# ALAN M. COHEN

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## SUMMARY


**Hands-on software/electronics/systems engineering consultant and manager in the medical device/life sciences industry, with significant experience in regulatory and quality affairs.** Extensive experience bringing medical devices to market. Problem-solver, team-builder and mentor with a wide range of expertise.

- **Technical Leadership:** Successfully created, built and led teams in creating sophisticated technology, including software and electronics. Skilled at working with multiple stakeholders (clinical, engineering, business, marketing and sales) to optimize development goals and outcomes.
- **Product Innovation:** Led or contributed to international teams in the design and development of medical devices including proton therapy, laser ablation, cardiac therapy, vital signs monitoring, telehealth, nervous system diagnostics, in-vitro diagnostics and others.
- **Quality and Regulatory:** Experienced in developing and using quality management systems (QMSs) and design processes that are compliant with FDA, EU, IEC, ISO, HIPAA, and other regulations and standards, and in aiding preparation of FDA 510(k) submissions. Very good knowledge of FDA regulations and guidances on software validation and submissions, FDA design controls, and medical device standards including IEC 62304 (software), ISO 60601 series (device safety and effectiveness), ISO 14971 (risk management), and ISO 13485 (quality management).
- **Creative Problem-Solving:** Holder of eight US patents for medical testing, signal processing, and other technologies. Frequently called on to "turn around" projects.
- **Published Author**: *Prototype to Product: a Practical Guide to Getting to Market* (O'Reilly), a systems-level approach to bringing software-driven products to market, published in August 2015. Have also authored a college textbook on computer communications, numerous published articles, and spoken at national meetings on medical technology topics.


## EXPERIENCE

**PROTOM INTERNATIONAL, Wakefield MA** **Jan 2015-Present**

**Consultant, System Engineering and Quality/Regulatory (3 days per week while writing a book)**

*Creating and implementing engineering and quality processes per FDA regulations to ready the Radiance 330® Proton Therapy System for commercial use. Worked with internal and external resources (including consultants, vendors and customer) on various efforts, including:*

- *Leading a retrospective design review process to ensure that documentation, traceability and reviews at the subsystem level are adequate after the development of a very complex device.*
- *Leading the effort to ensure that traceability is adequate from highest-level requirements through verification testing.*
- *Worked alongside engineering, documentation, and IT resources to specify and update bill of material (BOM) and to build tracking process.*
- *Reviewed and updated quality system (SOPs and Work Instructions).*
- *Consulted on numerous regulatory and quality issues.*

**PYRAMID TECHNICAL CONSULTANTS, Lexington MA** **Feb 2012-Nov 2014**

**Consultant, System Engineering and Quality/Regulatory (3 days per week while writing a book)**

*Helped guide efforts to develop, document and test software and hardware subsystems being developed for ProTom's Radiance 330® Proton Therapy System so that they are appropriate for use in a regulated medical device. In particular, I helped lead efforts to bring software processes and documentation to a level sufficient to achieve ProTom FDA 510(k) clearance for the Radiance 330® in 2014.*

- *Led the development of internal subsystem software and hardware requirements based on customer requirements and Pyramid business requirements.*

- *Led the effort to create processes and tools to maintain traceability between software and hardware requirements, documentation, and verification testing.*
- *Worked with Pyramid's engineering group to update, solidify, and document software architecture to reduce complexity and increase testability.*
- *Guided development of Pyramid's software release process.*
- *Consulted on numerous regulatory issues.*

**LOGIC PD, Maynard MA** **2007–2012**
**Director, Eastern Systems Engineering Group and Medical Practice Team Leader**

*Logic is a contract product design, development, and manufacturing firm specializing in regulated markets (medical, aerospace and military), that employed roughly 100 engineers and designers (and hundreds of manufacturing employees) during my tenure.*

- Program management of complex medical/life science device development efforts, including requirements gathering and creation, software development (embedded and applications), electrical engineering, mechanical engineering, industrial design, and interaction design/human factors.
- Founded and led company-wide Medical Practice Team, creating strategies and tactics to establish Logic as a developer of medical/life science devices and software. As a result, turnkey development of major subsystems for FDA-controlled devices grew to more than 40% of revenues.
- Led the company's effort to develop software processes compliant with IEC 62304, the international medical device software standard recognized by FDA, EU, and most of the rest of the world.
- Led efforts to introduce software safety best practices to Logic, including static code analysis and MISRA C standards.
- As a hands-on manager, continued to write production code in C, C++, C#, and SQL.
- Co-founded the *Design Services Quality Team*, which gained ISO 13485 certification.
- Acted as the regulatory lead or consultant on many of Logic's medical device projects.
- Worked closely with Logic's manufacturing group to smooth NPI (new product introduction) processes.
- Initiated company's industry thought leadership efforts through conference presentations and published articles. Corporate representative at numerous conferences and meetings.

**DUKE-RIVER ENGINEERING, Newton MA** **2004–2007**
**Director, Medical Devices**

*Duke-River was a small consultancy specializing in productization of startup technologies in the medical device market.*

- Oversaw medical product software development and SQA (software quality assurance) efforts.
- Sold engineering services into the medical device market.

**E-GREEK.COM, Waltham MA** **2002–2004**
**Co-Founder and President**

Oversaw development of a high-capacity, database-driven web-based application to connect members of fraternities and sororities, both undergraduate and alumni. E-Greek's membership exceeded 16,000 members.

**BOSTON MEDICAL TECHNOLOGIES, Wakefield MA** **1993–2001**
**Co-Founder and Chief Technology Officer**

- Directed development, marketing and sales of 40 research cardiac monitoring systems into leading teaching hospitals worldwide (including Mayo Clinic, Massachusetts General Hospital, Cleveland Clinic and Boston Children's Hospital). Consulted to medical clients, including design of robust data collection system

for the cardiac catheterization lab at Boston Children's Hospital, following extensive interviews and observation of staff needs.
- Sought and gained $5.5 million initial venture capital funding.
- Created and grew the software engineering group to 12 people, and developed the Anscore autonomic nervous system test instrument ahead of schedule and within budget. Technologies included within the FDA-cleared device included Windows applications, firmware, Oracle databases with geographical redundancy and failover, and encrypted remote transfer.
- Significant role in writing FDA 510(k) application, which resulted in clearance in less than 40 days after application submission.
- Led BMT's vigorous intellectual property effort, culminating in the award of patents in fields ranging from digital signal processing to medical testing techniques.

## EDUCATION

**BS, Cornell University, Ithaca NY**: Electrical Engineering Major, Neurobiology Minor

## PUBLICATIONS/PRESENTATIONS/PATENTS

- ***Prototype to Product: a Practical Guide to Getting to Market*** (O'Reilly, 2015), a systems-level approach to bringing intelligent products to market. Manuscript is complete and in, anticipated release of print edition is August 2015.
- **Numerous articles on various aspects of information technology and medical technology** in publications such as *Medical Electronics Design, EE Times,* and *Medical Electronics Device Solutions*.
- ***A Guide to Networking*** (International Thompson Publishing, 1991; 2nd edition, 1995), a college textbook on computer communications adopted by many schools, including Northeastern University and the University of Texas. Over 20,000 copies sold.
- **Experienced presenter on technology topics** ranging from RF and computer communications to understanding the FDA approval process. Venues include *Embedded System Conferences* in Boston and Chicago, *DesignMed* in Anaheim, CA, keynote address at *RTECC-Boston*, and *MassChallenge*.
- **Sole inventor or co-inventor on eight issued US patents**, covering medical instrumentation, radio communication techniques, and remote medical telemetry.