

# Derek Beaupre

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## Overview

20 years of expertise in a range of medical devices with start-up companies, including Project Management, Product Development, Design Transfer and Quality Assurance/Regulatory Affairs:

- Quality Assurance/Regulatory Affairs – Failure Modes and Effects Analysis; hazard/safety analysis; reliability engineering; software validation; internal Quality auditing; FDA MF and 510(k) submissions and Design Dossiers for CE Mark approval; writing and implementing Quality Systems Manuals and Standard Operating Procedures for ISO 13485 certification and compliance with FDA Quality System Regulations.
- Department Management tasks – direct drafters/designers, documentation control, and QC personnel; manage engineering and regulatory consultants; plan goals, budgets, and personnel.
- Product Development – comprehensive experience from concept through production for various medical products including capital equipment, reusable, disposable and implantable devices.
- Project Management – lead project teams for product development, mechanical design projects, product verification and clinical validation, and equipment installations including clean room setup.
- Design Engineering – numerous projects using design for manufacturing and assembly including sliding patient treatment table; handheld electromechanical instruments; disposable products including cell sorting cartridge, minimally-invasive probes, infusion devices, and sharps containers.
- Manufacturing Engineering – transferred multiple product lines from Massachusetts to California; process verification; pilot production; design transfer to manufacturing; fixture/equipment design and qualification.

## Medical Device Experience

**Tomophase** – Burlington, Massachusetts, 2012 – Present

- Director, Quality Assurance & Regulatory Affairs, July 2012 – Present
- *Optical Coherence Tomography* – OCT Imaging System and disposable probe using near infrared light to evaluate tissue microstructure by providing high resolution cross-sectional real-time depth visualization.

**Semprus BioSciences/Teleflex** – Cambridge, Massachusetts, 2011 – 2012

- Manager, Quality Assurance/Engineering, February 2011 – July 2012
- *Surface Modification Technology* – Non-leaching anti-fouling surface modification of PICCs, dialysis catheters, orthopedic implants, and contact lenses.

**Enginivity/Vital Signs, a GE Healthcare Company** – Lexington, Massachusetts, 2010 – 2011

- Engineering Manager, November 2010 – February 2011
- Project Engineer, May 2010 – November 2010
- *Patient Warming Devices* – Intravenous fluid warming and full body patient warming systems.

**Beaupre Consulting** – Hampton, New Hampshire, 2010 – Present

- Principal Consultant, January 2010 – Present
- *Medical Device Consultant* – Specializing in Project Management, Product Development Engineering, and QA/RA for 510(k) submissions. Primary clients include Metis Manufacturing, OC2 and Tomophase.

**Axya Medical/Tornier, Inc.** – Beverly, Massachusetts, 2007 – 2009

- Project Engineering Manager, October 2007 – December 2009
- *Orthopedic Implants and Instruments* – Suture anchors for sports medicine repair, implants for wrist fixation, and associated instruments for site preparation and insertion.

**Cytonome, Inc.** – Boston, Massachusetts, 2004 – 2007

- Director, Quality Assurance, February 2005 – September 2007
- Senior Product Development Engineer, August 2004 – January 2005
- *High Speed Optical Cell Sorter* – Innovative equipment for clinical grade cell sorting to maintain sterility with exceptional sorting speed while providing high purity and yield, as well as protecting the operator.

**Hemedex, Inc.** – Cambridge, Massachusetts, 2001 – 2004

- Quality Assurance Manager, March 2004 – August 2004
- Senior Product Development Engineer, November 2001 – March 2004
- *Perfusion Monitoring System* – Two-piece system using thermistor technology for measuring absolute tissue perfusion in real-time with a reusable bedside monitor and a disposable minimally invasive interstitial probe.

**Axya Medical** – Beverly, Massachusetts, 2000 – 2001

- Senior Project Engineer, February 2000 – October 2001
- *Suture Welding System* – Three-piece system uses ultrasonic technology for welding suture with a reusable handheld welding instrument, a disposable suture positioner, and a power generator. Replaces knot tying in arthroscopic, laparoscopic, and open surgical procedures.

**Ablation Technologies** – San Diego, California, 1998 – 2000

- Senior Mechanical Engineer, December 1998 – February 2000
- *Prostate Cancer Treatment System* – Three-part system incorporating a fiberglass sliding patient treatment table, a high-power electromagnetic coil, and Palladium-Cobalt alloy temperature self-regulating implants to ablate cancerous tissue without injuring surrounding cells. Also, an interstitial device applicator for improved insertion of the implants.

**Winfield Medical/Maxxim Medical** – San Diego, California, 1997 – 1998

**Infusion Technology/Winfield Medical** – Danvers, Massachusetts, 1993 – 1997

- Project Engineer, April 1997 – December 1998
- Quality Engineer, January 1996 – April 1997
- Mechanical Engineer, April 1993 – January 1996
- *Infusion Pumps, Disposable Infusion Sets, and Accessories* – Patient controlled and multi-therapy infusion pumps possess electronic hardware, software, plastic housings, and metal brackets. Infusion sets required mechanical and solvent bonding of extruded PVC and silicone tubing, along with injection molded plastic connectors.
- Disposable products including a *needle-less injection port* for intravenous injections that is self-sealing, yet doesn't require a needle; *needle-stick protection devices* that attach to syringes or infusion sets; *sharps containers* made of puncture-resistant blow molded plastic with injection molded plastic traps and lids; *biohazard bags* from extruded and printed film.

## Education

**Rensselaer Polytechnic Institute**, Troy, New York

- Bachelor of Science, Biomedical Engineering, May 1992
- Dual Concentration in Biomechanics and Biomaterials with a minor in Biopsychology

**Sampson's Prosthetics** – Schenectady, New York

- Biomedical Engineering Intern, May 1991 – August 1991
- *Prosthetic Hand* – Custom-fitted device for golfing, features a combination of carbon fiber technology for enhanced spring action, stainless steel for strength, and plastic for low weight.

## Professional Development

- ISO Management Representative – ASQ, April 2005
- Operating Room Protocols – Education Design, April 2001
- Basic Project Management – University of New Hampshire, February 2001
- Internal Quality Auditing – Winfield Medical, August 1997
- Failure Modes and Effects Analysis – University of Wisconsin-Madison, February 1995
- FDA Design Control Requirements – United States Food & Drug Administration, May 1994

## References

- Available upon request and at <http://www.linkedin.com/in/derekbeaupre>