MICHAEL BOJANOWSKI

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PROFILE	Innovative engineering leader with 15 years of experience creating and launching products that delight customers and improve people's lives. Key qualifications include:

- Leader of high output R&D teams that quickly launch and validate life changing devices and products.
- Experience distilling user needs into design requirements and pairing with new technologies to create cutting edge medical products and processes.
- Project manager on multiple medical devices that include peripheral vascular, drug delivery, robotic electrosurgical instruments, cardiovascular implants, and advanced manufacturing processes.
- Extensive CAD experience in Solidworks and Creo (Pro/E) to take designs from a napkin sketch to a manufacturable 3D model with GD&T drawings.
- Implementation of design for manufacturing principals into products and procedures that reduced iterations and brought medical devices to market in 8 months.
- Creation of high functioning business systems for R&D, quality, IP and manufacturing areas.

EXPERIENCE

Partner   K1C Consulting-Denver, CO   Oct. 2019-Present

Working alongside our clients as a design partner in the medical device, semiconductor and IoT industries to quickly launch products that integrate new technologies to improve and save lives.

- Design of MRI frame for guided laser neurosurgery
- Brainstorming and user needs for cranial drain device for treating subdural and intraparenchymal Hematomas.
- Creation of new proposals, time tracking systems, accounting and marketing initiatives.

R&D Manager   TriSalus Life Sciences (Surefire Medical)-Westminster, CO   Sept. 2017-Oct. 2019

Responsible for building and leading an exceptional R&D team focused on improving outcomes in patients with liver and pancreatic cancer with state of the art drug delivery devices.

- Led R&D team in launching four different peripheral vascular devices with FDA 510K clearance and CE marking in less than 2 years.
- Collaborated directly with physicians, researchers, marketing and sales in development of new drug delivery devices that utilize the body's vascular system to overcome issues treating solid tumors.
- Selected and partnered with numerous vendors to supplement development and manufacturing capabilities.
- Member of leadership team responsible for direction of company, new product lines, financing and communication of R&D progress to board members and potential investors.

Senior R&D Engineer   TriSalus Life Sciences (Surefire Medical)-Westminster, CO   April 2017-Sept. 2017

Lead development of new microcatheter drug delivery systems and accessories that improved user experience and reduced manufacturing costs.

- Designed microcatheter (0.029" OD) with expandable nitinol valve that overcame weaknesses of poor flexibility and improved usability by incorporating input from voice of customer studies.
- Created design control and system engineering documents based on research and customer inputs.
- Established new systems for CAD design, design control, statistical methods and incorporated lean/six sigma tools such as Kaizen, DMAIC and KT Analysis.

Co-founder Lumed Science-Denver, CO Nov 2014-April 2019

Responsible for all aspects of a medical device startup, including engineering, marketing, manufacturing and sales to build a solid company foundation.

- Collaborated with dentists to address their needs and bring to market an FDA approved, patent pending dental lighting device in eight months.
- Designed and validated the world's first completely autoclavable intraoral light utilizing new battery and LED technology.
- Pitched to local and New York based investors to raise capital investment of $300K.
- Created quality management and business systems to meet FDA and ISO requirements.
- Established and maintained relationships with industry KOLs and large dental device distributors.

Founding Partner K1C Consulting-Denver, CO February 2016-April 2017

Consulted for medical device and semiconductor clients facing complex design and manufacturing challenges.

- Developed three new manufacturing processes for polymer vascular coils that took the design from the engineering bench to a validated manufacturing process at endovascular startup.
- Researched and designed a new method of handling microscopic semiconductor vertical probes that eliminated production waste and reduced process steps by 30% at MEMs manufacturer.
- Responsible for new proposals, time tracking systems, accounting and marketing.

Sr. Mechanical Engineer-R&D ConMed-Centennial, CO Oct 2011-Nov 2014

Designed and launched new electrosurgical devices used in laparoscopic and robotic surgery.

- Designed, validated, and supported 510(k) for first robotic argon beam coagulation system with two patents issued.
- Designed new adhesive bonding method to eliminate field failures on vessel sealing product line.
- Redesigned mechanism components using design for manufacturing principles to reduce production scrap and eliminate 100% inspection of parts.
- Project manager of five design projects with up to a $400K budget and five direct team members.

Manufacturing Engineer II ConMed-Centennial, CO Dec 2009-Oct 2011

Created and designed equipment and processes for new electrosurgery products.

- Designed laser surface preparation processes and equipment for high volume assembly.
- Project manager and designer of a $360K manufacturing line for semi-automated assembly.
- Led implementation and validation of nine different semi-automated processes.
- Lean Six Sigma leader and participant in reduction of production scrap from 30% to 5%.
- Author of numerous protocols and SOPs including design for manufacturability and statistical methods procedures.

Sr. Manufacturing Engineer Accellent- Arvada, CO May 2008-Dec 2009

Responsible for development of new cardiovascular products for high volume manufacturing.

- Led development of 30+ medical device manufacturing projects.
- Project manager and designer of equipment and processes for Class III IVC filter.
- Implemented new processes in stent manufacturing, laser cutting and welding of an IVC filter, precision metal stamping and resistance welding of guidewire assembly.
- Created device master records, validation plans and protocols, product risk assessments, work instructions and manufacturing documentation.

Mechanical Quote Engineer Flextronics-Broomfield, CO June 2007 - May 2008

Analyzed new customer RFQs and determined vertically integrated solutions for a variety of industries.

- Created and trained U.S. based team on automated system for quoting of complex electronic systems.
- Worked with internal and external suppliers to determine costs of machined components.
- Developed relationships with custom component manufacturers in the U.S. and abroad.

Project Engineer   Point Technologies-Boulder, CO & Costa Rica   July 2004 - April 2007

Responsible for design, and development of new medical and semiconductor products and manufacturing processes

- Project manager responsible for $3 million relocation of manufacturing facility to Costa Rica which was under budget and on time.
- Created and presented new product designs and processes to customers and company executives.
- Designed and implemented automated plating and electrochemical processing lines.

EDUCATION   **University of Colorado, Boulder, CO**   Bachelors of Science in Mechanical Engineering, 2004
President of Society of Venture Engineers, 2003-2004
Engineering Outreach Undergraduate Fellow, 2003-2004

TRAINING & CERTIFICATION   Design for Lean Sigma-2013
OR Protocol: Codes of Conduct and Safety- 2012
ANSYS Workbench Mechanical-2012
Geometric Dimensioning and Tolerancing- ASME Y14.5M-1994- 2004 & 2010
GMP Process Validation and Principals -2010
Lean Six Sigma - 2009
Training Skills for Managers- 2008

HONORS   National Science Foundation I-Corps Mentor for pre-SBIR technologies
Panelist at CU bioengineering retreat
Guest speaker at CU product introduction class on new product development

ACTIVITIES   Adventure racing and long distance relays
Mountain biking, skiing, and hiking
Home brewer