

Donald J. Shave

Objective

Whilst presently retired, I do still occasionally seek challenging opportunities with vibrant, energetic companies that have a need for an adaptable, experienced senior person who has a notable record in compliance-driven program/process/people leadership; with SW apps/systems & software V&V; with medical imaging device development; and with solutions for new web designs and for computer security problems.

Skills

Professional engineer, experienced in compliant, womb-to-tomb medical imaging-related product development, management and regulatory leadership.

Established expertise with multiple tools, apps and processes, including:

- Medical Imaging Compliance-related processes (21CFR Part 820, ISO-13485, etc)
- Web apps... HTML, CSS, PHP, SQL, etc, each under Crimson Editor, Microsoft Expression 3, etc
- Six-Sigma & Lean process improvement techniques
- Excel-based tools/apps
- VB++/VBA (typ. used as Excel macro)
- C/C++ (using ClearCase for SCM)
- Java (under Eclipse with ANT, ...)
- Scripting tools (Windows & DOS scripting, JavaScript, ...)
- Microsoft's Office suite (Excel, Word, PPT, Project, Access, ...)
- Functional business process tools such as eNPI, ePRD, eLibrary & others;
- Databases (Oracle/Cube, PROMIS/APF, ...)

Personable, Credible, Experienced and Passionate; Attention to detail; Willingness to engage challenging assignments; Definition of new processes, tools & software to address key business problems

Education

Carroll University, Waukesha, Wisconsin, USA – BSCS, IS/IT focus, 2011 graduate, GPA 3.3 of 4.0

Computer Data Institute, London, England – CDI certificate, graduated with honors

Army Apprentices College, Harrogate, England – high-school equivalent, graduated with high honors

Hourly rates, Availability

Dependent upon position & role, the hourly rate can range from \$45 to \$125; availability is likely immediate.

Contact

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Detailed Work History (CV) for Don Shave

Dates	<u>Business Component</u> <u>Location</u>	<u>Position / Role</u> <u>Accomplishments</u>
Sep, 2016 to date	<u>Retired</u> Atlanta, GA, USA	Retiree Having spent many, many years being extremely busy (shown below), I today enjoy working recreationally with my ancestral family tree, websites and others. <u>Accomplishments</u> - Active Grampy for several grandchildren
Jan, 2009 to 2016	<u>Creative Logic Software, LLC</u> Atlanta, GA, USA & Hartland, WI, USA	Consultant My CLS business is now closed; we did provide contract-based activities that would have improved your business or your personal needs; services are shared online here
<i>In the 1980's Details below</i>	<i>Washington, D.C. area</i>	<u>Accomplishments</u> - Developed and supported validation test-cases in 2013 for DevFactory, an international provider of enterprise software. - Database Integration (Nov 2011 to Feb 2012) – retained by AlphaSource (key GEHC supplier) to analyze and integrate a large data-set addressing over 40,000 system service parts; also redeployed and reorganized the complex data for use as part of their online data. - Extensively analyzed a QMS for a MedNest client (Nov-09 to Mar-10) with recommendations to improve – MedNest, an NJ company, guides international clients seeking entry to the US medical systems market - Facilitated MedNest with their 3-day meeting; an international business meeting was held in Boston, MA (Jun-10) - Working to help address a business-critical legal concern, I provided detailed guidance/advice to the legal team for the paper-based QMS compliance archive (Oct-11 to Nov-11) - Developed a number of web-based sites for clients
Sep, 2007 Mar, 2008	<u>GE Healthcare, Global Imaging Subsystems, X-Ray Detectors</u> HQ, Waukesha, WI & PKI, Santa Clara, CA	XRD Yield Green Belt 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

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Dec, 2006 Sep, 2007	<u>GE Healthcare, Central QA</u> HQ, Waukesha, WI	QA Manager (acting) Managed compliance tasks for engineering programs <u>Accomplishments</u> QMS deployment and enforcement for MICT engineering
Jun, 2004 Dec, 2006	<u>GE Healthcare, Global FCT & Global MICT Engineering</u> HQ, Waukesha, WI	Engineering Quality Leader Define & deploy key processes, training & coaching around key engineering aspects of the QMS <u>Accomplishments</u> - Focus on compliance for CT & PET Engineering - International compliance visit to Haifa, Israel for audit prep
Jan, 2004 Jun, 2004	<u>GE Medical Systems, Global FCT Engineering</u> HQ, Waukesha, WI	Manager, FCT IBQ Engineering - 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	<u>GE Medical Systems, Global CT Engineering</u> HQ, Waukesha, WI	Global Manager, CT Customer Centricity - 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: IB Quality, Validation, 6 Sigma & Compliance - Continued back-office support for staff
Feb, 2001 Jun, 2003	<u>GE Medical Systems, Global CT Engineering</u> HQ, New Berlin & Waukesha, WI	Manager, CT Quality System - 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, including audits in Mexico and multiple compliance training visits to Beijing, China and Hino, Japan - 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

