# Mark Petersen

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## QUALIFICATIONS

Proven quality systems professional, positioned for career pivot to software systems development, quality / testing or data analysis. Recent software development boot camp graduate seeking a fulltime, part time or contract opportunity to contribute to project success and user satisfaction. Resume highlights:

**Quality Systems**: Seven years of experience in pharmaceutical and medical device quality management from FDA approval and compliance / regulatory processes to internal audits and compliance process ownership.

**Software Development**: Completion of training and code development projects (backend, frontend) using SQL, C#, HTML, CSS, .NET Framework, JavaScript, Visual Studio, and Python with best practices in version control and agile methodology.

**Data Analysis and Communications**: Proficient in all Microsoft Office applications, Visio and SAP for analysis and communication of information in formal reports, project meetings and executive reviews.

**Teamwork and Collaboration**: Served as team lead and project manager on several multi-departmental CAPAs (corrective and preventative action) and internal audits. Noted for excellence in working with diverse, multi-cultural teams.

## PROFESSIONAL EXPERIENCE

### *BIOTRONIK, Inc(www.biotronik.com)* — *Lake Oswego, OR*

**Compliance/Quality Specialist** — December 2015 – May 2018

- Established and managed OEM Supplier Evaluation Process including development of Quality Agreements representing multimillion-dollar sales opportunities.
- Performed internal audits and managed resulting corrective actions.
- Developed and maintained quality project dashboards throughout project lifecycle including key performance indicators and milestones for executive review.
- Participated in FDA facility inspections at BIOTRONIK, Inc.(USA) and preparation of annual FDA reports as required for products and devices that have been approved by pre-market approval (PMA) process.

### *Genentech Inc. (member of Roche Group, www.gene.com)* — *South San Francisco, CA*

**Quality Assurance Specialist II (full time contractor)** — October 2014 – December 2015

- Recruited for regulation and QA of Genentech's strategic CMO initiative with Samsung BioLogics
- Managed activities to support release of commercial product including approval of master process documentation, resolution of investigations, and assessment of change controls.
- Developed and maintained quality risk management plans ensuring CMO inspection readiness.

### *Berkeley Advanced Biomaterials Inc. (www.hydroxyapatite.com)* — *Berkeley, CA*

**Quality Assurance Specialist II** — March 2014 – October 2014

- Responsible for CAPA (*corrective and preventative action*) from initiation to effectiveness verification
- Developed and conducted formal group training on CAPA best practices
- Managed QC processes and streamlined existing systems to maximize process efficiency.
- Collaborated with external testing partners in result analysis of various biological testing equipment.

**CAPA / Complaint Coordinator** April 2012 - March 2014

- Responsible for management of all CAPA reports, deviations and complaints.
- Accountable for data management for regulatory and certification compliance
- Worked across departments to investigate and close process issues and product complaints
- Served as backup to quality control technician and quality engineer performing functions such as new product validations, manufacturing equipment calibration and maintenance program.

### *Genentech Inc.* *Hillsboro, OR*

**Inspections Technician (full time contractor)** April 2011 – April 2012

- Responsible for final packaging and inspection of commercial pharmaceutical products
- Trained in process knowledge for full compliance of cGMPs, Standard Operating Procedures (SOPs),
- Assigned to a process improvement task force utilizing SWOT and other system analysis tools

## EDUCATION

**Tech Academy – Software Developer Boot Camp** September 2018 – January 2019
(www.learncodinganywhere.com)

- 1,000 hours software development training using C#, Python, JavaScript, HTML, CSS, SQL, & Git
- Front-end and back-end web and software development projects (samples available on GitHub)
- Training included best practices for version control, agile methodology, project management

**Johns Hopkins Nuclear Medicine Technology Program** June 2010 – February 2011
Johns Hopkins Hospital, Baltimore MD

- Completed 500 in-clinic service hours towards nuclear medicine technologist training (25h/week)
- Course completions in nuclear medicine technology, medical terminology and disease diagnosis

**Bachelor of Science, Chemistry** Degree Awarded: January 2010
University of Oregon, Eugene OR

## ADDITIONAL SKILLS & CERTIFICATIONS

- Tech Academy (www.learncodinganywhere.com)Software Developer Boot Camp graduate.
- Trained in cGMP standards, SOP's for global pharmaceutical production.
- Proficient in: Microsoft Office Suite, Visio, WEBEX, Oracle, TrackWise, SAP, Livelink, VisualStudio, Git
- Proficient in investigative and system mapping tools, Lean six sigma project methodology and tools.
- Knowledgeable in certifications and government regulations such as 21 CFR Part 820, Part 803, Part 1271, ISO 13485, ISO9001, ISO 14971 and other FDA/EDQM standards.
- Six Sigma Yellow and Green Belt (Oregon State University, ASQ certified #17926).
- ASQ Certified Quality Process Analyst (#65314868 – 5050.
- ASQ Certified Quality Auditor (#65314868 – 66408).
- ASQ Certified Quality Engineer (#101354).