Robert C Weiller – Bob
2881 Torry Court, Carlsbad CA 92009
(925) 890-0817 ▪ Weiller.R.Engineer@gmail.com

SUMMARY: Innovative mechanical engineer with 5 years' experience developing market-disrupting FDA-approved medical devices. Proven ability to deliver cross-functional design solutions ensuring product success from concept to commercialization.

PROFESSIONAL EXPERIENCE

MASS CUSTOM – Carlsbad CA — May 2017 – Present

Freelance Design and Product Development

Launched design consulting business to test the viability of mass customization solutions delivered through additive manufacturing. Services included turnkey product design from concept to pilot manufacturing, design evaluation and refinement, full product documentation and mechanical drafting. Primary categories were premium mountain bike racing components (hand guards), and concepting consumer products.

QUIDEL CORPORATION – San Diego CA — March 2012 – April 2017

Product Development Engineer – Mar '15 to Apr '17

Designed, prototyped and optimized FDA approved microfluidic devices and lateral flow diagnostics compliant with ISO 13485 quality systems. Led projects to acquire new manufacturing equipment and upgrade existing production lines to facilitate high-volume production of new R/D products and solutions. Developed and implemented procedural verification algorithms in diagnostic instruments for use with new lateral flow products and platforms.

Principal Projects:

- Provisional Patent: US 20170059566A1; Designed and optimized bidirectional lateral flow device used to diagnose early and late stage Lyme disease. Platform doubled the independent test-analytes evaluated from a patient sample, with no increase in COGS.
- Conceived, implemented and validated multi-phase manufacturing method for high-volume production of bidirectional lateral flow devices. Validated production capacity greater than 1.0M units annually with yield-rates equal to or better than 97%.
- Designed injection-molded microfluidic component housings. Managed $500K+ mold subcontracts for mold and tooling acquisition. Drafted and executed technical mold validation protocols and reports. Authorized final mold approval and buy-off.
- Created Excel VBA script allowing R/D scientists to re-evaluate instrument data with adjusted cut-off and assay-method-parameters. Interface output signal results and search range 'windows' to simplify assay development troubleshooting.
- Lead-engineer on cross-functional RD team responsible for evaluation and procurement of new capital equipment required for projects in early phases of development.

Manufacturing Engineer – Mar '12 to Feb '15

Developed and implemented automation upgrades and retro-fits onto manufacturing equipment and assembly lines producing FDA approved products. Wrote and executed IQ, OQ, and PQ validation protocols for new production methods and equipment modifications as required by internal quality systems for ISO 13485 compliance. Wrote validation reports, manufacturing work instructions, equipment guidelines and in-process sampling plans to ensure product consistency.

Principal Projects:

- Converted manual hand-assembly procedures to automated production methods by implementing automatic fluid dispensing systems. Automation solution increased production-rates more than 7X's.
- Implemented and validated high-speed closed-loop cutting process for 'Sheeting' (cross-web-cut) of lateral flow devices around a registration feature. New capability enabled R/D project expansion into multi-directional lateral flow devices.
- Re-designed 'Slitting' (along-web-cut) module assembly improving process consistency and enabling automated handling of fabrics with low/variable tensile strengths. Eliminated tensile strength failure modes and lowered monthly scrap-rates by 5%.
- Engineering lead on cross-functional team responsible for qualifying and implementing product-packaging improvements. Built consensus on project objectives and created common vision between technical and non-technical team members.
- Implemented retro-fit to drying system on fluid-dispense equipment and integrated DAQ process logging. Retro-fit improved yield-rates by 28% and DAQ process logging provided data for subsequent 510(k) submissions.

LISI MEDICAL JEROPA – Escondido CA **March 2013 – December 2016**

Consultant for CNC Grinding of FDA-Approved, ISO 13485 Compliant Surgical Tools

Provided design input and manufacturing guidance for CNC grinding of FDA-approved surgical tools. Trained manufacturing and engineering teams in CNC programming, tool design and equipment setup. Developed and produced customized cutting tools for use with screw-machines and CNC milling centers.

