President

AREAS OF EXPERTISE

• **Medical device development**	• **Verification and validation**
• **Requirements analysis**	• **Software design and code**
• **Process development**	• **Engineering management**

INTRODUCTION

Consultant is a medical device software engineer and manager with 30 years of experience in embedded software development, including: team leadership, requirements analysis, process development, subcontractor management, software design and code, verification and validation.

WORK EXPERIENCE

07/2011 – Present
Industry Consultant
Example projects include:
- Developed IQ/OQ/PQ protocols for production test fixtures used in AED assembly, supervised their execution, and wrote the validation reports.
- Project manager for FDA remediation of supplier test fixtures. Coordinated team of 8 engineers to document and qualify fixtures at supplier sites. Conducted informal supplier audits. Participated in IQ, PQ, and software tool validations.
- Developed unit and system tests for new breast pump. Wrote several requirements documents. Coordinated software V&V subcontractors.
- Revised software design and C++ code on the UVA blood pathogen product previously developed jointly with Baxter. Wrote test procedures, reviewed execution by testers, modified SRS in DOORS Next Generation, and analyzed defects.
- Developed Orion spacecraft simulation detailed requirements. Developed graphical simulation of spacecraft electronics in Python. Wrote automated test software in C++ and TCL. Migrated defense system requirements into DOORS. Modified system requirements in DOORS for Boeing 787.
- System engineer assigned to remediation and development of design controls.
- Wrote C software for a hospital patient warming device. Wrote specifications and supervised system testing for railroad safety equipment projects. Wrote product development process. Contributed to proposals and patent applications.
- Refactored C software for a lighting controller.
- Maintained C++ software for a touchscreen climate controller.
- Provided business development consulting and managed a software developer.
- Supervised renovation of facility (7000 sq. ft.) and contents.
- Continued involvement in project management and software maintenance.
- Managed all financial and administrative functions, including corporate taxes and payroll.
- Managed a number of projects, and participated as a technical contributor when FDA expertise was required.

- Handled the varied managerial tasks that come with running a small business, e.g. legal matters, shareholders, facilities, personnel, subcontractors, vendors, etc.

02/1998 – 03/2007
Industry Consultant
Example projects include:
- Participated in multiple projects for Transfusion Therapies, Clintec, and Fenwal divisions. Designed ClearQuest issues tracking process. Authored product definition and system requirements documents. Coordinated unit test process improvement group. Led a team of 9 pharmacists and testers to validate intravenous nutrition software. Internationalized C++ infusion pump software. Served on multiple software defect review boards. Spent a year as acting R&QE representative. Developed C++ software for several products. Software Lead for a team of 8 developers on UVA blood pathogen product. Wrote and executed numerous test plans. Developed and validated automated test tools.
- Performed requirements analysis, design, code review, and unit test activities on various projects.
- Developed engineering SOPs and wrote a number of project specifications. Developed C++ control software and GUI for a Class II medical device. Project manager for two other medical product development efforts, including verification testing.
- Redesigned, documented, developed, and integrated image transfer server processes in C++ on a QNX workstation for a nuclear imaging system.

05/1995 – 07/1997
Aksys, Ltd., Lincolnshire, IL
Principal Engineer
Duties:
- Created software development, QA, and V&V plans and standards. Authored two revisions of the PHD system requirements and the original draft of the instrument requirements. Moved to the quality department 1/97, as Sr. Principal Software Quality Engineer. Recruited and supervised three software test engineers; developed policies and procedures governing software quality and test; analyzed national and international regulations and formulated compliance approach.

10/1990 – 05/1995
Industry Consultant
Example projects include:
- Maintenance and lab testing of C fault management software.
- For the MRE (mid-range engine) engine control program: Designed classes using Booch object-oriented methodology; developed diesel engine control software in C++ for the pSOS RTOS; developed C++ unit test library with associated UNIX makefiles and scripts.
- Devised test vectors to validate aircraft engine control algorithms.

- Designed algorithms for artillery aimpoint and effects calculation. Developed C software to convert TACFIRE V10 messages from variable to fixed format; also programmed data entry menus and databases. Edited first draft of Software Functional Description document.
- For the MTACCS (Marine Corps Tactical Command and Control System) program, FDS-1 release: Helped design the class hierarchy using CRC object-oriented methodology. Developed a portion of the classes in C++.

06/1988 – 09/1990
Telos Federal Systems, Ft. Wayne, IN
<u>Associate</u>
Duties:
- Wrote two proposals and supported software engineering improvement program.
- Redesigned and extended tracking software in Ada.
- Developed simulation scenario generator.
- Integrated the tracking and scenario software to form a complete electronic warfare simulation testbed.

06/1986 – 06/1988
Software Consulting Specialists, Ft. Wayne, IN
<u>Associate</u>
Duties:
- Developed a prototype CASE tool for object-oriented design, taught an in-house Ada course, and co-authored three SBIR proposals.
- Designed and programmed a menu-driven operator interface in Ada.
- Created an Ada- callable math library in 8087 assembler.
- Developed tracking software for electronic warfare.

EDUCATION

1990
Saint Francis College, Fort Wayne, IN
<u>Master of Business Administration</u>: Management concentration

1986
Rose-Hulman Institute of Technology, Terre Haute, IN
<u>Bachelor of Science</u>: Economics & Computer Science (double major)