

# Donald J. Shave

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**Objective** – secure a position in a dynamic organization that is seeking a person with a remarkable record of compliance-driven program/process/people leadership, software applications, systems & software V&V; medical imaging device development and solutions for computer security problems and new web designs.

**Experience/Skills Summary** – professional engineer in medical device development, experienced in product development, management and regulatory compliance. Expertise with C/C++, VB++/VBA, Java (Eclipse, ANT), Windows- and Java-script, Excel-based tools/apps; Microsoft Office suite; GE's eNPI, PRD, eLibrary & others, Oracle/Cube, PROMIS/APF; 21CFR/ISO13485; Six-Sigma & Lean process improvement techniques. Personable, credible, experienced and passionate; attention to detail; willingness to engage challenging assignments; definition of new processes, tools & software to address key business problems.

## **President & CEO, Creative Logic Software, LLC**

*April 2009 – Present*

- Consulting services utilizing compliant processes are provided for leadership of projects, programs & people; for software expertise in data-mining networked, local or paper data; for validation of systems & SW with an extensive knowledge base; and for medical imaging device development.
- Solutions to PC computer security problems and for new web designs are also provided.

## **GE Healthcare, Waukesha, WI**

### **Six-Sigma & Software Engineer, Global Imaging Subsystems**

*September 2007 – April 2009*

- Designed/deployed an automated tool to display feedback to technicians operating the semiconductor fab (clean room) at a California supplier – improved overall production yield of these \$100k ICV parts.
- Other key roles included development of a CAN bus interface to a collimation device for the detector Tester system to address an upcoming obsolescence issue. Used a commercial USB-based IXXAT driver with C++ on Windows platforms. Fully compliant to 21CFR with formal, controlled documentation.

### **Lead Quality Engineer, CT & PET Business**

*February 2001 – September 2007*

- Led multiple cross-functional global teams to successfully pass many Quality Management System audits (FDA, GMed, UL, ISO & self-audits). Drove implementation of process improvements globally to address resolution of numerous non-conformance & CAPA findings that were tracked/closed.

### **Manager of Engineering Staff, CT Business**

*January 1999 – February 2001*

- Senior staff role, leading global process development/implementation of business-critical operational activities; responsibilities included prediction, control and management of budget, headcount, program planning, facilities and others. Managed >\$40M global budget to quarterly/year-end targets. Created automated tools (Excel-based VBA) to facilitate staff leaders with headcount, budget and other targets.

### **Program & Project Management, Global X-Ray**

*July 1993 – January 1999*

- Global program leader for development & introduction of a Tilting C-arm X-ray product; a 3-year project with a \$7MM+ development budget and a cross-functional global program team of over 120 people.
- Completely revised system installation approach, saving time & money and improving quality to the customer; work was recognized with a substantial management award and GE stock options.
- Multiple other roles were held in this timeframe and in earlier roles with GE.

## **Education**

Enrolled in a BSCS program at Carroll University, Waukesha; 2011 target, GPA at 3.4 of 4.0

Graduated with high honors from the Computer Data Institute, London, England

Graduated with high honors from the British Army Apprentices College, Harrogate, England

