Michael Lehotay

Medical Device and Software Quality Engineer
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Summary

Software and manufacturing quality engineer with a demonstrated history of success in the medical device industry. Experienced in guiding multidisciplinary teams through all phases of product lifecycle from concept to retirement. Strong and versatile professional with a B.Sc. in Computer Science from the University of Toronto.

- Fifteen years quality engineering experience in the medical device industry
- Extensive experience verifying and validating medical device software to assure compliance with ISO 13485, FDA, and EU MDD/MDR regulations
- Experience developing and testing software in conformance with IEC 62304 SDLC standard
- Experience generating and maintaining risk management files in conformance with ISO 14971
- Experience as Software Quality SME in FDA and ISO 13485 quality system audits
- Certified Software Quality Engineer (American Society for Quality)
- Certified 13485:2003 Internal Auditor (Exemplar Global MD & AU)
- Experience with DICOM standard for exchange of medical images and related information
- Excellent verbal and written communication skills
- Excellent reasoning ability and investigation skills
- Ability to multi-task and work with all levels of management
- Detail oriented with ability to learn new skills quickly
- Understanding of the manufacturing environment, workflow, and planning activities
- Highly PC literate and excellent working knowledge of MS Office applications

Employment History

Owner / Medical Device Quality Assurance Consultant
Lehotay Consulting, Toronto, Ontario, Mar 2021 – Present

- Developed agile SDLC procedure to replace existing waterfall design process for Health IT products
- Provided quality oversight for client product teams in ISO 13485 and IEC 62304 remediation project
- Performed root cause analysis per IEC 62740 on software issues for an EMR product
- Reviewed customer complaints, code reviews, design specifications, hazard logs, and other QMS records to facilitate client software failure investigations

Quality Engineer
SciCan Ltd, Toronto, Ontario, Jun 2020 – Sep 2020

- Provided quality assurance support for the production and service of dental autoclaves conforming to FDA and EU MDR regulations and to ISO 13485
- Maintained CAPA system and coordinated CAPA activities
- Monitored production nonconformances and issued production or shipping holds when necessary
- Planned revalidation of manufacturing process for relocation of assembly line

Quality Engineer
IBM Watson Health, Cambridge, Massachusetts, Nov 2016 – Oct 2019

- Provided design quality assurance for the development of medical device software conforming to FDA and EU MDR regulations and ISO 13485, ISO 14971, and IEC 62304 standards
- Coached multidisciplinary teams to create project development plans, design inputs and outputs, design history files, risk management, test strategy, verification and validation plans, test traceability, and other design control deliverables
- Reviewed and approved design verification and validation test plans, protocols, and reports
- Developed and implemented corrective actions for improvement of design control processes
- Participated in assessment of development tools and approved tool validation documentation

Quality Engineer
Optos Inc / Nikon Corporation, Southborough, Massachusetts, May 2015 – Nov 2016
Optos Inc, Southborough, Massachusetts, Oct 2013 – May 2015

- Developed test methods and procedures for verification and validation of OCT and ultrasound ophthalmic imaging devices to conform with ISO 13485, IEC 62304, and FDA quality system regulations
- Performed risk analysis and product testing to support design changes in accordance with ISO 14971
- Developed IQ/OQ/PQ protocols and reports for validation of process improvements
- Played key role on small team to plan, implement, verify, and validate software release for addition of DICOM support to OCT device software
- Championed MRB process to ensure proper handling and disposition of non-conforming product
- Maintained technical files for OCT and ultrasound devices in conformance with EU MDD
- Performed internal audits to ensure conformance to FDA and ISO quality system requirements
- Performed incoming inspection of raw materials and investigated non-conformances
- Inspected products at all stages of the production process to ensure compliance with QMS requirements
- Acted as document controller to manage documentation changes in compliance with internal document control processes
- Assisted in integration of quality management system following closure of OCT and ultrasound production facility in Miami

Quality Engineer
Optos Inc, Miami, Florida, Jan 2012 – Sep 2013
OPKO Instrumentation, Miami, Florida, Aug 2010 – Jan 2012

