Duane Edmonds

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STATEMENT

Experienced product development professional with more than 20 years of experience and 9 years dedicated to the medical device industry with a proven record of building relationships and helping diverse, cross-functional teams deliver innovative solutions. Solid background in business management, automation and robotics, design and development, verification and validation testing, risk management, data analysis and visualization, business intelligence and quality management, and global compliance.

EXPERIENCE

Ekso Bionics, Inc. — Richmond, California

3/2015 – 9/2019 Director, R&D and Compliance – Director, Medical Products and Systems

- Accountable for medical device product development, product lifecycle, design controls, design verification, product and process validation, risk management, and customer complaint handling activities and processes
- Functional manager for a strong, focused R&D team
- Program Manager for medical device product development
- Management Representative
- Responsible for product adherence to and consistency with the Quality Management System (QMS)
- Quality Council – Coordinated cross-company efforts to improve processes (effectiveness and efficiency), product quality and device reliability using data from post-market surveillance activities
- Developed and implemented company-wide risk management processes
- Directed the generation of Clinical Evaluation Reports (CERs) to support products in the European Union and authored a Clinical Evaluation standard operating procedure (SOP)
- Responsible for global adverse event monitoring and reporting
- Implemented a complaint handling system to enable data-driven improvement processes
- Performed expl. data analysis on complaints database and identified Quality performance metrics
- Managed department budget in a dynamic environment and provided consistent, detailed reporting on projections vs actuals, working closely with accounting and executive teams

6/2011 – 3/2015 Director, Software Engineering

- Led a strong team of Software & Controls Engineers and Embedded System Engineers responsible for design, development, and testing of software for all medical products
- Responsible for creating, maintaining, and communicating the company's medical device software development processes (e.g., coding standards, code reviews, testing and release processes)
- Developed standard processes for prod. development, risk management, and human subject testing
- Served on review board for product stage and phase gate reviews, accountable for approval of product safety and effectiveness, development stage progress, design outputs and documentation

7/2009 – 3/2012 Program Manager

EksoGT (Class II medical robotic exoskeleton)

- Led an exceptional development team in developing a first-of-kind battery-powered, bionic exoskeleton system to enable more efficient neurorehabilitation for people with lower-extremity weakness (e.g., spinal cord injury (SCI), stroke) – over 112 million steps taken globally (2019)
- Guided the project through a stage-gated product development process through requirements generation, planning, hazard analysis, risk assessment and mitigation, design, verification and validation through design transfer into full production
- Helped to coordinate the company's efforts to implement a global QMS to support the product release schedule for the launch of the company's first commercial and first medical product; authored and assisted with the development of several core SOPs for product lifecycle management (stage gate reviews, design control, software development, verification and validation, design transfer, risk management, post-market surveillance).
- Obtained device CE certification enabling access to the European Union market 3 months after U.S. release; developed and packaged Technical Documentation and supported review by Notified Body

Human Unified Load Carrier (HULC)

- Led successful $6M R&D project to develop and build rugged, hydraulic load-carriage (up to 200 lbs. at 3 mph) exoskeleton prototypes for field evaluation (e.g., VO_2 max metabolic costs) by military personnel at the Soldier Research, Development and Engineering Center in Natick, Massachusetts
- Coordinated development, procurement, and build efforts between engineering, procurement, and production teams in Orlando, Florida (Lockheed Martin) and Berkeley, California
- Reported detailed, monthly cost and performance progress using Earned Value Management (EVM)

10/2006 – 7/2009 **Agilent Technologies** (Velocity11) Santa Clara, California

Research & Development Hardware and Systems Engineer – Automation Solutions

- Responsible for helping to move a 5-axis direct-drive microplate handling robot (DDR) from early feasibility exploration through to production
- Designed and implemented multi-threaded embedded software for a multi-axis embedded motion controller including motion path generation, custom low-level diagnostic interface, scheduler, system monitor, and exception handling
- Developed a torque-based servo gripping routine for a single-axis embedded controller
- Responsible for servo control performance optimization and throughput
- Designed parameterized path planning and trajectory algorithm to coordinate motion on a 3-axis microplate handling system, including collision avoidance
- Developed custom, lightweight unit testing framework
- Designed rich, diagnostic command line interface that decreased overall system downtime

9/1999 – 10/2006 **Berkeley Process Control**, Inc. Richmond, California

Project Manager and Controls Engineer

- Project Manager for various semiconductor wafer handling and robotics development projects
  - Coordinated engineering, procurement, and production efforts
  - Guided hardware, software, and control system development
  - Tracked development effort and material costs
  - Negotiated equipment acceptance definitions
- Technical Lead for design and development of motion control system software
  - Designed control software for multi-axis coordinated motion, error handling, and user interfaces
  - Developed robust and automatic, machine-to-machine calibration (autocalibration) algorithms
  - Designed a custom and secure communication protocol with integrated data integrity validation
- Developed an algorithm that allows the exact specification and control to a non-radial, linear point-to-point path and motion profile for 200mm and 300mm wafer handling robotic arm
- Designed and developed a control scheme for a "pneumatic servo" system (accurate position control of an instrumented pneumatic cylinder) involving control hardware selection and software design

11/1997 – 8/1998 **Vibration Control and Electromagnetics Laboratory** College Station, Texas

Research Assistant – Advisor: Dr. Alan B. Palazzolo

- Developed fuzzy logic expert system control of active magnetic bearings in energy storage flywheels
- Designed 8-pole magnetic bearing stator laminate stack to optimize coil-winding efficiency
- Developed flexible algorithm for optimization of constrained magnetic bearing laminate stacks

STANDARDS FDA Title 21 CFR 820 (Quality System Regulation), Medical Device Directive 93/42/EEC (European Union), ISO 13485 (Quality Management Systems), IEC 62304 (Software Lifecycle Processes), ISO 14971 (Risk Management), IEC 60601 (Safety and Essential Performance), MEDDEV 2.7/1 (Clinical Evaluation)

COMPUTER Infor CSI, Microsoft Project, Omnify, pivot tables, C/C++, Python, Java, MATLAB, Octave, Git, Subversion, UNIX, GNU/Linux, Vim, Bash, R, regression modeling, embedded programming, regular expressions

EDUCATION **University of California**, Berkeley

8/1998 – 9/1999 Advanced Control Systems; Department of Mechanical Engineering
3.78 G.P.A.; Successfully passed Preliminary Examinations for doctoral degree candidacy

8/1993 – 7/1998 **Texas A&M University**, College Station
Bachelor of Science Degree; Department of Mechanical Engineering
Concentration: Dynamics and Control Systems
3.96 G.P.R. (major); 3.93 G.P.R. (overall); graduated *summa cum laude*