*Additional information is available on request*

## Detailed Work History for Don Shave

DATES	Component/Location, Manager	Position / Role Accomplishments
Apr, 2009 to date	<b>Creative Logic Software, LLC</b> Hartland, WI, USA Self-employed	<b>President &amp; CEO</b> - Consulting services are provided by my business using processes that ensure compliance to all required regulatory agencies for leadership of projects, programs & people; for software expertise in data-mining networked, local or paper data; for verification and validation (V&V) of systems & software with an extensive knowledge base; and for medical imaging device development. - Solutions to PC computer security problems and for new web designs are also provided.
Mar, 2008 Apr, 2009	<b>GE Healthcare, Global Imaging Subsystems, X-Ray Detectors</b> HQ, Waukesha, WI Gil Wu	<b>XRD Tester System Software Engineer</b> - Design and deploy critical changes to key functions in the tester system required for compliance of manufactured XRD digital panels.  <u>Accomplishments</u> - Finalized the incomplete compliance remediation tasks from 2007 for an engineering tester system tool which is in daily use by the Tester system team. This tool provides a GUI access to all system functions for development work, and is built with Microsoft Visual Basic 6, running on the Win2K platform. As I developed the verification plan for the tool, I found and addressed multiple missed development issues with the GUI, meeting compliance to 21CFR with controlled formal documentation of the system requirements, the software design and the verification plan;  - Created an additional CAN bus interface for the tester system collimator to address an upcoming obsolescence issue with the current NSI board interface; this used a commercial USB-based IXXAT driver. The interface was built using Microsoft Visual C++ 6 on a Windows 2000 platform, meeting compliance in the same way as described above. Despite significant obstacles presented by the team when I uncovered a critical compatibility issue during the development, I persisted with my approach, resolving this with support from IXXAT; compliance with 21CFR was achieved in the same way as above. The release of this tool has been deployed with the standard configuration package for a new tester PC and is in use today.  - Developed the initial phase of a replacement imaging tool for display of acquired X-Ray digital images, based on the ImageJ platform, an established industry standard open-source tool that was developed at the National Institutes of Health for imaging in general. The tool was built in Java, using the Eclipse SDK on a Windows XP platform,  ClearCase is the SCM. The business justification for the project was based on a need to eliminate annual licensing costs for the existing IDL platform;  I met both cost and a difficult schedule demand with this task. As this project was part of an assessment, work is needed to add features for product release.

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Sep, 2007 Mar, 2008	<b>GE Healthcare, Global Imaging Subsystems, X-Ray Detectors</b> HQ, Waukesha, WI Kay Schmidt PKI, Santa Clara, CA John O'Donnell	<b>XRD Yield Green Belt</b> - Drive reductions in manufacturing yield issues at GE's key digital detector panel supplier.  <u>Accomplishments</u> - Designed a fully automated multiple PC platform tool to display effectiveness data (OEE) to the technicians who operated the semiconductor FAB. The displays, mounted near each LITHO station in the FAB, provided the operators with sequential displays of vertical bar graphs showing uptime, planned downtime and unexpected conditions at each station and shift for the prior 24 hours and the prior 13 weeks.  Full automation for this tool was achieved using a master/slave approach, with a command directive file on a common server that is written by the master station; the tool is initiated, terminated and controlled by Windows scheduled tasks at each station.  The tool is structured around a single Excel spreadsheet with embedded VBA code that resides on the common server; each station has a configuration file, defining the master station, what is to be displayed and other settings.  The intent and business justification for this project was to provide continuous feedback to the operators of both short- and long-term results of their daily activities, and is in use today.
Dec, 2006 Sep, 2007	<b>GE Healthcare, Central QA</b> HQ, Waukesha, WI Levi McKelphin	<b>QA Manager (acting)</b> - Managed compliance tasks for engineering programs <u>Accomplishments</u> - QMS deployment and enforcement for MICT engineering
Jun, 2004 Dec, 2006	<b>GE Healthcare, Global FCT &amp; Global MICT Engineering</b> HQ, Waukesha, WI Karen Fleming Gary Strong	<b>Engineering Quality Leader</b> - Define & deploy key processes, training & coaching around key engineering aspects of the QMS <u>Accomplishments</u> - Focus on compliance for CT & PET Engineering
Jan, 2004 Jun, 2004	<b>GE Medical Systems, Global FCT Engineering</b> HQ, Waukesha, WI Mike Fritts	<b>Manager, FCT IBQ Engineering</b> - Managed consolidated IB teams for CT, PET & Nuc in Mke as well as US & international folks - Supported compliance & other areas <u>Accomplishments</u> - Managed the FCT IB Quality team with incessant, increasing issues around FCT's IB of >35,000 systems - Continued with an also-increasing load of back-office support for compliance ("FDA's coming"), training, facilities, & staff
Jun, 2003 Jan, 2004	<b>GE Medical Systems, Global CT Engineering</b> HQ, Waukesha, WI Bob Armstrong	<b>Global Manager, CT Customer Centricity</b> - Addressed Compliance across the board (on demand) - Grappled with the growing burden from CSOs, PQRs & PSRs by hiring some folks & working the process - Allowed both Validation & 6-Sigma to continue on their current track <u>Accomplishments</u> - Managed a team with four key areas: IB Quality, Validation, 6 Sigma & Compliance - Continued back-office support for staff

