Kenneth Chang

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Experience

Research & Development Engineer
MedeonBio, Sunnyvale, CA, 07/2016 - Present

- Led design, prototyping and development of Generation 2 Nitinol(NiTi) implant. Implants incorporated clinical and physician feedback; new size to allow for wider treatment criteria and effectiveness, reduced delivery profile to allow expanded delivery system compatibility. Drafted and released technical documentation along with design verification testing protocol and reports.

- Responsible for critical catheter components, silicone seals, and nitinol capture wire for Generation 2 delivery system. Collaborated extensively with outside manufacturers to refine manufacturability and moved production in house where possible to reduce lead times. All components successfully received and utilized in device build.

- Managed design, prototyping and development of custom Retrieval Sheath Assembly for the Generation 2 NiTi implant, incorporating clinical experience and feedback from FIH trials. Retrieval Catheter assembly successfully built as part of Generation 2 device build.

- Evaluated animal study data and experiences to create Generation 1 implant and delivery system designs for First-in-Human trials. Upsized animal implant to fit human anatomy and worked with testing partners to perform FEA, MRI and corrosion testing. Implemented new features into delivery system design to prevent accidental deployment. Authored Manufacturing Process Instructions, Travelers, technical documentation and test protocols and reports. Responsible for hands-on training of physicians at trial sites.

- Collaborated with Senior engineer to refine half a dozen experimental concepts into two main designs for further animal studies. Created delivery system for implant based on stent delivery systems. Preclinical implant and delivery system used in design evaluation and long term animal studies to great success. Conceptualized implant retrieval procedure using off-the-shelf products.

- Participated in early feasibility and concept exploration phase of the project. Developed and performed benchtop feasibility testing to assess viability of project concept. Worked hand in hand with Senior engineer to develop and test delivery procedure in animal cadaver studies. Experimented with and constructed early prototypes of silicone training and demo models used to educate veterinarians and physicians.

- Brainstormed and developed experimental designs and features for Nitinol implants. Created and rapid prototyped using local laser cutting vendors and in-house shape setting to evaluate alternative geometries, anti-migration features and retrieval assistance features. Achieved rapid turnaround, creating engineering prototypes in under a week. Researched chemical coatings to improve implant life and bioabsorbables alternatives.

- Managed and coached summer intern over a three month period. Provided technical support, guidance, and feedback through the course of two intern projects. Intern successfully produced benchtop training model currently used for clinical training, and developed benchtop test method to evaluate calcification resistance of implants.

- Independently learned plot.ly and Tableau to create marketing presentation with publicly available

Medicare and Open Payments data to glean insights on market breakdown, intelligence on key market leaders, and information on key opinion leaders.

○ Supported patent filing of intellectual property, helping draft claims, create drawings, and evaluating competitor patents to determine freedom to operate.

Process Data Systems & Engineering Co-Op

Genentech, Vacaville, CA, 06/2015 - 06/2016

○ Designed and implemented Column Chromatography Preparation module for process monitoring data system, including automated data pull in Visual Basic, and supporting databases in Oracle.

○ Wrote back end automated data pull, organization and export system in Visual Basic.

○ Developed Statistical Process Control tools such as Control and Pareto charts in JMP for use in process monitoring and improvement.

R & D Engineering Intern

Shockwave Medical Inc., Fremont, CA, 06/2014 - 09/2014

○ Designed and documented new bench-top testing flow model simulating heart valve and vessel geometry used to evaluate prototype lithoplasty catheter designs. Model measured Fractional Flow Reserve to quantify effectiveness, and used gypsum test phantoms to simulate calcification.

○ Optimized test phantom production process for annealing temperature, thickness, and time so properties accurately simulated calcified blood vessels. Tested phantoms using Instron to verify material strength was similar to clinical results.

────── Personal Projects

Histopathology Cancer Classifier

01/2019 - 03/2019, Machine Learning Application Project

○ Developed machine learning classifier to determine whether histopathological images contained malignant cells. Classifier written in Tensorflow. Researched publications to determine architecture to implement. Final design utilized Spatial Transform Layers feeding Convolution layers, before final classification layer. Achieved Validation and Test accuracy of 84.36%.

Chimera

06/2019 - 07/2019, Video Game Development Project

○ Independently learned Unity and C# to develop a 2D wave-based survival shooter in under a month. Programmed player movement, weapon upgrades, UI, and enemies. Implemented procedural generation of wave composition and elite enemies, allowing for wide gameplay variety.

Cascade

12/2019-Present , Graph Database Project

○ Developing a script tool in Python and Neo4j to map physical interaction of complex assemblies for advanced Failure Mode Effects Analysis and Impact Analysis.

Cartographer

11/2019-Present , Graph Database Project

○ Developing a graphical relations database to analyze physician influence for Market Intelligence, Key Opinion Leader identification and Customer Relation Management. Database planned to utilize data on physician procedure volumes, payments from manufacturers, and peer reviewed publications to judge influence.

Patents and Publications

- Patent US20180318114A1: Implantable devices and methods to treat Benign Prostate Hyperplasia (BPH) and associated Lower Urinary Tract Symptoms

Skills

CAD	Solidworks, Inventor	Programming	Python: Numpy, Pandas, Tensorflow, Keras, SQLite, Neo4j Selenium Webdriver
			C#: Unity
Prototyping	3D Printing, Laser Cutting, Catheter Hot Box, Machining	Software	MATLAB, Tableau, Latex, InkScape, Microsoft Project
Languages	Mandarin Chinese		

Education and Courses

2012–2016 **B.S. Biomedical Engineering**, *University of California, Davis*, GPA: 3.3/4.0.

Additional Coursework

- Deep Learning Specialization
  Coursera, Completed Mar 2018
- Machine Learning
  Coursera, Completed Aug 2017
- Introduction to Data Science in Python
  Coursera, Completed Oct 2017
- Solidworks Advanced
  GoEngineer, Solidworks VAR, Completed Aug 2017