



Doug Stephens

45 Clive Avenue, Guelph ON Canada, N1E 3S5
(416) 666-9342 Email: dstephens@dpstech.ca

- Senior software engineer
- Quality management consultant & auditor
- Software lifecycle process expert
- Excellent communications skills

Technical Skills

- **Programming:**
Delphi, VB, C++, ASP.net
- **Design Modelling:**
Use Cases, Data Flow, ER
- **SQL Database:**
Oracle, DB2, SQL Server
- TCP/IP socket communications
- Multi-threaded applications
- Real time control systems
- Windows (NT, XP, 2000)
- Office: Word, Excel, PowerPoint, Project, Visio
- Crystal Reports
- DOORS

Process Skills

- Software Lifecycle Processes
- Requirements Specification
- Verification & Validation
- SOPs, Work Instructions
- Risk Analysis & Mitigation
- Quality Management Processes
- FDA (21 CFR 11, 820, 58)
- Team Leadership
- Presentations & Proposals
- Pharmaceutical GXP

Work Experience

2004 – current Quality Management Consultant Europe (Toronto based)	Conducted formal software quality audits for pharmaceutical organizations involved in clinical trials, focussed on FDA compliance. Performed risk analysis on various systems and strategies. Provided validation training and assessments of internal systems.
2002-2004 PGP Research & Development Manager Brussels, Belgium	Managed a team of developers working on a sophisticated Lab Information System product interfacing with automated blood analyzers and assorted lab systems and devices. Developed new software development lifecycle and Quality processes. Wrote SOPs and Work Instructions. Conducted Risk Analysis studies and wrote Validation Master Plan. Implemented the DOORS system for requirements management.

<p>1998 – 2002 Labotix Automation Software Engineering Manager Peterborough, Ontario Omaha, Nebraska</p>	<p>Working with a multi-disciplinary team of engineers, I designed and developed real time automation control software interfacing to blood analyzers, lab information systems and custom engineered robotic modules such as conveyors, barcode scanners, sorters and aliquoters. Managed onsite customer installations all around the world. Developed applications to improve quality such as bug reporting, change control and configuration management. Provided team leadership and mentoring.</p>
<p>1998 Manulife Financial Electronic Forms Consultant Toronto, Ontario</p>	<p>Provided consulting and software development services to aid in the movement from paper forms to electronic forms for this large insurer. Evaluated various e-Forms products. Worked with management to define strategy. Developed Lotus Notes and VB applications to convert and manage electronic forms and for publishing to the corporate Domino driven website.</p>
<p>1995 – 1997 IBM Canada Technical Project Leader Markham, Ontario</p>	<p>Lead a team of programmers and end users to specify and build a sales order processing system in a multi-platform environment. This was a high profile application with interfaces to various IBM business partners and resellers and was critical to the company's strategy in this key marketing channel. Designed and implemented several nationwide financial planning applications.</p>
<p>1992 – 1996 Software Entrepreneur Toronto, Ontario Denver, Colorado</p>	<p>Designed and developed a software product allowing retailers to order satellite based TV subscriptions by modem and PC using custom protocols and components. I successfully sold this system to the industry's largest distributor (Echosphere Corporation) and continued to provide enhancement and support services for several hundred retailers.</p>
<p>1990 – 1992 Bilrite Industries Programmer, Consultant Toronto, Ontario</p>	<p>Independently designed and programmed a data collection system for Canada's largest rubber manufacturer, interfacing with various sensors in the mixing and production process to provide quality control and cost reduction data. Ran 24/7 for eight years with uptime of over 98%.</p>

Education

I hold a degree in Mathematics and Computer Science from the University of Waterloo and try to maintain a scientific approach in all aspects of my work. With a sound basis in first principles I am quick to absorb new skills and adapt easily to new situations.