

Robert Duane Edmonds

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STATEMENT	Passionate leader and development professional with more than 23 years of experience and a passion for building relationships and helping diverse, cross-functional teams deliver innovative solutions. Solid background in business management and coaching, automation and advanced robotics, software development, interface design, 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 – 8/2022	Vice President of Engineering	<ul style="list-style-type: none">Accountable for automation and robotics engineering, cloud computing, Laboratory Information Management System (LIMS) development, and program management. Led a team committed to making a difference in fast-turnaround, high-availability, high-throughput COVID-19 qRT-PCR (quantitative reverse transcription PCR) clinical diagnosticsEstablished engineering and program management standards and processesGuided data-driven enhancements in assay efficiency, testing capacities, lab efficiency, system uptime, and reliability in California's highest-volume, CLIA-certified PCR laboratory (20 million COVID tests, 11-hour average turnaround, \$13 average price per test, peaked at 128,000 tests in 24 hours)	
8/2021 – 1/2022	Director of Automation Engineering	<ul style="list-style-type: none">Increased overall testing capacity by 30% through the systematic identification and implementation of assay, process, and automation improvementsManaged the development, implementation, verification, and assay validation of a variable-ratio, high-throughput automated sample pooling system	
	Johnson & Johnson	Santa Clara, California	
9/2020 – 7/2021	Program Manager, Robotics and Digital Solutions (RAD), Advanced Development	<ul style="list-style-type: none">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 (e.g., gastric bypass, ventral hernia, hysterectomy, partial nephrectomy) and workspace analysis	
	Ekso Bionics	Richmond, California	
3/2015 – 9/2019	Director of R&D and Compliance + Director of Medical Products and Systems	<ul style="list-style-type: none">Accountable for medical device product development, product lifecycle processes, design controls, verification, product and process validation, risk management, and customer complaint handling activities and processesProgram Manager for medical device product developmentResponsible 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 activitiesDeveloped and implemented company-wide risk management processesCoordinated the preparation 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 reportingDeveloped a complaint handling system and complaint database to enable data-driven analysis and enable process improvementsPerformed customer complaints data analysis and identified performance improvement opportunitiesManaged the R&D budget in a dynamic environment and provided consistent, detailed reporting on projections vs actuals, working intimately with accounting and executive teamsUS Patent US10694948B2 – Methods of exoskeleton communication and control (published 2020-06-30)	
6/2011 – 3/2015	Director of Software Engineering	<ul style="list-style-type: none">Led a strong team of Software, Controls, and Embedded Systems Engineers responsible for design, development, and testing of software for all medical productsResponsible 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 US 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)

Agilent Technologies (acquired VelocityII in 2008)

Santa Clara, California

10/2006 – 7/2009

R&D Hardware and Systems Engineer, Agilent Automation Solutions

- Responsible for the development of a 5-axis direct-drive robot (DDR) microplate-handler from initial concept feasibility exploration into full 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
- Built custom unit testing framework
- Developed rich, diagnostic command line interface that aided troubleshooting and decreased downtime

Berkeley Process Control

Richmond, California

9/1999 – 10/2006

Project Manager + Controls Engineer

- Project Manager for various semiconductor wafer handling and robotics development projects
 - Guided engineering 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 validated data integrity
- 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

Texas A&M Vibration Control and Electromagnetics Laboratory

College Station, Texas

11/1997 – 8/1998

Undergraduate 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 Development), ISO 14971 (Risk), IEC 60601-1 (Safety/Essential Performance), MEDDEV 2.7/1 (Clinical Evaluation), HIPAA

STRENGTHS	Objectives & Key Results (OKRs), medical device development (design controls, risk management, requirements management), program and project management (Microsoft Project, Smartsheet), agile software development (Kanban, Scrum, Jira, Test Driven Development), mechatronics, embedded systems (C, C++, Linux), data analysis and visualization (SQL, R, Python, Tidyverse), domain-specific language (DSL) development, graphical user interface (GUI) development (JavaScript/TypeScript, ReactJS, Figma, Material UI)	
INTERESTS	Open source software development, data analysis and modeling, business analytics, functional programming, algorithms, language-oriented programming, Scheme, Racket, Scala	
EDUCATION	University of California	Berkeley, California
8/1998 – 9/1999	Advanced Control Systems, Department of Mechanical Engineering 3.78 GPA, Successfully passed Preliminary Examinations for doctoral degree candidacy	
8/1993 – 7/1998	Texas A&M University	College Station, Texas
	Bachelor of Science Degree, Department of Mechanical Engineering – Dynamics and Control Systems 3.96 GPR (major), 3.93 GPR (overall), Graduated <i>summa cum laude</i>	