Luis E Gallardo

LEAD MECHANICAL ENGINEER & SYSTEM ARCHITECT

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EXPERTISE

Mechanical & Systems Engineering:
Precision Machine Design, System Architecture, Electromechanical Integration, Motion Control (Gantries, Actuators), Opto-Mechanical, Dx Fluorimeter Integration, Fluidics, Thermal Analysis (FEA), CFD, Tolerance Analysis, Plastic Part Design, GD&T.

Development & Development Regulations:
Medical Device (ISO 13485, FDA/EU MDR), Design Verification & Validation (V&V), Design for Manufacturability (DFM), Root Cause Analysis, Risk Management (FMEA).

Tools & Manufacturing: SolidWorks,
SOLIDWORKS Simulation, Mastercam, PDM/PLM, 3D Printing, CNC Programming, 3D Scanning, Injection Tooling, Sheet Metal, Machining.

EDUCATION & CERTIFICATIONS

BACHELOR'S DEGREE
Universidad Iberoamericana: Dual Major Mechanical & Electrical Engineering 2005.

PROFESSIONAL CERTIFICATE
UCSD Extended Studies: Professional Certificate, Engineering Management 2002.

CERTIFICATE
PALOMAR COLLAGE
MACHINING TECHNOLOGY CNC HAAS LATHE/MILL & MASTERCAM 2026

CERTIFICATE
Northwestern University Kellogg School of Management: Product Strategy 2023.

SUMMARY

Hands-on leader and product design expert specializing in the end-to-end development of complex electromechanical systems, molecular diagnostic (Dx) instruments, and Class II & III medical devices. Blends hands-on technical proficiency in advanced thermal analysis, rapid prototyping, and CNC machining with a proven track record of scaling R&D concepts into high-volume global manufacturing (NPI). A strategic driver of cross-functional teams, adept at navigating strict regulatory environments (ISO 13845 MED DEV QMS, IEC 60601-1 MED ELECT EQUIP) and modernizing engineering workflows to accelerate the delivery of high-reliability.

PROFESSIONAL EXPERIENCE

FOUNDER / DIRECTOR OF PRODUCT DESIGN | VANTAGE PRODUCT DEVELOPMENT| NOV 2022 – PRESENT

- Founded and scaled a mechanical engineering consulting firm specializing in medical device development, providing optimized new product development services and integrating in to client workflows.
- Architected system designs for automated diagnostic instruments, successfully integrating precision motion gantries, optomechanical assemblies, and thermal control modules.
- Led the development of architecture, and prototyping phases for a benchtop multiplexer used in a cutting-edge laser-based therapy system.
- Accelerated diagnostic (Dx) instrument programs by implementing critical design improvements and streamlining internal and external manufacturing workflows for consumables.
- Designed and developed high-volume Molecular Dx fluidic cartridges, leading the progression from early-stage rapid prototyping and bench testing through the optimization of complex injection-molded components.
- Modernized engineering infrastructure and operations, integrating SolidWorks CAD, advanced FEA/thermal analysis, 3D printing, PDM, cloud infrastructure, and CNC programming into a rapid development pipeline.
- Established full-scale internal business operations, managing IT network infrastructure, cybersecurity, CAD software licensing, strategic vendor partnerships, and daily firm management.

BECTON DICKINSON, MEDICATION MANAGEMENT SOLUTIONS | STAFF MECHANICAL ENGINEER | JUN 2021 – NOV 2022

- Drove reliability engineering for automated medication dispensing robotics, optimizing electromechanical actuators and sensor systems to ensure zero-downtime performance in high-availability hospital environments.
- Spearheaded the R&D to production transition, providing hands-on leadership for manufacturing preparation, product verification, and the scaling of prototypes into high-volume manufacturable assemblies.
- Led engineering integration for a corporate acquisition, evaluating the incoming automated pharmacy company's technical department, resolving legacy field issues, and aligning their processes with BD's stringent manufacturing standards.

PROFESSIONAL EXPERIENCE

PRINCIPAL MECHANICAL ENGINEER | PHILIPS RESPIRATORY CARE DIV. |JUN 2018 – JUN 2021

- Engineered critical mechanical subsystems for Class III life-support ventilators, directing the design of precision flow modulation systems, blower assemblies, and oxygen sensor integrations.
- Secured critical regulatory compliance (ISO 60601-1) by translating user needs into robust technical requirements, developing stringent life-testing protocols, and authoring formal Design Verification and Validation (V&V) reports.
- Directed injection molding certifications and material selection, ensuring uncompromising adherence to biocompatibility, regulatory, and mechanical performance standards.
- Partnered cross-functionally with Electrical and Software teams to successfully mitigate EMI/EMF susceptibility and validate structural integrity during critical-care drop testing.

LEAD MECHANICAL ENGINEER | ABBOTT LABORATORIES, RAPID DX DIVISION SEP 2016 – JUN 2018

- Led mechanical development for a flagship molecular diagnostic (PCR) instrument, taking full ownership of precision motion gantries and electromechanical actuator design.
- Orchestrated cross-functional alignment across Optical, Mechanical, and Firmware disciplines to ensure the high-precision integration of optical components within the motion control architecture.
- Accelerated system integration and phase-gate approvals through rapid prototyping of complex electromechanical modules and the rigorous execution of comprehensive test plans.

SR. MECHANICAL ENGINEER | PULSE ELECTRONICS MAY 2015 – SEP 2016

- Spearheaded the engineering of state-of-the-art magnetic integrated products, developing complex filtered electronic connectors, plastic housings, and precision metal shielding for EMI/EMF suppression.
- Managed global New Product Introduction (NPI) across manufacturing facilities in China, Taiwan, and Korea, optimizing high-volume plastic injection molding and stamping workflows.

PRIOR ENGINEERING LEADERSHIP

- **Sr. Product Development Engineer** | Toolbox Medical Innovations: Led precision fluidic consumable development and advanced laser fusion attachment methods for in vitro diagnostic (IVD) production environments.
- **Sr. Mechanical Engineer** | Nortek Security & Control: Accelerated NPI for health monitoring and motorized systems, achieving full production launch in international manufacturing facilities.
- **Sr. Mechanical Design Engineer** | Holdrite: Drove end-to-end product innovation for commercial systems, specializing in complex injection molding, stamping, and machining.
- **Sr. Mechanical Product Engineer** | RainBird Corp: Engineered robust indoor-outdoor electronic packaging and solenoid-activated valve systems optimized for high-volume manufacturing.

PUBLICATIONS & PATENTS

- Whitepaper: Thermal Architecture Optimization and Cooling Methodology Selection for a High-Power Electronic Enclosure
- US Patent 8,141,826 B1: Pipe Holding Bracket
- US Patent 8,317,142 B2: Shower Bracket
- US Patent 7,963,567 B2: Anti-Rotation Pipe Locator and Holder