

RKT Technologies, Inc.

a New Hampshire corporation

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NOTE: For detailed information on rates, availability, and business relationships with clients and agencies, please visit the Web at <http://www.rkt-tech.com>.

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CURRENT AVAILABILITY AND OBJECTIVE (7/23/2013)

Currently available for contract software development engagements in any of the following areas:

- Medical Device software development (senior/principal software developer/architect, software team leader);
- Medical Device software regulatory consultant (verify that client's software development policies and procedures conform to the FDA Quality System regulation; verify that software development and validation conforms to FDA rules and guidances);
- Medical Device software development using Agile (preferably Scrum) development processes where I can trade my extensive medical device and iterative software development experience for some formal Scrum experience;
- Software development in another regulated industry, e.g. aviation, transportation, military.
- Software development in non-regulated industries where my regulated-industry experience will directly contribute to robust and reliable software.

SUMMARY OF EXPERIENCE

- ***SPECIALTIES:***
 - Software development for medical devices and other regulated industries.
 - Real time embedded systems software design and development using commercial and custom multitasking real time operating systems
 - Independent verification and validation of software development processes.
- DoD Secret Security Clearance, last current in October of 1998
- 42 years' experience in the electronics industry.
36 years' experience in embedded systems hardware and software design.
32 years' experience as an independent consultant.

- High Level Languages: C, C++, on a variety of microcontrollers and microcomputers small and large. Microsoft Visual C++ / Visual Studio on Windows 2000 and XP. VBScript on SCADA systems.
- Assembly Languages on a wide range of microcontrollers
- Methodologies: Structured Analysis and Design (SASD); Object Oriented Analysis, Design, and Programming (OOA, OOD, OOP), Unified Modeling Language (UML)
- Target systems: ARM series, 80x86, 68xxx, Z80 and variants, 8051 and variants, PIC series, Linux, PC, PowerPC
- Operating Systems and Platforms: MicroC/OS-II, FreeRTOS, VxWorks / Tornado, MS Windows 2000 / XP (Microsoft Visual C++ / Visual Studio), Unix, Solaris, Linux
- Standards: FDA Quality System Regulation (21CFR820) , AAMI TIR45:2012, IEEE SE; DOD STD 2167A; RTCA/DO-178A/B; MIL STD 498, ISO 9001, IEEE/EIA 12207, ANSI/AAMI SW-68, ISO 14971, ISO 13485, AAMI TIR45:2012
- Verification and Validation - Experience as an Independent Verification and Validation Reviewer for software developed in regulated industries such as medical devices, with responsibilities including:
 - Verification and Validation of software
 - Serving as moderator and independent reviewer at design reviews
 - Evaluating and recommending changes and additions to software policy documents.
- Networking: Voice over IP (VoIP), TCP/IP, SCADA
- Product Development: Experienced in designing, implementing, and documenting software for medical devices requiring approval under the FDA Quality System regulation; avionics devices requiring FAA TSO approval; and military devices developed using IEEE/EIA 12207 and IEEE Software Engineering Standards as guidelines.

DETAILS OF EXPERIENCE

RKT Engineering, Inc. / RKT Technologies, Inc., Londonderry, NH
September 1977 to Present

In 35 years as Owner and President of RKT Engineering, Inc. (a Massachusetts corporation) and its successor corporation RKT Technologies, Inc. (a New Hampshire corporation), I have provided hardware and software design consulting and technical services to a number of companies in the Greater Boston and Southern New Hampshire area and elsewhere in the Eastern and Central USA.

Most Recent Projects

(2012 – 2013) – Designed and provisioned a Private Branch Exchange (PBX) for the US Air Force Auxiliary / Civil Air Patrol, a large national public-service search-and-rescue organization; designing and implementing hardware and software modules that connect the PBX directly to HF and VHF radios to allow direct communication with aircraft and ground teams in the field.

(2009 - 2012) – Developed a user interface and served as a software and regulatory consultant and software team leader for a class 3 medical device that delivers RF energy to the patient. Recruited, and provided leadership and supervision to, a team of 3 senior software engineers and 1 senior software quality assurance engineer. Software development was in C++ for MicroC/OS-II, and design used Unified Modeling Language on Sparx Systems Enterprise Architect. Device made it through FDA PMA Supplement approval in half the normal time.

(2008 - 2009) – Implemented a master-slave communications system on an infusion pump for veterinary use; software development in C for FreeRTOS. Provided regulatory consulting services to that client as they evaluated whether to certify the infusion pump for human use.

(2008) – Served as software quality assurance and regulatory consultant for a collaboration among a number of university research centers to develop an artificial pancreas for Type 2 diabetes sufferers.

Following are descriptions of my other projects, categorized by industry segment and highlighted in approximate reverse chronological order within each category:

Aviation / Marine / Maritime

- (2007 – 2008) – Performed a full requirements analysis and assisted in the top-level design for a digital communications system for Boeing 757 airliners and freighters being developed to FAA DO-178B standards, using C++ on MicroC/OS-II operating system. Client retained my services in doing the requirements analysis while they searched for a qualified permanent employee to continue the development.
- (2004 – 2005) – Designed and implemented the software for a feasibility prototype of a SCADA (Supervisory Control And Data Acquisition) system to monitor and control the operation of appliances in a shipboard galley for the US Navy. System was implemented using the Iconics Genesis32 SCADA platform and Visual Basic code. Also served as advisor for system- and hardware- related issues.
- (2001 – 2003) Software architect and key software developer for a navigational system for installation on oceangoing ships. Also served as mentor to other software engineers in the areas of C++, VxWorks, Tornado IDE, and Unified Modeling Language (UML).

