PROFESSIONAL SUMMARY

Versatile Engineering Executive with success in managing complex equipment projects from specification development to full scale manufacturing by assembling the necessary team, and executing the plan through energetic participation in the process.

- Breadth of experience in product development, operations, quality systems, service, and customer support for products ranging from patient life support devices to imaging/patient monitoring systems.
- Expert in Project Management, Estimation (project and device cost), Design Control, Risk Management, SOP's, Requirements Analysis, Risk Analysis, Fault Tree Analysis, FMECA, and Verification/Validation of complex medical device systems.
- True and tried methods and processes for robust designs leading to successful commercial introduction.
- Extensive experience working as project manager, technical lead, system architect and design engineer
- Experience working with several Design firms in Human Factors and ID leading to summative and formative studies that feed into the FDA and 60601-1 approval processes.
- Managed projects of up to 60 people and $6+ million annualized budget. Strong network and proven management of critical design element contractors and vendors.
- Versed in the business and operating procedures of startups to large sized companies. Experience in commercializing products that have a high research content. Experienced in interfacing with customers to understand their requirements.
- Robust processes for selecting Contract Manufacturer and established methods for successful Transfer to Manufacturing.
- Introduced products to manufacturing. Managed controlled builds. Implemented product support and service. Support customers. Successful deployment of products which involved 60601-1, I60601-1-2 (EMC/ESD), 62304 (software) UL/NRTL/CB certification, CE Marking, FDA, 510(k), GMP, AAMI and ISO.
- Domains – Patient Monitoring, Pulmonary, Anesthesia, X-ray Imaging, Satellite Camera, Baggage Inspection, Alcohol detection, THC detection.
- Products – Anesthesia Machine, Ventilators, Heart-Lung Bypass Machine, Venous Oxygen measurement, Cardiac Output, Pressure, Cornea cutter, Imaging Systems using x-rays, Camera.

PROFESSIONAL EXPERIENCE

Pivotal MEDesign LLC | Draper, Utah **Jan 22 - present**

CEO

Pivotal is a consulting firm providing design services in various domains with specialty in medical products covering human factors, industrial design, program management, software, electrical, mechanical, optics, x-ray, ultrasound, limited controlled builds and transfer to manufacturing. We also specialize in guiding and preparing software documents for FDA and CE submission.

Aproio LLC | Sunnyvale, California **May 17 – Dec 21**

Principal | Partner

Aproio is a consulting firm providing design services in various domains with specialty in medical products covering human factors, industrial design, program management, software, electrical, mechanical, optics, x-ray, ultrasound, limited controlled builds and transfer to manufacturing.

Triple Ring Technologies | Newark, California **May 06 – May 17**

Vice President Development and Operations, Executive Team

Triple Ring is a consulting firm providing design services in Medical, Commercial, Space and Security areas covering human factors, industrial design, program management, software, electrical, mechanical, optics, x-ray and limited manufacturing. Started when Triple Ring had a handful of people to today with 100+ employees and consultants. Hundreds of projects, 80 in a year and 40 at any given time, ranging from concept to transfer to manufacturing have been completed for over 200 clients. Have received IRB and 510(k) approvals, UL certs and CB certs.

Established most of the systems, tools, templates and processes, with emphasis on risk management, that are in existence today along with a very unique QMS System with ISO 13485 certification. The entire quality system is made up of a quality manual and 11 forms, run with an equivalent of two people, and have taken it through numerous registrar audits and client audits receiving occasional minor non-conformity. The QMS system is highly streamlined and can scale according to needs of any medical organization.

With the work I have done, Triple Rings Project Management methods are at par with the best in the industry and are key to client satisfaction and company profitability. They have evolved over the years and are setup for managing, tracking and efficiently executing projects in controlled or non-controlled environments, with teams of one to 60, scaling easily with the requirements of the project.

Responsible for managing and growing a large diverse R&D organization with hands on participation in proposal writing and running complex projects providing services in product and project strategies, scaling early stage concepts to high volume manufacturing, executive management, program management, project plans, resourcing, requirements, risk management, quality and regulatory.

BC Tech | Santa Cruz, California **Jun 04 – Apr 06**

Vice President of Product Development

BC Tech was a consulting and manufacturing organization providing services exclusively to the medical community in the areas of disposable, implant, electro-mechanical, software and electrical hardware engineering. Responsible for managing a large diverse R&D organization. Involved in business development, client interface, project resources, project management, requirements, risk analysis, systems engineering, verification and validation and process improvement. Managed up to 24 technical people and over 15 projects in parallel.