- Developed verification procedures, validation procedures, and work instructions for OCT and ultrasound ophthalmic imaging devices to conform with ISO 13485 and FDA quality system regulations
- Generated and reviewed verification and validation test reports to ensure appropriate objective evidence of test results was collected
- Setup and maintained JIRA and MediaWiki servers
- Maintained customer and inventory web application to ensure traceability of system components
- Led cross functional team meetings to monitor complaint, CAPA, and NCR systems
- Investigated internal issues and customer complaints to determine root causes and provided recommendations for successful resolutions
- Tested, supported, maintained, and documented software functionality
- Provided technical support for production and service staff, distributors, and customers
- Functioned as an information source to all company departments when special and critical quality issues occurred

Quality Assurance Analyst
OPKO Instrumentation, Kingston, Ontario, Nov 2007 – Jul 2010
Ophthalmic Technologies Inc, Kingston, Ontario, Mar 2006 – Nov 2007

- Designed and performed test procedures for OCT and ultrasound ophthalmic imaging software
- Developed software validation procedures to conform with ISO 13485 and FDA requirements
- Maintained build environment for all PC and Mac software products
- Maintained Subversion, CVS, Request Tracker, and software backup servers
- Provided technical support for production and service staff, distributors, and customers
- Maintained customer support website
- Documented software features
- Performed minor C++ and Java programming tasks

Research Assistant
Queen's University, Kingston, Ontario, Sep 1999 – Aug 2004

- Designed and performed biochemical experiments to measure glycosyltransferase enzyme activities and determine the effects of various human diseases on glycosylation pathways
- Co-authored five articles in peer-reviewed medical journals
- Trained graduate and undergraduate students in use of laboratory equipment and techniques including HPLC, high voltage electrophoresis, ion exchange and paper chromatography, liquid scintillation counting, and preparation of human and animal tissue homogenates
- Designed and maintained the laboratory website
- Provided Windows & Mac OS support for all lab personnel

Education

Data Science Immersive
General Assembly, Toronto, Ontario, Feb 2020
Completed 12-week data science training program covering data analysis with python, machine learning and modeling techniques, and data visualization. Created and deployed multiple interactive web applications.

Certified Software Quality Engineer
American Society for Quality, Dec 2016
Certified mastery of ASQ CSQE Body of Knowledge including software quality development and implementation, software inspection, testing, verification and validation, and implementation of software development and maintenance processes and methods.

B.Sc., Computer Science
University of Toronto, June 2006
Completed major program in computer science. Also studied biochemistry and linguistics. Was awarded the Woodsworth College Book Box Scholarship in Recognition of Outstanding Achievement in Mathematics.

Publications

Brockhausen I, Carran J, McEleney K, Lehotay M, Yang X, Yin L, Anastassiades T. N-Acyl derivatives of glucosamine as acceptor substrates for galactosyltransferase from bone and cartilage cells. *Carbohydrate Research*. 2005 Sep 5; 340(12): 1997-2003.

Yang X, Lehotay M, Anastassiades T, Harrison M, Brockhausen I. The effect of TNF-alpha on glycosylation pathways in bovine synoviocytes. *Biochemistry and Cell Biology*. 2004 Oct; 82(5): 559-68.

Yang X, Qin W, Lehotay M, Toki D, Dennis P, Schutzbach JS, Brockhausen I. Soluble human core 2 beta6-N-acetylglucosaminyltransferase C2GnT1 requires its conserved cysteine residues for full activity. *Biochimica et Biophysica Acta*. 2003 May 30; 1648(1-2): 62-74.

Brockhausen I, Lehotay M, Yang JM, Qin W, Young D, Lucien J, Coles J, Paulsen H. Glycoprotein biosynthesis in porcine aortic endothelial cells and changes in the apoptotic cell population. *Glycobiology*. 2002 Jan; 12(1): 33-45.

Brockhausen I, Yang J, Lehotay M, Ogata S, Itzkowitz S. Pathways of mucin O-glycosylation in normal and malignant rat colonic epithelial cells reveal a mechanism for cancer-associated Sialyl-Tn antigen expression. *Biological Chemistry*. 2001 Feb; 382(2): 219-32.