405 E Court St
Ludington, MI 49431
Doug@System-Int.Com
(231) 571-8784

Douglas Canfield

SUMMARY

Highly versatile software manager and developer with over fifteen years experience developing medical devices and software. Software validation expert. Excellent liaison between technical teams and senior management. Lifetime of practical experience with appliance repair, home remodeling, electro-mechanical and software based hobbies.

Passionate for integrity, quality and excellence.

ACHEIVEMENTS

- Develop multiple instrument control applications for Ethicon Endosurgery.
- Develop and validate software for Motorola eSensor® 4800 molecular diagnostic system (FDA cleared, commercialized).
- Manage hardware and software development / validation for Genmark Diagnostics eSensor ® XT-8 molecular diagnostic instrument (FDA cleared, commercialized).
- Author instrument and software sections of FDA 501(k) submissions.
- Author, implement and defend complete ISO/FDA complaint software quality systems.
- Surprisingly literate on the life and habits of aardvarks.
- Defend company design control compliance before ISO, and FDA.
- Manage diverse team of developers, engineers and technicians.
- Resolve product reliability issues, saving a multi-million dollar client.

SKILLS

Management:	Hiring, Mentoring, Conflict Resolution, Project Management, Employee Review, Budgeting, Document Approval
Regulatory:	FDA 21 CFR Part 820, Part 11, ISO 13485, ISO 14971, IEC 62304 IEC 61010-1, IEC 60601-1, FDA and ISO audits
Documentation:	Requirements Definition, Hazard Analysis (FMEA, FTA), Design Description, Validation Protocol, Traceability (DOORs, RMTrak)
Programming:	Visual Basic / C# .NET, LabVIEW, Scripting, Machine Control (G Codes), Assembler (Familiar)
Interface:	RS-232/485, CAN, Ethernet, GPIB, SCXI, PC plug in cards, Thermocouples, Strain Gages, LVDTs.
Troubleshooting:	Analog and Digital electronics, Mechanical systems, Software debugging
Design:	Solidworks, AutoCAD, Visio, pencil and napkin

EDUCATION

Miami University, Oxford Ohio BSME. (Manufacturing Engineering) – 3.98 GPA

Miami University, Oxford Ohio Masters in System Analysis – 3.96 GPA
(Thesis not completed).

- Graduated Summa Cum Laude
- Multiple Scholarships
- Honorable Mention – MCM (Mathematical Contest in Modeling.)

INTERESTS

Church, Puzzles, Reading, Community Service (volunteer)

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WORK EXPERIENCE

Hycor Biomedical August 2011 – Present
Software Engineering Manager Manage development of PC based instrument control software for next generation immuno-analyzer (one direct report, five contractors). Develop software requirements and guide software development for million dollar software effort. Provide all software changes for existing products. Provide hardware and software troubleshooting for existing product instruments and software. Defend company design control compliance for ISO and FDA audits.

System Integration (www.system-int.com) Jan 2009 – August 2011
Proprietor of System Integration. Specialize in medical device development and machine interfacing. Several simultaneous contracts developing machine control software and remediating Hycor Biomedical software quality system.

Osmetech Molecular Diagnostics June 2005 – December 2008
Sr. Manager, Instrument Engineering Coordinate activities within the Instrument Engineering *group* (four direct reports, exempt and non-exempt). Manage internal activities among staff: document revision, instrument and software troubleshooting. Author Instrument and software elements of 510(k) submissions. Completely rewrite software quality system. Defend manufacturing and design control of instrument and software during regulatory (FDA, ISO) audits. Manage development of eSensor® XT-8 platform (Instrument and internal software infrastructure). Manage multiple contractors for XT-8 development including software, hardware, industrial and graphic design.

Clinical Micro Sensors, A Motorola Company May 2000 – June 2005
Manager, Product Hardware Coordinate activities within the Product Hardware group (five direct reports, exempt and non-exempt). Manage validation activities for instrumentation and for testing software. Manage documentation for transfer to manufacturing. Lead troubleshooting efforts and preventive maintenance program. Assist in project definition, requirement specification and partner selection for next generation instruments. Specify and enforce departmental policy ensuring adherence to GMP and FDA compliant practices.
Sr. Software Engineer. May 2000 – April 2002.
Design and code applications to control and troubleshoot eSensor instrument. Specify and implement communication interfaces between computer and instrument. Work with contractors to specify circuit design and troubleshoot persistent problems.

System Integration August 1995 – May 2000
Proprietor of System Integration. Specialize in custom programming using LabVIEW, Visual Basic and C/C++ to interface PCs with machines.

Miami University August 1997 – May 1998
Visiting Assistant Instructor. Develop curriculum and teach first-year structured programming using Visual Basic (concurrent with own business).

Institute of Advanced Manufacturing Sciences June 1991 – August 1995.
Engineering consultant. Use PC's to collect and analyze data. Develop math models using novel thermal compensation and non-contact gauging for machine tools. Implement data acquisition process including wiring, programming computers and designing special fixtures. Maintain company PCs and network.