

Youssef El Bassiouni

Mechanical Engineer | Quality & Manufacturing Engineering
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PROFESSIONAL SUMMARY

Mechanical Engineer with hands-on experience in medical device manufacturing and precision machining environments. Strong background in quality engineering, process validation, statistical analysis, and continuous improvement. Proven ability to lead root cause investigations, CAPA, and IQ/OQ/PQ activities while collaborating cross-functionally to improve product reliability, regulatory compliance, and manufacturing efficiency.

PROFESSIONAL EXPERIENCE

Quality Engineer – Applied Medical, CA (Jun 2025 – Present)

- Ensure compliance with FDA regulations, ISO 13485, and internal QMS requirements.
- Design, validate, and execute engineering test methods including Gage R&R; and MSA.
- Apply SPC, hypothesis testing, sample size determination, and confidence interval analysis.
- Develop and execute IQ, OQ, and PQ protocols for equipment and process validation.
- Lead NCIRs, root cause investigations, and CAPA activities.
- Collaborate with Design and Manufacturing on pFMEA and risk mitigation.
- Author technical reports documenting validation and investigation results.

Quality Assurance Lead – Velco Tool & Die, CA (Jun 2024 – Jun 2025)

- Supervised quality control operations across CNC machining processes.
- Managed engineering drawings, inspection records, and quality documentation.
- Oversaw MRB activities and drove corrective and preventive actions.
- Coordinated supplier rejections, internal audits, and calibration programs.
- Prepared and presented monthly MRB and quality performance reports.

Suspension System Lead – CSU Fullerton (Aug 2022 – May 2023)

- Led CAD design, manufacturing, assembly, and testing of a Rocker-Bogie suspension system.
- Performed iterative testing and design optimization to improve mechanical performance.

EDUCATION

B.S. Mechanical Engineering – California State University, Fullerton (2023)

TECHNICAL SKILLS

Quality & Manufacturing: CAPA, MRB, QMS, SPC, pFMEA, IQ/OQ/PQ, Root Cause Analysis

Engineering Tools: SolidWorks, AutoCAD, G-Code

Data & Analysis: Statistical Analysis, Test Method Validation, Technical Reporting

Software: Microsoft Office, Windows, macOS

Languages: Arabic (Native), English (Bilingual)