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Oct, 2000 Feb, 2001	<u>GE Medical Systems, Global</u> <u>CT Engineering</u> HQ, New Berlin, Wisconsin	Manager, CT eEngineering - Staff role leading process development and implementation for business-critical operational & administrative responsibilities including prediction, control & management of budget, headcount, program planning, facilities & others - 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	<u>GE Medical Systems, Global</u> <u>CT Engineering</u> HQ, New Berlin, Wisconsin	Manager, CT Product Planning/NPI Process 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
Oct, 1998 Jan, 1999	<u>GE Medical Systems, Global</u> <u>X-Ray Systems Engineering</u> HQ, Waukesha, Wisconsin	Emperor Global Program Lead - 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 / complimented by Jack Welch! - 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, led service deliverables, ensuring issues reach rapid closure, organized and delivered milestones to plan
Apr, 1998 Dec, 1998	<u>GE Medical Systems, Global</u> <u>X-Ray Systems Engineering</u> HQ, Waukesha, Wisconsin	Apollo Feasibility Sys Service Integration Lead Small team LPI role for Apollo feasibility sites in US, providing organization and leadership to ensure uptime & Customer sat <u>Accomplishments</u> Provide leadership to growing team; ensure rapid service response for customer, transition to centralized team

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Jan, 1998 May, 1998	<u>GE Medical Systems, Global</u> <u>X-Ray Systems Engineering</u> HQ, Waukesha, Wisconsin	SenoVision Mammography Supplier Lead - 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	<u>GE Medical Systems, Global</u> <u>X-Ray Uptime Systems Design</u> HQ, Waukesha, Wisconsin	Global I&W 6-Sigma Champion - 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 – transitioned lead role to Buc team for execution
Jul, 1996 Sep, 1997	<u>GE Medical Systems, Global</u> <u>X-Ray Vascular Program</u> <u>Management</u> HQ, Waukesha, Wisconsin	Vascular Americas Leader - LPI for New World Program, driving redefinition of 2-year-old program back to re-approval of M0, on track for M1 and execution with new deliverables – program was suspended Sep/96 to utilize all Vascular resources globally on completion of business-critical LCA program - LCA Sys Eval Leader – 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	<u>GE Medical Systems, Global</u> <u>X-Ray R&F Program</u> <u>Management</u> HQ, Waukesha, Wisconsin & Buc, France Office & Fischer Imaging, Denver, CO	TC Program LPI - New Product program team leader, developing and introducing the Tilting C-Arm system (Tilt-C), a new type of X-Ray system for clinical & surgical Interventional Procedures - New entry to \$1,50MM+ market for GE Medical Systems - 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 <u>Accomplishments</u> - Key leader in all phases of the 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

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Jul, 1990 Apr, 1994	<u>GE Medical Systems, X-Ray</u> Waukesha, Wisconsin	Engineering Functional Manager <ul style="list-style-type: none"> - 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> <ul style="list-style-type: none"> - 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 (details above) - Up to 15 people in my functional unit; developed plans and work assignments, performance appraisals, salary plans, budgets, & other administrative tasks
Jan, 1987 Jul, 1990	<u>GE Medical Systems, X-Ray</u> HQ, Waukesha, Wisconsin	Senior Software Systems Analyst <ul style="list-style-type: none"> - Software team leader for several positioning devices for the ADVANTX product line – a X-Ray diagnostic imaging control system (5MM+ LOC) / networked multi-processor/multi-tasking architecture... the positioner subsystem architecture was based on Intel 80x86 μ-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> <p>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</p>
Mar, 1985 Jan, 1987	<u>Creative Logic Software</u> Washington, D.C. area (Self-employed)	Consultant <ul style="list-style-type: none"> - 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> <p>Managed a successful independent business providing varied computing services to several different companies</p>

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Nov, 1981 Mar, 1985	<u>Fairchild Corp.</u> Maryland	Software Engineer - 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 (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	<u>Burroughs Corp.</u> Midland Bank HQ, London & World Bank, Washington D.C.	Computer Field Service Engineer - 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, USA - Provided leadership, training & direction to teams of FE's
Sep, 1977 Apr, 1978	<u>Control Data Institute</u> London Computer Maintenance School	Scholar - Maintenance and Programming of various computer devices - UK Government-sponsored Trade School <u>Accomplishments</u> - Graduated with High Honors
Dec, 1970 Oct, 1977	<u>British Army</u> Royal Corps of Signals	Communications Operator - 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 <u>Hotels, Restaurants;</u> & <u>Family Businesses</u> Bournemouth, England	High School & Summer Jobs - Worked many Hotel & Restaurant kitchen jobs - Maintained large gardens with my father's landscaping business - Apprentice Electronics Technician at my uncle's store