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Feb, 2001 Jun, 2003	<b>GE Medical Systems, Global CT Engineering</b> HQ, New Berlin & Waukesha, Wi Bob Armstrong	<b>Manager, CT Quality System</b> - Staff role leading quality-oriented process development & implementation for business-critical operational & administrative responsibilities including prediction, control and management of the budget, headcount, program planning, facilities and other areas - GTO-wide eEng role, including work on eNPI & ePRD - Deployed processes & tools for financial control as well as web-based reports for heads, materials, T&L expenses and others - Continued delivery of these key operating mechanisms and tools despite significant personal medical complexities <u>Accomplishments</u> - Managed all aspects of the Quality System for CT. Extending role to reach global areas. - Managed annual Base-cost Budget to quarterly & Y-E Global targets: 2001 annual budget \$48MM. - Deployed financial tracking processes & tools to facilitate overall Engineering budget predictability and allow control. - Managed WWPP, OP & other product planning tools/processes. - Developed new program processes/process improvements and tools (web and non-web) to support them.
Oct, 2000 Feb, 2001	<b>GE Medical Systems, Global CT Engineering</b> HQ, New Berlin, Wisconsin Bob Armstrong	<b>Manager, CT eEngineering</b> - Staff role leading process development and implementation for business-critical operational & administrative responsibilities including prediction, control & management of budget, headcount, program planning, facilities & others - GTO-wide eEng role defined including work on eNPI, ePRD, and ePDM (Legacy Apps). - Deployed processes & tools for financial control & web-based reports for heads, materials, T&L expenses and others. - Continued delivery of these key operating mechanisms and tools despite significant personal medical complexities. <u>Accomplishments</u> - Managed annual Base-cost Budget to quarterly & Y-E Global targets. 2000 \$41MM & 2001 \$48MM. - Deployed financial tracking processes & tools to facilitate overall Engineering budget predictability and allow control. - Managed WWPP, OP & other product planning tools/processes. - Developed new program processes/process improvements and tools (web and non-web) to support them.
Jan, 1999 Oct, 2000	<b>GE Medical Systems, Global CT Engineering</b> HQ, New Berlin, Wisconsin John Chiminski Bob Armstrong	<b>Manager, CT Product Planning/NPI Process</b> - Staff role, leading process development and implementation for business-critical operational & administrative responsibilities. <u>Accomplishments</u> - Deployed processes & tools for financial control as well as web-based reports for heads, materials, T&L expenses and others. - Managed annual Base-cost Budget to quarterly & Y-E targets. 1999 \$23MM (Mke), 2000 \$41MM Globally & 2001 \$48MM. - Deployed financial tracking processes & tools to facilitate overall Engineering budget predictability and allow control. - Managed WWPP, OP & other product planning tools/processes. - Developed new program processes/process improvements and tools (web and non-web) to support them. - Continued delivery of these key operating mechanisms and tools despite significant personal medical complexities.

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Oct, 1998 Jan, 1999	<b>GE Medical Systems, Global X-Ray Systems Engineering</b> HQ, Waukesha, Wisconsin Carol Murawski Jean-Yves DiBartolomeo (dotted line) Jim Bland (dotted line) Dave Mliner (dotted line)	<b>Emperor Global Program Lead</b> - Global Program Manager role for fast-track NPI with development team in Beijing, China. Global RAD value-tier offering in \$200MM market; GEMS did not compete in this market segment. - Delivered milestone MR/MS (announcement) and M3 (pilots) Showed new product at RSNA. - Team recognized for Competitiveness with ALL-STAR award. - Personal leadership recognized with Management Award. <u>Accomplishments</u> - Provided program leadership to fast-track global team in 3 poles, lead service deliverables, ensure issues reach rapid closure, organize and deliver milestones to plan.
Apr, 1998 Dec, 1998	<b>GE Medical Systems, Global X-Ray Systems Engineering</b> HQ, Waukesha, Wisconsin Carol Murawski Sonia Dubreuil (dotted line) Fabrice Rousseau (dotted line)	<b>Apollo Feasibility Sys Service Integration Lead</b> - Small team LPI role for Apollo feasibility sites in US, providing organization and leadership to ensure uptime & Customer sat. - Developed communication processes, WWW plans and scope of new organization (AACP). <u>Accomplishments</u> - Provide leadership to growing team; ensure rapid service response for customer, transition to centralized team.
Jan, 1998 May, 1998	<b>GE Medical Systems, Global X-Ray Systems Engineering</b> HQ, Waukesha, Wisconsin Carol Murawski Sonia Dubreuil (dotted line)	<b>SenoVision Mammography Supplier Lead</b> - Off-pole LPI role to GEMSE Mammography NPI SenoVision program team for critical US supplier in Long Island, New York. - Developed and executed recovery plan with supplier. <u>Accomplishments</u> - Led supplier recovery to meet deliverables and restore missed program schedule.
May, 1997 Dec, 1997	<b>GE Medical Systems, Global X-Ray Uptime Systems Design</b> HQ, Waukesha, Wisconsin Tracy Accardi Jeff Pelletier Davy Hwang (dotted line)	<b>Global I&amp;W 6-Sigma Champion</b> - LPI role for all deliverables related to Global cost reductions for Installation & Warranty expenses for the Vascular business. - Developed detailed project scope report, including estimated savings, resource requirements, and deliverable timing for over 70 key activities. <u>Accomplishments</u> - Coordinated and drove global 6-Sigma activities for Installation and Warranty cost reductions to meet GDXR business goal of \$7MM reduction in 1998. Transition lead role to Buc team for execution.

