

Embedded Medical Consulting, LLC

Systems

Devices

Design & Process

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June, 2006 - Present

Embedded Medical Consulting, LLC

President/Chief Engineer

- See accompanying Major Projects List at the end of this resume.

January, 2003 – June, 2006

Tyco Healthcare/Mallinckrodt, Reading, Ohio

Manager, Software Engineering

- Major contributor in the conversion from structured C code to OOD, C++, Rhapsody, Doors/Synergy CM, PolySpace and CodeTEST, including the financial justification for the purchase of these tools.
- Provided significant direction and input on SDLC and ISO software procedures.
- Supervised up to eight direct reports including annual performance reviews. Hired four employees. Managed co-op program.

Project Leader

- Managed one of four Pilot Projects used to validate the new Tyco Healthcare internal-growth Product Development Process. Made several presentations to Mallinckrodt Vice Presidents.
- Responsible for managing entire project including development of business plan and project financials, schedule, requirements management, 510(k) submission, Risk Analysis, FMEA and design reviews.
- Managed the effort to collect customer requirements, including focus groups and market research, with significant travel to Paris, Berlin, Vienna, Houston, Philadelphia, Pittsburgh and Atlantic City.
- Successfully managed communications between all functional departments, especially improving the involvement of International Marketing, Service and Technical Publications in the product development process.
- Major participant in the design and implementation of the device's servo system, including brushless DC motor control with PMD servo processor, an algorithm to control pressure without a transducer, and many of the backup safety-related servo controls.
- Rhapsody, MQX, ColdFire, CodeWarrior with Kernel Awareness, PEG, Requisite Pro, PVCS, PolySpace and CodeTEST.

April, 1998 – January, 2003

Tyco Healthcare/Mallinckrodt/Liebel-Flarsheim, Reading, Ohio

Senior Electrical Engineer

- Designed, implemented, tested and maintained a number of Class II medical devices that inject contrast into patients for Angiographic, CT and MRI scanning procedures.
- Significant Requirements Management, Configuration Management and SDLC experience.
- One unique device operates in both Angio and CT mode. Its software was greatly enhanced with new features and bug fixes. Device contains three subsystems, each controlled by a Motorola 68332, and each backed-up by three PIC16C63/PIC16C73 micros. Elaborate communications carried out over RS422,

- RS232 and SPI busses. State machine architecture with RTX, written in C.
- Significant experience with brushed DC motor controls, AMC servo amplifiers and PMD servo controllers.
- Significant experience using custom-designed algorithm to control system pressure without a transducer.
- Very knowledgeable of real-time operating systems including interrupt, timer and task decomposition.
- RTOS experience dating back to Digital Equipment days and VMS.
- Requisite Pro, PVCS, CodeWarrior, Single-Step. RTX with Kernel Awareness, Multi-Edit, X-Ray.
- Provided additional senior-level software support on MRI device and hand-held CT device to get projects out on time.
- All devices sold internationally, meeting IEC 60601-1 standards and carry a CE Mark.

July, 1991 - April, 1998

Reliance Medical Products, Mason, Ohio

Electrical Project Engineer

- Solely responsible for all electrical and software project management, design, implementation, test and manufacturing support.
- Designed programmable controllers for multi-axis AC motor control of a variety of Class I patient examination chairs intended for the fields of optometry, ophthalmology and plastic surgery.
- Patented programmable software and membrane switch technology allows customers to tailor the operation of their chairs to fit their needs, virtually eliminating customer Specials and service calls.
- Designed programmable controllers to control a variety of ophthalmic instruments and room lighting for Class I ophthalmic instrument stands.
- Incandescent and halogen bulb dimmer controls using zero-crossing solid state relays, soft-start and auto-shut-off provided for longer bulb life, intensity memory feature provided.
- Patented programmable infra-red room light control for both incandescent and fluorescent lighting.
- Microchip and Motorola 8-bit micros, serial EEPROM: PIC16C65, PIC16C64, PIC16C62, PIC16C58, PIC16C57, 24LC01B.
- C, Microchip and Hi-TECH C-compilers, assembly.
- All designs initially met U.L. 544, and later, UL2601.

September, 1988 - July, 1991

University of Cincinnati College of Medicine, Cardiac Transplant

Research Engineer/Laboratory Coordinator

- Responsible for establishment and operation of Mechanical Assist Laboratory. Supervised student assistants.
- Projects included a transcutaneous transformer for transmission of electrical power to the inside of the body, and a permanent non-blood-contacting heart assist device.

