

Bhakti Khandagale

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<https://www.linkedin.com/in/bhakti-khandagale/> | <https://github.com/bkhandag> | <https://bkhandag.github.io/Bhaktis-Portfolio/>

EXPERIENCE

Novo Nordisk

Seattle, WA

Product Manager/Lead Systems Engineer – Software as a Medical Device

November 2019 – present

- Developed a first-of-its kind Mobile Patient App-Web App-Cloud Titration System for a [Diabetes Drug Clinical Trial](#)
- Launched the Titration System in US and in several countries in EU, total enrollment of 2000 patients and 500 doctors.
- Delivered the Titration System on an accelerated timeline of 8 months resulting in 25% reduction in cycle time.
- Created and submitted submission Packet for the Titration System to US FDA and EU EMA authorities
- Drove successful product cycle from initial stakeholder meetings, development, and delivery, to products complaints handling with weekly reporting to VP and CVP of Product Development, Regulatory, and Medical.
- Collaborated with UX, patients, doctors, and clinical trial team to define product vision, roadmap, and feature prioritization
- Implemented the iOS-web-AWS System according to ISO 13485, IEC 62304, cybersecurity and privacy standards
- Resolved product complaints with incremental maintenance software releases to fix bugs with adherence to regulations.

Eli Lilly and Company

Indianapolis, IN

Sr. Device Development Engineer – Firmware Delivery Devices and Connected Solutions

March 2016 – November 2019

- Developed and commercialized a connected Insulin pen firmware system with wearable BLE connectivity
- [Tempo Smart Button](#) Sensor System Patent Pending US Sr No 88224775
- Developed state-of-the-art, \$1bn Closed Loop Automated Insulin Delivery System, [Artificial Pancreas](#)
- Lead development of hardware for Nordic microcontroller (embedded software system)

Eli Lilly and Company

Indianapolis, IN

Sr. Engineer – Research and Development IT

June 2015 – March 2016

- Developed a Search Tool utilizing a nontraditional database based on user-entered ontologies to enable research for drug R&D department electronic Lab notebooks and FDA submission documents repository.
- Search application was key contributor to reduce drug development timeline from 10 years to 5 years
- Generated test protocol, test cases and conducted User Acceptance Testing for Search Tool

Stryker Orthopedics

Mahwah, NJ

Engineer, Contractor

June 2014 – June 2015

- Delivered new features/enhancements for expense tracking system for business units across the US
- Resolved customer complaints in expense tracking and medical invoicing by interacting with customers, root cause analysis, bug identification, and bug fixing.
- Acquired user specifications and data through interviews and surveys, site visits, and workflow and business process analyses.

UTi Worldwide

Portland, OR

Engineer, Contractor

March 2013 – June 2014

- Implemented Enterprise Resource Planning tool by acquiring stakeholder input to generate user needs and requirements for affiliates in the EMEA, APAC, and Americas areas across multiple time zones.
- Performed data analytics utilizing PL/SQL queries on Toad. Facilitated communications between customer and software development team through systematic process requirement documentation.
- Developed and reported on setup, test scripts, project management, and functional design documentation.

EDUCATION

PURDUE UNIVERSITY

West Lafayette, IN

Bachelor of Science in Computer and Electrical Engineering

December 2012

SKILLS

Skills: Product management, Competitive landscape research, process development, system testing & test plan development, proficient in data analysis Excel, Word, Sharepoint, github, HTML, Bootstrap, Node.js

SOCIAL IMPACT AND FUN STUFF

- Enhanced organizational commitment to diversity and mentored women in engineering through
 - Led float building activities in the Indy Pride Parade
 - Led the site Diversity and Inclusion Committee
 - Executed site outreach activities in the Women's Leadership team.
- Recruited at Purdue University with co-ordination with Minority in Engineering Program (Purdue-MEP)

Interests: Camping, hiking, listening to audio books, sharing a meal/having a party with family and friends