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Jul, 1996 Sep, 1997	<b>GE Medical Systems, Global X-Ray Vascular Program Management</b> HQ, Waukesha, Wisconsin Davy Hwang Tracy Accardi John Chiminski (dotted line) Dow Wilson (dotted line)	<b>Vascular Americas Leader</b> - LPI for New World Program. Drove redefinition of 2-year-old program back to re-approval of M0, on track for M1 and execution with new deliverables. Program suspended Sep/96 to utilize all Vascular Engineering resources globally on completion of business-critical LCA program. - LCA Sys Eval Lead. Led audit of GEMSE Systems Engineering evaluation files in support of FDA/ISO inspection. Leader for America's systems evaluation team, driving clinical scenario evaluation and testing. - Global Vascular FMI Coordinator. Led development and deployment for multiple concurrent Vascular FMIs. - \$3.5MM LCA M4 FMI deploying to 110 customers world-wide; Most complex FMI ever deployed at GE Medical Systems. Personal leadership recognized with Management Award. - V3 XRT FMI deploying globally to 325 Vasc & R&F customers - Other Vascular FMI's deploying to 250+ customers <u>Accomplishments</u> - Key leadership role in Global Vascular Business Team with focus on program rollout and IB Customer Satisfaction. - Resolution of quality issues in the Vascular IB resulted in turnaround in share growth for Vascular business in 1997.
Jul, 1993 Jul, 1996	<b>GE Medical Systems, Global X-Ray R&amp;F Program Management</b> HQ, Waukesha, Wisconsin Bob Hauck Paul Hartke Srini Seshadri (dotted line) Dow Wilson (dotted line)	<b>TC Program LPI</b> - New Product program team leader, developing and introducing the Tilt-C, a new type of X-Ray system for clinical & surgical Interventional Procedures. - New entry to \$1,50MM+ market for GEMS. - 3-year/\$7MM+ development, with a cross-functional program team of over 100 people at peak, as well as several major suppliers, geographically split around the US and Europe. - Full production achieved within 3 months of original plan date. - Leadership recognized with significant Management Award. <u>Accomplishments</u> - Key leader in all phases of program through production - Champion & change agent for internal process improvements: - Changes in engineering program management techniques - Automated system validation techniques (cyclor) - Cost prediction and management tools (Q&P sheet) - Completely revised system installation approach (SCAT), saving time & money and improving quality to the customer
Jul, 1990 Apr, 1994	<b>GE Medical Systems, X-Ray</b> Waukesha, Wisconsin John Raker Wes Klages Claude Benchimol Emmanuel Derome	<b>Engineering Functional Manager</b> - Rebuilt X-Ray group software staff, hiring 20 engineers in 1 year. - Led continued software development process improvements; ISO-9001 process representative for software group. - Developed reorganization concepts for group, including software cluster subgroups and leaders. - Resolved issues with several poor performers in my group. - Functionally responsible for many concurrent software projects. <u>Accomplishments</u> - America's pole software deliverables for all projects in R&F/Mobile businesses, as well as Apollo and InSite projects. - Concurrent TC program leadership responsibility (see below). - Up to 15 people in my functional unit; developed plans and work assignments, performance appraisals, salary plans, budgets, & other administrative tasks.

