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MASS CUSTOM – Carlsbad CA May 2017 – Current

Freelance Design and Product Development

Launched design consulting business focused on providing turn-key design engineering solutions for new products from concept inception through pilot manufacturing. Created customer value by offering in-house SLA 3D-printing, rapid-prototyping, design evaluation, product documentation and mechanical drafting to expedite product development cycles. Primary business sectors targeted include consumer home goods, high-end mountain bike racing components, and customizable performance eyewear.

Principal Projects:

- Designed and fabricated customizable Enduro racing hand guards for sponsored OEM factory team riders. Built parametric component and assembly model with PTC Creo to deliver unique product performance and equipment integration solutions tailored to each rider.
- Provide design guidance and proof-of-concept demonstrations highlighting emerging opportunities for product customization and consumer focused design flexibility. Presented proof-of-concept proposal in September '17 at largest annual bicycle industry tradeshow.

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. Lead 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 for diagnosis of 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 housing and components. 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 to 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 troubleshooting during assay development.
- Lead engineer on cross-functional RD team managing evaluation, selection and procurement of capital equipment required for projects in early development phases.

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 ensuring products met or exceeded package insert specifications.

Principal Projects:

- Conceived, integrated and validated encoder-triggered fluid dispense system additions onto manufacturing equipment then migrated product lines from manual hand-assembly line to automated manufacturing line. Upgrade increased production-rates by more than 7X.
- Implemented and validated high-speed closed-loop cutting process for 'Sheeting' (cross-web-cut) of lateral flow devices around a registration feature. New material handling capability contributed to R/D project expansion into multi-directional lateral flow devices.
- Re-designed and fabricated 'Slitting' (along-web-cut) module assembly improving process consistency and enabling automated handling of fabrics with low/variable tensile strengths. Eliminated all tensile strength failure modes, and lowered monthly scrap-rates by 5%.

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 guidance on manufacturing techniques for FDA-approved surgical tools such as bone-screw taps, bone drills and dental burrs. Trained manufacturing and engineering teams on CNC programming and in-process QC methods for medical grinding applications. Developed, optimized and produced customized cutting tools for specialized products built on screw-machines and CNC milling centers.

Principal Projects:

- Improved production method and sequence 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 for surgeons.

- Programmed measurement algorithms for touch-probe system on CNC grinding equipment. Algorithms provided automatic in-process QC evaluation of finished product, and returned data-sets for Closed-Loop process adjustments and occasional to re-grinding.
- Trained engineers and machine operators in cutting tool design, programming of CNC grinding equipment (Rollomatic 628XS), and mechanical machine-setup procedures.