



LINDA McINNIS,

QUALITY ENGINEER, DESIGN ASSURANCE & TECHNICAL WRITER

LindaMcInnis@yahoo.com

P.O. BOX 5531,
WAYLAND, MA 01778
(508) 231-6421

OBJECTIVE

To work on useful software that helps people lead better lives. My part in that is to make sure that what I work on is safe and effective by testing, doing risk and hazard analysis.

I often work with the technicians on products under test to understand the needs and precautions of the job and to make sure that user interface issues don't stand in the way of the productive use of the software.

I started my working life as a hardware technical writer then moved into software finally moving to QA. I made the move after writing more bugs than the entire QA department and being asked by the QA manager to transition from writing to QA.

EXPERIENCE

Consultant

Software Quality Matters, LLC, Wayland, Massachusetts

March 2013 -- present

Consultant in Software Test and Documentation.

Software Test Engineer, Medical Device

Volcano, Billerica, Massachusetts

March 2011 – March 2013

- Write Sprint tasks, Team using Agile Methodology
- Write and Run manual software V& V test cases for this Medical Imaging product
- Created FMEA, Traceability, Verification Plans, Hazard and Risk analysis.
- Wrote defect reports, helped clarify specifications, reviewed IFU and Operator manual
- Did a proof of concept for automating testing (basically that widgets can be seen, etc.)

Skills used: Test Complete, XML, Redmine, JIRA, Team Center, Code Collaborator, Confluence, Subversion, Uses Cases, SQL, GMP / GLP / GCP

Contract Technical Writer, Data Warehouse

Dataupia, Cambridge, Massachusetts

March 2011 – April 2011

Revised Release notes for the Satori server.

Skills used: Word

Instructor, Software Engineering Masters program

Brandeis University, Waltham, Massachusetts

March 2009 – August 2011

Taught a course online titled Foundations of Software Quality Assurance in the Graduate Software Engineering Program.

Skills used: Wordpress, Fogbugz

Skills

GMP / GLP / GCP
Adobe Photoshop
Adobe Flash
Eclipse IDE
MS Office Suite
Open Office
Java (reading)

Simple Scripting:
JavaScript
Python
Shell scripting
XML
Visual Basic
HTML/XHTML

Oracle
Sybase
SQL

TeamCenter
Code Collaborator
Confluence
JIRA
DOORS
Clearcase
Cvs
Fogbugz
Subversion
Redmine
PVCS
Lotus Notes
UML
Use cases
Linux/UNIX
Windows Vista/XP
Mac
iPhone
iPad
Quick Test Pro
Test Complete
Silktest
Certifications
Six Sigma – Green Belt
Regulatory Affairs (in process)

Software Quality Engineer, Medical Device

February 2010 – February 2011

Haemonetics, Braintree, Massachusetts

- Wrote and ran manual V& V test cases for medical device and Mobile Data Transfer
- Create Traceability Matrices from SRS to tests in DOORS
- Software Validation plan, bug reports, testing reports

Skills used: Doors, Word, Excel

Software Quality Engineer, Medical Device

April 2008 to October 2009

Instrumentation Laboratory, Bedford, Massachusetts

- Wrote manual Test Scripts and manually tested a Linux-based Blood Gas Analyzer
- Entered bugs into PVCS Tracker, generated metrics, Participated in Change Control Board
- Created an analysis of Software Compliance Risks

Skills used: Linux, Word, Excel

Sr. QA Engineer\QA Lead, Medical Record

October 2007 to April 2008

Document Management

Sceris, Inc., Sudbury, Massachusetts

- Tested this Document Management software manually and in Silktest.
- Wrote test plans, entered bugs in QA Radar.
- Reviewed Documentation
- Worked with Support on problem escalation and resolution.

Skills used: PVCS, Word, Excel, Silktest, QA Radar

Sr. QA Engineer, Medical Device

2005-2007

Boston Scientific, Natick, Massachusetts

- Provided Regulatory Software Validation and Verification for this medical device company.
- Wrote Validation and Test Plans per FDA regulations, Reviewed specifications, Built traceability matrices,
- Provided development process regulatory oversight.
- Developed an enterprise-wide educational program for understanding the business model, products and critical thinking for working in regulated environment through a program called Lunch and Learn.

Skills used: Word, Excel, Powerpoint

QA Practice Manager and Consultant

2000-2005

Noble Associates, Wayland, Massachusetts

The practice included the following clients:

Exa Corporation, Burlington, MA Commercial Software (Redhat Linux) Wrote Test Automation Interface specification for this computational fluid dynamics product; Developed test plan template; Wrote GNATS User Guide; Hired QA personnel; Tested PowerPrep software

Tyco Healthcare, Mansfield, MA Medical Device

Wrote Validation test scripts for the OQ and PQ of this Documentum based Regulatory product including tests to determine CFR, Part 11 FDA electronic signature compliance.

Ovid Technology, Norwood, MA Medical Publishing

Tested content and search capability of the Medical CD series such as Embase and Medline

Scully Signal Company, Wilmington, MA Embedded/Wireless

Wrote Installation, User and Administration Guides for this wireless monitoring application written in C++ ; Wrote a Quick Start for the same product; Developed Test strategy; Tested this embedded hardware/software communications device manually; Developed automated tests using Test Complete.

Full Spectrum Software, Framingham, MA Software Testing Contract House

Developed automated performance test scripts using Test Complete for a large scale tracking application. Tested and documented system defects.

Ryan Partnership, Wilton, CT

Developed Test plans and tested web sites manually and using Silktest scripts for this marketing company. Sites tested included Dove.Com, Skoal.Com, Berkeley.com.

World Wrestling Entertainment (www.wwe.com), New York, New York

Tested the changes from one web host to another, tested from a user perspective (black box); Tested the purchase transaction processing area

Vistaprint

Conducted black box website testing of fourteen sites written in the .Net and XML, found problems with browser combinations (e.g. Mozilla, Opera, AOL), uncovered server bandwidth problems; Working with marketing, tested html e-mail marketing releases

Tim Rosa Associates

Wrote documentation for FDA approval process including SOP's, IQP's, IOQ's for pharmaceutical companies; Wrote Computer Validation documents such as Fileserver, Database configuration records; Edited websites and tested them for content links to see if they were logical and worked and if their structure made sense; Wrote programs to automated testing of websites; Recommended by this client to Millennium Pharmaceuticals and subsequently did regulatory work for them.

Millennial Net

Consulted for this company which developed a wireless self configuring networking system that enables clients to place transceivers anywhere which automatically find the quickest route to return information (e.g., applications using this technology include oilfield piping); Edited, added graphics and polished marketing documentation for maximum sales effectiveness

EDUCATION / CERTIFICATIONS

Regulatory Affairs, Certificate

San Diego University, San Diego, California

Currently in progress

Six Sigma, Green Belt

Value Train, Atlanta, Georgia

2005

Physics, Bachelor of Science

Worcester Polytechnic Institute, Worcester, Massachusetts

Studies focused in geophysics and oceanography.

Major Qualifying Project: produced fault plane depiction of tectonic activity in Baja California.

Interactive Qualifying Project: created science demonstrations for the Worcester Science Center.

Minor: English

Work Study: Editorial Assistant for the *Journal of Theoretical Biology*.