- System provides a central redundant fault-tolerant computer that takes inputs from Inertial Navigation Systems (INS), Global Positioning Systems (GPS), depth sounder, magnetic compass, speed-through-water sensor, and redundant weather sensors, and outputs information to shipboard displays and other shipboard systems.
- Central computer provides services including Dead Reckoning capability so that the ship's position could be estimated in case of failure of the INS and GPS.
- Central computer consists of two PowerPC processors in a CompactPCI chassis.
- Designed central computer software using UML on Rhapsody Modeler with implementation in C++ on VxWorks 5.4 and Tornado 2.1.
- Designed and implemented a graphical display on Linux / Xfree86 using a TCP/IP network connection to display the real-time value of variables in the VxWorks target system software, for use in debugging and verification.
- Provided code modification and code review services and assisted in testing and debugging of the Graphical User Interface (GUI) for this system, which was implemented on a ruggedized PC using Microsoft Visual C++.

Telecommunications

In addition to projects described under "Most Recent Projects":

- (2005 - 2006) – Served as senior software engineer for a multi-device, multi-node Voice over IP communications network implemented on embedded Linux in C++.
- (2000 – 2001) Key software developer for a Voice Over IP (VoIP) test system for use in testing and validating VoIP gateways.
 - Platform was PowerPC on CompactPCI and VxWorks with development under Tornado 2 in C and C++ using Object Oriented Analysis, Design, and Programming (OOA/D/P) including UML and Use Cases.
 - Designed and implemented some simulation and test software on Linux / Xfree86.
 - Served as mentor and instructor to other software engineers in the areas of VxWorks and real time programming.
 - Served for a time as acting Principal Software Engineer / Technical Lead for this project while the client went about the process of hiring someone on a permanent basis to assume that role.

Medical Devices

In addition to projects described under “Most Recent Projects”:

- (2003 – 2004) Served as Principal Software QA Engineer for a new type of endoscope. Duties included making sure that the software development was in full conformance to the FDA Quality System Regulation / 21 CFR 820, ANSI / AAMI SW-68, ISO 14971, 21 CFR 11, and each of the stakeholders’ internal Standard Operating Procedures. Also served for a time as acting Software Project Engineer for the project, with duties that included managing the activities of a group of off-site software developers, and assisting in defining the job description and qualifying a permanent employee to take over that role.

Military

- (2004) – Hired to perform a major system upgrade to a Night Targeting System Upgrade Kit for helicopter flight simulators that I had developed in 1995-1997. Original project was developed to run across three separate processors, with two of the three processors executing single tasks. This year’s upgrade involved moving to a new, faster CPU with a single processor. This required an extensive restructuring of the system software to run in multiple tasks (a total of 19 prioritized tasks) on VxWorks 5.5.1 using Tornado 2.2.1 as IDE.

As part of this project, I designed and wrote a multi-tasking data simulator on Microsoft Visual Studio / Visual C++, to send and receive formatted data concurrently across 6 serial ports to the target system. This tool involved creating several dialog boxes to configure the outgoing messages and specify the expected configuration of the incoming messages.

Industrial

- (2007 – 2008) – Served as independent software quality assurance analyst for a new type of ice cream vending machine; system used a Linux-based multi-tasking software package driving custom hardware to dispense individual servings of ice cream of the customer’s choice of flavors and mix-ins.
- (2007) Performed a major software rehabilitation and refactoring project on a complex machine vision system whose software documentation has become obsolete, and the C++ software has become unmaintainable.

Other (Prior to 2000)

Following is a brief summary of projects completed prior to the year 2000. Details on each of these projects are available on request.

- (1999) Cardiac medical device; software modifications, PIC assembly language
- (1999) Medical device for ophthalmic surgery; specification; IV&V; regulatory consulting
- (1999) Avionics; software test tool modifications; Visual C++
- (1998 - 1999) Medical device; software development / refactoring / regulatory consulting; C; personnel search consulting
- (1997 – 1998) Medical device; software QA / IV&V; C++
- (1997) Military; software QA; system and software specifications and design
- (1997) Avionics; software specification
- (1997) Government (NWS); user interface design; C
- (1996 – 1997) Medical device; software IV&V and defect repair; C
- (1995 – 1997, 1998 - 1999) Military; software development; C / VxWorks
- (1994) Telecom switching; software development; C and 80x86 assembler
- (1994) Avionics; software QC / testing
- (1994) Medical device; independent software design/documentation review
- (1993 – 1994) Medical device; software development; Borland C
- (1992) Medical device; hardware and software development; C
- (1991) Industrial machine; hardware and software development; user interface

From 1977 to 1991, completed numerous system, hardware, and software development projects in areas such as industrial controllers and voice / data security systems, using C and assembly language on a variety of microcontrollers. Details are available on request.

REFERENCES: Available on request.