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Jan, 1987 Jul, 1990	<b>GE Medical Systems, X-Ray</b> Waukesha, Wisconsin John Raker	<b>Senior Software Systems Analyst</b> - Software team leader for several positioning devices for the ADVANTX product line. This is a large X-Ray diagnostic imaging control system (over 5MM lines of code) with a networked multi-processor/multi-tasking architecture. The positioner subsystem architecture is based on Intel 80x86 $\mu$ -processors, with up to 100,000 lines of PLM-86 code in each device. Team leader of up to 8 software engineers with several suppliers to develop real-time software for applications, diagnostics and calibration for each positioning device. - Lead role in the software group for redefining and improving critical processes for software design and development. - Software coordinator for Model Period 7, a major ADVANTX product release, planning/executing all software deliverables. Drove significant process improvements related to this position; coordinated and directed the activities of 25 engineers, as well as communicating all software needs and issues to cross-functional groups (Mktg, Mfg, Svc, etc.) <u>Accomplishments</u> - Technical/project leadership of varied software developments over a 3½ year period in a number of areas of the ADVANTX X-Ray control software system, with teams of up to 25 engineers.
Mar, 1985 Jan, 1987	<b>Creative Logic Software</b> Washington, D.C. area (Self-employed)	<b>Consultant</b> - Designed and implemented real-time software programs: A custom BIOS for an IBM-PC compatible service training computer, upgrades for a communications encryption unit and a communications message switching system. - Analyzed and documented real-time software for several subsystems of a TDMA communications node. - Developed a custom computer accounting system & provided training services for a State Government Health Department. - Developed real-time software to provide service tools for calibration and installation of an X-Ray ADVANTX Diagnostic Imaging positioning device (the 8835 Spot-filmer). <u>Accomplishments</u> - Managed a successful independent business providing varied computing services to several different companies.
Nov, 1981 Mar, 1985	<b>Fairchild Corp.</b> Maryland Ken Grish	<b>Software Engineer</b> - Designed/implemented embedded real-time control applications: Avionics Reconnaissance Sensor Control Subsystem MIL-STD-1553 Bus Control & Monitoring Unit 16Mbps Satellite TDMA Communications Encryption System Remote-site Diagnostics Package for a large communications network <u>Accomplishments</u> - Lead Engineer for teams of up to 8 software engineers. Responsible for overall systems and software design, timely delivery of high-quality product software, planning and coordinating team members' work, training and technical reviews of team members & other engineers, and configuration management of all project software.
Apr, 1978 Nov, 1981	<b>Burroughs Corp.</b> Midland Bank HQ, London Eric Burnett HQ, World Bank, Washington D.C. Jack Curtis	<b>Computer Field Service Engineer</b> - Maintenance of mainframe CPU's & intelligent peripherals. Developed diagnostic software. <u>Accomplishments</u> - Overall responsibility for large computer installations at the headquarters of The Midland Bank in London, England, and at the World Bank headquarters in Washington, DC - Provide leadership, training & direction to teams of FE's

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Sep, 1977 Apr, 1978	<b>Control Data Institute</b> London Computer Maintenance School	<b>Scholar</b> - Maintenance and Programming of various computer devices. - UK Government-sponsored Trade School. <u>Accomplishments</u> - Graduated with High Honors
Dec, 1970 Oct, 1977	<b>British Army</b> Royal Corps of Signals	<b>Communications Operator</b> - Established and operated military radio networks in England, Northern Ireland and West Germany. - Graduated with High Honors from the Army Apprentices College. <u>Accomplishments</u> - Maintained & Operated military armored vehicles and various radio, teleprinter, and FAX equipment. - Promoted in May 1975; placed in charge of a 3-man independent detachment reporting to a Brigade-level Officer
1967-1970	Several <b>Hotels &amp; Restaurants;</b> <b>Family Businesses</b> Bournemouth, England	<b>High School &amp; Summer Jobs</b> - Worked Hotel & Restaurant kitchen jobs. - Maintained gardens with my father's landscaping business - Apprentice Electronics Technician at my uncle's store