June, 1981 - August, 1988

Digital Equipment Corporation, Blue Ash, Ohio.

Field Service Engineer III

- Account representative responsible for overall site management. Developed realistic, results-oriented action plans to ensure customer satisfaction.
- Maintained several major accounts including Cincinnati Bell, the University of Cincinnati, and several area hospitals. Developed excellent customer relations skills.
- Provided technical support for junior engineers. Chosen to speak to U.C. students regarding technical career development.

EDUCATION:

September, 1980 - June, 1987

University of Cincinnati

College of Applied Science, Cincinnati, Ohio

Bachelor of Science, Electrical Engineering Technology

- Graduated Summa cum Laude with Bachelor's Degree and a 3.76 grade point average.
- Member of Tau Alpha Pi National Honor Society.

SPECIAL ACTIVITIES:

GO Cincinnati (2006 – present)

Habitat for Humanity (New Orleans (2009); Cincinnati, 2010/2011)

GO Mamelodi, R.S.A. (2007)

Residential Rental Properties

Softball

Baseball

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MAJOR PROJECTS LIST

Medical Industry: Appointed Project Manager for the development of a major new product: created and supervised a seven+ member cross-functional product development team. Team achieved first major goal by successfully displaying product at a major show. Project is on schedule to meet most other goals.

Medical Industry: Patient Examination Chairs and Instrument Delivery Systems with IR Room Light Controls: several projects to redesign HW and SW per IEC 60601-1, cost savings, obsolete parts, new compiler and development tools, PIC32MX320/18F65K22/16F883/16F873A/16F877A, MPLAB XC32 Compiler, HI-TECH PICC™ Compiler, OOD, C, CE Marking, Full Project Management, Requirements Management, Trace and Verification.

Medical Industry: Medical Power Injector: design and implement HW and SW changes on device with three subsystems, changes required per obsolete FLASH and RTC IC and need for RoHS-compliant parts, project greatly expanded to include bug fixes to meet six-sigma quality requirements, 68332(3), PIC16C63/73(3), RTXC Quadros™, CodeWarrior®, SingleStep™, C. Full Project Management, Requirements Management, Trace and Verification. 30-piece Pilot Run proved changes were very successful in meeting quality goals.

Medical Industry: Major Engineering Procedures Project: develop and implement numerous engineering procedures per ISO 13485:2003 and FDA Part 21 CFR820:30 including Product Development, Software Development, Risk Management, Requirements Management, Design Verification & Validation, and Engineering Change, trained employees accordingly. Assist client with ISO Audits in 2006 and 2007.

Medical Industry: Major Documentation Project of an Instrument Delivery System: document and trace a full set of requirements including Marketing Specification, Product Requirements, high-level Software/Electrical/Mechanical Requirements, and low-level Software/Electrical/Mechanical Design Requirements in DOORS®, write Verification Protocol and Trace.

Blasting Industry: CE Marking Project for two Loggers and one Blasting Machine including Product Development Procedure, Software Development Procedure, Risk Analyses, and FMEA's, review Operations Manual, develop document numbering/filing system required for version control

Medical Industry: Powered Emergency Transport Cot: assist company with Product Development Procedure to include FDA-compliant Design Controls and Software Development documentation including: Software Development Procedure, Planning, Requirements & Traceability, and Verification Planning & Protocol.

Medical Industry: design and implement a Telelogic DOORS® Requirements Management System and Validate

Medical Industry: ENT Cabinet: electrical redesign to IEC-60601-1, discrete logic design, no software, Full Project Management, Requirements Management, Trace and Verification.

Medical Industry: Medical Power Injector: software conversion from HC11 to HC12, Assembly Language, Project Planning

Blasting Industry: Detonator Logging Machine: add new software features, PIC18F4610, Assembly, LCD, TOD IC, EEPROM, Testing

Medical Industry: ENT Light Source: electro-mechanical design of a high-output LED-based Light Source

Medical Industry: Medical Power Injector: design and implement a Flow Rate Meter, USB-based encoder input, Windows-based application, C#, allows for independent measurement of Flow Rate and Volume.

Trademark Notice: Many of the names listed above have been trademarked by Microchip Technologies; Motorola, Inc; Metrowerks Inc; Software Development System, Inc; Quadros Systems, Inc; Richard Barry; ARC International; Hi-Tech Software