CAFÉ E-Xpress Morning Lecture Series #5

Ishwar K. Puri, Dean, McMaster Engineering invites you to join us for a series of CAFÉ E-Xpress morning lectures, that will bring McMaster engineering alumni, students and faculty together for expressions of interest in a changing technical world. Invited alumni and professors will speak about current topics related to career trajectory, hot flashes in the lab and ideas that spark. We hope you can join us!

From Process to Product Based Evidence -
The changing Landscape of Software Intensive Medical Device Evaluation

Novel medical devices currently on the market and under development include implantable pacemaker/defibrillators, tele-robotic surgery systems and closed loop insulin infusion pumps (the “artificial pancreas”). All of these device rely upon software for their safe, effective, and secure operation. Regulator approval of software intensive medical devices has typically relied upon software process oriented standards compliance. Compliance with a process oriented standard provides indirect evidence of software and hence device safety and reliability, but the history of device recalls shows that this indirect evidence is insufficient. In order to provide more direct evidence of device safety and reliability, the U.S. Food and Drug Administration (FDA) recently changed its approval process for infusion pumps (including insulin pumps), so that the production of an explicit assurance case that demonstrates that the device is safe and effective is now a strongly suggested regulatory requirement.

In this talk we will discuss the limitations of the current process oriented regulatory approval of software intensive medical devices and the possible motivations for the FDA’s suggestion. We will provide some background on assurance cases and describe an assurance case template that could be used to guide system development and the creation of a part of a regulatory submission for an insulin pump or other safety critical, software intensive medical device.

This talk is based on joint work with my colleagues Drs. Alan Wassyyng and Tom Malbaum at the McMaster Centre for Software Certification, as well as Dr. Yihai Chen of Shanghai University and Dr. Hao Wang of Aalesund University College, Norway.

Tuesday, March 17, 2015
Ron Joyce Centre – DeGroote School of Business
Guest Speaker:
Dr. Mark Lawford,
Professor, Department of Computing & Software
Assistant Professor, Department of Materials Science & Engineering

Mark Lawford is a Professor in McMaster University’s Department of Computing and Software and the Associate Director of the McMaster Centre for Software Certification. He has a B.Sc. (’89) in Engineering Mathematics from Queen's University, Kingston, where he received the University Medal in Engineering Mathematics. His M.A.Sc. (’92) and Ph.D. (’97) are from the Systems Control Group in the Department of Electrical and Computer Engineering at the University of Toronto. His research interests include software certification, application of formal methods to safety critical real-time systems, and supervisory control of discrete event systems. He worked at Ontario Hydro as a real-time software verification consultant on the Darlington Nuclear Generating Station Shutdown Systems Redesign project, receiving the Ontario Hydro New Technology Award for Automation of Systematic Design Verification of Safety Critical Software in 1999. He joined McMaster University’s Department of Computing and Software in 1998 where he helped to develop the Software Engineering programs and Mechatronics Engineering programs. He has been a guest co-editor of joint special issues on Software Inspection of IEEE Software and IEEE Transactions on Software Engineering. He served as the Section Chair for Computer Systems on the Computer Science Evaluation Group (EG-1507) for the 2010 NSERC Discovery Grant Competition. In August 2010 he was a visiting researcher at the Center for Devices and Radiological Health, Office of Science and Engineering Laboratories of the U.S. FDA.

He is a licensed Professional Engineer in the province of Ontario and a Senior Member of the IEEE.

7:30 am  
Registration & Breakfast

8:00 am  
Guest Speaker – Presentation

8:30 am  
Question & Answer Period

9:00 am  
Farewell

Please Register at  
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