Duane Edmonds

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STATEMENT Experienced product development professional with more than 22 years of experience and a passion for building relationships and helping diverse, cross-functional teams deliver innovative solutions to improve patient outcomes. Solid background in business management and coaching, automation and robotics, collaborative robotics, design controls, verification and validation testing, risk management, data analysis and visualization, descriptive and predictive analytics, quality management and global compliance.

EXPERIENCE

SummerBio. Menlo Park, California

1/2022 – p. Vice President, Engineering

- Accountable for automation robotics, systems and controls development, cloud computing, Lab Information Management System (LIMS), and program management on a team committed to leadership in fast-turnaround, high-throughput, high-availability and high-quality SARS-CoV-2 (COVID-19) RT-PCR clinical laboratory tests
- Guiding engineering and program management departments to enhance capacity, capability, uptime, consistency and reliability of California's highest-volume, CLIA-certified PCR test provider

8/2021 – 1/2022 Director, Automation Engineering

- Increased overall capacity by 30% through the systematic identification and implementation of assay, process, and automation improvements
- Managed the development, implementation, and validation of a new variable-ratio sample pooling system

9/2020 – 7/2021 **Johnson & Johnson** Santa Clara, California

Program Manager, Robotics & Digital Solutions, Advanced Development

- Managed multiple cross-functional teams in the design and development of the Ottava surgical robotic system (robot-assisted surgery)
- Drove the development of system architecture and requirements, system hazard analysis risk management activities, simulation and data analysis, and support of procedure development and workspace analysis

3/2015 – 9/2019 **Ekso Bionics** Richmond, California

Director, R&D and Compliance – Director, Medical Products and Systems

- Accountable for medical device product development, product lifecycle processes, design controls, verification, product and process validation, risk management, and customer complaint handling activities and processes
- Program Manager for medical device product development
- 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
- Developed a complaint handling system and complaint database to enable data-driven process improvement
- Performed customer complaints data analysis and identified performance improvement opportunities
- Managed the R&D budget in a dynamic environment and provided consistent, detailed reporting on projections vs actuals, working intimately with accounting and executive teams
- U.S. Patent US10694948B2 – Methods of exoskeleton communication and control (published 2020-06-30)

6/2011 – 3/2015 Director, Software Engineering

- Led a strong team of Software & Controls Engineers and Embedded Systems 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 software 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

EksoNR (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 in more than 30 countries (2019)
- Guided the program stage-gated product development process through requirements generation, hazard analysis, risk assessment and mitigation, verification and validation, and design transfer into production
- Coordinated 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., VO2 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 – Agilent Automation Solutions

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

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

Project Manager and Controls Engineer

- Project Manager for various semiconductor wafer handling and robotics development projects
  - Guided hardware, software, electrical, control system development, procurement, and production
  - Tracked development effort and material costs
  - Negotiated equipment acceptance definitions
- Controls Systems 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 light, custom and secure communication protocol with integrated 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

Fuzzy Logic Expert System Control of Magnetic Bearings on High-Energy Energy Storage Flywheels

STANDARDS 21 CFR 820 (QSR), Medical Device Directive 93/42/EEC, ISO 13485 (QMS), IEC 62304 (Software Dev.), ISO 14971 (Risk), IEC 60601-1 (Safety/Essential Performance), MEDDEV 2.7/1 (Clinical Eval.), HIPAA

SKILLS Objectives & Key Results (OKRs), Design Controls, Agile, Scrum, Kanban, Jira, Confluence, Microsoft Project, OnePager, Linux, Git, embedded development, C/C++, Python, MATLAB, SQL, R, business data analysis

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; Dynamics and Control Systems
3.96 G.P.R. (major); 3.93 G.P.R. (overall); graduated *summa cum laude*