Michael Lehotay

Software Quality Engineer and Data Scientist

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Employment History

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 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
Optos Inc, Miami, Florida, Jan 2012 – Sep 2013
OPKO Instrumentation, Miami, Florida, Aug 2010 – Jan 2012
OPKO Instrumentation, Kingston, Ontario, Nov 2007 – Jul 2010
Ophthalmic Technologies Inc, Kingston, Ontario, Mar 2006 – Nov 2007

Provided quality assurance for retinal imaging medical device over the entire course of the product lifecycle, spanning three corporate acquisitions and two manufacturing facility relocations.

ISO 13485 • IEC 62304 • ISO 14971 • V&V testing • Document control • Complaint management • CAPA • Incoming inspection • Nonconforming product • FDA & ISO audit SME • Internal auditor • Clinical testing for 510k submission • Maintained risk management file • Maintained technical file • Software build engineer • Software release management • Software defect management • Developed SOP, work instructions, other quality system processes • Developed requirements, user documentation, other design inputs • Provided level 3 tech support • Server administration (JIRA, subversion, etc)

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

IBM Data Science Professional Certificate
www.coursera.org, expected completion March 2020
Introduction to IBM Cloud, IBM Watson Studio, and IBM Data Science Methodology.

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 understanding of 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.