GMP & Quality System Requirements, FDA working and regulations; ISO 13485, ISO 14971, 21CFR:820, AAMI Industry Practices.
- Ability to troubleshoot medical equipment (PCR, Flow cytometer, Fluorescent microscope) and relevant software; optimizing experimental protocols for biosensor systems.
- Able to work well independently or as part of a team.
- Applicable knowledge of healthcare IT systems, data management, and statistical analysis.
- Excellent communication skills, able to work in a culturally diverse environment; strong oral and technical writing skills.

EDUCATION

May 2016 - **Master of Science (GPA: 3.44/4.00)** – *Biomedical Engineering, University of Texas at Dallas*

May 2014 – **Bachelor of Engineering (GPA: 7.66/10)** – *Biotechnology Engineering, PES Institute of Technology (India)*

WORK EXPERIENCE

Associate Consultant (Intertek Testing Services, Plano TX)

March 2016 - Present

- Provide market entry requirements to clients for various countries. Review of Risk Management procedures, verifying compliance to regulatory standards (ISO 14971, ISO 13485, IEC-60601-01).

Biodevelopment Intern (UT Dallas)

October 2015 – January 2016

Development of product lifecycle courses, content or tools (Quality System Manual for university research institutes)

- Quality, Regulatory, Safety, and compliance projects (Root cause analyses, Medical Device quality case studies, development of regulatory strategies for medical devices).
- Creating regulatory and quality course content, support for program adjuncts, review and/or audit of documentation

Graduate Student Researcher (Biomedical Microdevices and Nanotechnology Laboratory) August 2014 – April 2015

- Development of experimental protocols, design optimization of biosensing device, data acquisition and analysis of cardiac biomarkers on biosensors using electrochemical spectroscopy techniques.

ACADEMIC PROJECTS

- Design and construction of a Quartz Crystal Microbalance biosensing device for diagnosis of diseases characterized by agglutination.
- Prototyping, design, and development of business idea for a wearable medical device to detect early signs of pneumonia in infants.
- Research project on lung cancer data – Comparative data and statistical analysis.

TECHNICAL SKILLS

- **Certifications:** Medical Device 101: An education forum on FDA regulations and requirements for medical devices; Arduino India Maker Fellow Program, MIT Media Lab Design Innovation.
- **Laboratory:** Electrochemical instrument (GAMRY reference 600), Flow Cytometer, Fluorescent Microscope, Microtome, Real time and classical PCR, Gas Chromatography, HPLC, ELISA.
- **Software Tools:** OriginLab, Adobe Illustrator, AmpliLink, StepOne, MS Office, Keynote, Prezi.
- **Coursework:** Quality Systems Compliance, Medical Device Regulatory Strategies, Biomedical Microdevices, Nanotechnology and Sensors, Biomaterials and Medical Devices, Healthcare Informatics, Anatomy and Human Physiology, Cell and Molecular Biology, Bioinformatics, Biostatistics, Tissue Engineering, Health Diagnostics, Engineering Mechanics, Advanced Engineering Mathematics.
- **Operating Systems:** Linux, Windows, iOS

ACHIEVEMENTS

- Incubation award at a Medical Technology hackathon organized by CAMTech for the prototyping of a device aiding early detection of respiratory distress in infants.
- Second place in the poster presentation at a national level symposium (Symbiot) conducted by IEBT at Manipal Institute of Technology.