Principal Projects:

- Improved production method for manufacturing surgical cutting tools used in Orthopedic and Fixation procedures. Implemented CNC grind routines for select cutting-tool features to eliminate re-work and improve tool performance.
- Programmed measurement algorithms for integrated touch-probe system of CNC grinding equipment (Rollomatic 628XS). Automated in-process QC evaluation of finished product, and implemented data-driven closed-loop process adjustments.

KYOCERA TYCOM – Costa Mesa CA **January 2009 – February 2012**

Mechanical Design Engineer

Led three-member design manufacturing team. Interfaced directly with customers and internal sales-teams to develop initial product requirements and timeline considerations. Reported to senior leadership team on technical design feasibility and manufacturability of new business opportunities. Traveled to OEMs to review new equipment capabilities and provided technical guidance to Kyocera Tycom's steering committee.

Principal Projects:

- Developed parametric programming solution for 6 Axis CNC grinding equipment. Trained machine technicians on program implementation. Solution reduced machine setup time by 66%.
- Developed parametric surfacing CAD models of drills and endmills with proEngineer. Models simulated CNC machine capabilities and simplified design transfer from development to production.
- Led a medical scalpel development project with a team of surgeons. Project utilized proprietary Kyocera zirconia ceramic materials and required new prototype grinding methods for complete the project.
- Led team for three months to create revolutionary drill/reamer tool. Engaged directly with customer throughout design and product testing. Project opened up a new market valued at $35M/yr.

PATENTS

Provisional Patents

US 20170059566A1; "Immunoassay test device with two fluid flow paths for detection and differentiation of two or more analytes"

Patent Applications Awaiting Provisional Status:

U.S. Application Number: 62/472,182. "Substrate with Channels for Controlled Fluid Flow"
U.S. Application Number: 62/464,331. "Whole Blood Separation"

RESEARCH AND INTERNSHIPS

SHILEY EYE INSTITUTE, UCSD MEDICAL CENTER – San Diego, CA **May 2008 – August 2008**

Research and Development Student: Conducted material property testing with human donor cadaver corneal tissue. Research focused on characterizing human corneas in-vivo and required development of prototype apparatus to simulate biological load conditions. Project findings improved FEA modeling of human corneas and supported efforts for FDA clearance of U/V Riboflavin therapy as a minimally invasive treatment for corneal disease.

KYOCERA AMERICA INCORPORATED – San Diego, CA **April 2007 – December 2008**

Engineering Intern: Conducted product improvement testing of components used in JSF (Joint Strike Fighter) radar modules. Executed DoE test procedures and utilized SEM analysis to identify optimal raw material specifications.

STRENGTHS AND PROFICIENCIES

Design: Iterative Design and Rapid-Prototyping ▪ Prioritized Risk Mitigation ▪ Design for Additive Manufacturing (SLA, SLS) ▪ Design for Manufacturing and Six Sigma ▪ Parametric CAD Modeling ▪ Design Control and Device History File Management ▪ Data-Driven Product Design ▪ Design for Injection Molding ▪ GD&T and Mechanical Drafting ▪ Technical Writing and Product Validation

Equipment: CNC Grinding, Machining and Programming ▪ Prototyping Fabrication Tools (Laser Cutter, SLA/SLS 3D-Printer, Fixture Design) ▪ Test and Inspection Equipment (Tensile-Force Gauge, Optical Comparators, CMM Machines)

Software: PTC Creo ▪ proE Wildfire ▪ AutoCAD ▪ SolidWorks ▪ DraftSight ▪ StatGraphics ▪ JMP ▪ Excel-VBA script development ▪ MS Project ▪ MS Office Suite (Word, Excel, Outlook, Powerpoint)

EDUCATION

UNIVERSITY OF CALIFORNIA AT SAN DIEGO **Fall 2004 – December 2008**
Bachelors of Science in Mechanical Engineering