Consultancies **Sep 03 – May 04**

1. **NexRay Medical, a medical device manufacturer**
   - Validation lead for the NexRay Medical Scanning Beam Digital X-ray System encompassing Imaging Chain, Electromechanical Systems, UI, Storage/Retrieval System and DICOM. Created the validation process (Master Validation Plan), setup the validation team and wrote validation protocols.
   - Re-designed two user interfaces to work with touch screen and mouse. One for X-ray functionality and other for Image Storage and Retrieval.
   - Wrote System Requirement Specification, Software/User Interface Requirement Specification, SOP's for Design Control and Risk Management and performed Risk Analysis and Fault Tree Analysis.
2. **Radiant Medical, a medical device developer and manufacturer**
   - Advised Radiant Medical on design and manufacturing. Wrote the Manufacturing Plan.
3. **Data Spectrum, a Medical Consulting firm**
   - Advised Data Spectrum on development process. Wrote the Design Control SOP.

Cardiovention| Santa Clara, California **Nov 99 – Aug 03**

Director, Instrument Development **Mar 01 – Aug 03**

Consultant **Nov 99 – Feb 01**

Responsible for the equipment development for a start-up medical device firm developing novel extracorporeal circulatory support system for minimally invasive cardiovascular surgery. Product awarded Gold Medical Device Excellence Award for 2003 and 1st place in Design News, Excellence in Design Award. Used in over 2000 cases.

- Complete technical leadership of equipment program. Effectively managed the hiring, design, development, test, certification, manufacturing and service of a patient life support system. Design encompassed software, electrical and mechanical engineering and was outsourced across five organizations and several independent consultants. At its peak 30 people worked on all aspects of engineering including design, V&V, labeling, manuals etc.
- Identified and brought in key personnel to redesign enabling sensor development in early stages.
- Hands-on management: personally responsible for writing and or performing the Risk Analysis, FTA, FMECA, System Architecture, Specifications, User Specifications and System Verification and Validation.

- Aggressive execution: 20-month concept to clinic. CE mark was received 2 weeks after inspection. 510k (FDA's pre market approval process) in 8 months (similar systems have taken 12 -16 months). No software related questions from FDA. Second generation software, critical from user input was 510(k) approved one month after initial system approval.
- Operational oversight: selected/managed contract manufacturer, transferred product to manufacturing, wrote manufacturing processes and performed final testing: first units delivered in 3 months.
- Post market oversight: responsible for service and support. Wrote manuals and procedures and performed training, field upgrades and maintenance in US and Germany.
- Product designed for manufacturability and serviceability: Trained sales and clinical specialists to perform installation and preventive maintenance.

Realcontax | Mountain View, California **Jun 00– Feb 01**

Director, Quality Assurance

Responsible for Quality Assurance for an internet software company developing a novel system for real-time management of personal and professional contacts involving a J2EE Environment using Weblogic, Apache Server, XML and Oracle running on a combination of PC's and UNIX work stations.

- Selected test tools. Set up test cases using Segue's Silk Test and Silk Performer and 4Test language. Setup and used Silk Radar for defect tracking and CVS for code management.
- Set up relationships in India and Pakistan for transfer of testing.

Cardia Mariners / NexRay and NovaRay | Los Gatos, California **Oct 94 – Feb 00**

System and Verification Program Manager **1997 – 2000**

Director, Software Engineering **1994 – 1997**

Responsible for the equipment development for a start-up medical device firm developing a novel X-ray fluoroscopy imaging system including a 3-axis gantry.

- Developed the System Architecture, wrote requirements and test specifications and managed multidisciplinary group. Prepared schedules and budgets for all projects.
- Applications were developed for NT and embedded systems. Used Wind River OS. Eleven distributed systems, using the CAN bus communicated with each other.
- Interfaced with end users in hospitals to determine the user requirements.
- Provided key documents for 510(k) submission. Twice received FDA approval for the fluoroscopy instrument in a record 2 months.
- Setup process guidelines and development environment.
- Managed R&D computer systems. Designed and implemented the company network.

Abbott Labs / Hospira | Morgan Hill, California **Jun 83 – Oct 94**

Project Manager/ Line Manager/Technical Lead/Product Engineer

Responsible for projects related to invasive oximetry, pulse oximetry, cardiac output, infusion pumps and oxygen consumption for global market leader. Rapid acceleration of responsibilities within a large multidisciplinary organization.

- Served as manager, technical lead and system architect on $4 million project with 40 people.
- Designed hardware, wrote software using VRTX and PSOS.

- First candidate selected to participate in the Abbott Engineering Management Assessment program.
- Defined engineering processes, methodologies and environments consistent with FDA/GMP and ISO
- Established Software Quality Review board and Quarterly Software Day.

Ohmeda | Madison, Wisconsin **Nov 78- Jun 83**

Responsible for electronic and software design projects for anesthesia machine, anesthesia record keeper, ventilator, non-invasive blood pressure monitor and patient monitoring equipment for leading global company.

EDUCATION

MS Electrical Engineering, Northwestern University, Evanston, Illinois, 1978.
Awarded full scholarship.

BS Electrical Engineering, Northrop University, Inglewood, California, 1976, Magna Cum Laude.
Awarded scholarship.

Patents Extracorporeal blood handling system with automatic flow control and methods of use.
United States Patent Application 20040184953, 09/2004.