ASEAN, Australian Updates and Software Control in Medical Device

21 May 2015 (Thursday), 9.30am – 5.30pm

Singapore Manufacturing Federation, 2985 Jalan Bukit Merah, Singapore 159457

Concourse I

Time	Event	Speaker
AM Session - ASEAN and Australia Updates		
9.30 am	Registration	
10.00 am	**MTIG Introduction**	
10.15 am	**ASEANMed Regulatory Updates**	**Ms May Ng, MTIG ARQon, Singapore**
11.00 am	Tea Break	
11.15 am	**Australia Medical Device Regulation and Updates**	**Mr Michael Flood, Locus Consulting, Australia**
12.15 pm	Networking Session	
PM Session - Medical Apps and Software Validation		
2.00 pm	**Mobile Medical Apps: A Market and Regulatory Outlook**	**Dr Nealda Yusof Semoegy, Singapore**
2.45 pm	**Software Validation for Medical Device**	**Mr Philipp Rey ERNI, Switzerland**
4.45 pm	Tea Break and Networking session	
5.30 pm	End of session	

Organised by: Medical Technology Industry Group (MTIG),
Singapore Manufacturing Federation

Ms May Ng, Singapore
ARQon Pte Ltd
Asia Regulatory & Quality Consultant

Ms May Ng is the founder of ARQon, Asia Regulatory & Quality Consultancy for medical device and drug. She is currently focusing on Medical Device Design & Development Phases (MD^{3}P) for the local start-ups to achieve CE mark certification and US FDA approval, and also helping overseas companies as a one-stop product registration in ASEAN and Asia. She graduated in Biomedical Engineering and Medtech Manufacturing and gained her 17 years of experiences in the industry and regulatory perspective in HSA, IVD industry, and with the local manufacturer, Biosensors. Currently, she holds advisory roles in few local and regional associations eg. MTIG-SMF and ASEANMed.

Mr Michael Flood, Australia
Locus Consulting Pty Ltd
Principal

Mr Michael Flood is currently active in a number of standards development committees for medical devices, both within Australia and internationally. He has been a member of the Health and Food Sector Standards Board of Standards Australia and has recently finished his third term as Chairman of the College of Biomedical Engineers within Engineers Australia. In addition, he held visiting appointments at several Australian Universities and also is an adjunct lecturer in biomedical engineering at the Australian National University.

Dr Nealda Yusof, Singapore
Semoegy Singapore
Founder

Dr Nealda Yusof's experience in the medical technology sector spans 14 years. Specialising mainly in medical devices, she has been actively involved in the entire product lifecycle process ranging from research, regulatory, testing & validation, quality assurance, risk and crisis management, compliance and commercialisation. She advised multinational heavyweights in the healthcare sector such as GlaxoSmithKline and Edwards Lifesciences, and worked in close collaboration with NAMSA and Charles River. In 2012, she was appointed to an advisory role to the CEO in a renal care group and tasked to oversee teams in the United Kingdom, Germany, Egypt and Turkey.

Mr Philipp Rey, Switzerland
ERNI Consulting AG
Principal Consultant

Mr Philipp Rey has 15 years of experience developing software and 11 years of developing software in med-tech. He is experienced as a project leader in various Software Projects. He is both a ISTQB® / SAQ Certified Software Tester and also a Certified Project Manager IPMA. His qualification is IREB® / SAQ Certified Professional for Requirements Engineering. He is experienced in the specification of requirements in the medical device development industry and optimization of software development processes.

To complete Registration

1) **Email the completed form to below contact:**
   a) Ms Cherie Ong
      Email: cherie.ong@smfederation.org.sg
      DID: 6826 3039   Fax: 6826 3068

REGISTRATION	
Name (Dr/Mr/Ms/Mrs):	
Company:	**Designation:**
Address:	**Postal Code:**
Email: **Mobile:**	**Office DID:**

Seminar Fee *(*fee inclusive of GST)*

SMF Member & Affiliate Member (GS1 Singapore Limited):
☐ **S$53.50 for AM/PM Session** ☐ **S$107.00 for both AM and PM Sessions**

Non-Member:
☐ **S$214.00 for AM/PM Session** ☐ **S$428.00 for both AM and PM Sessions**

For those Company who are interested to register as member, please submit the SMF member registration form, which can be requested separately. Currently, member registration is at SGD50.00 for trial period of 6 months for new members.

Payment Mode: By Cheque

I enclose my Bank Draft/Cheque No._____ for S$_____
(payable to "Singapore Manufacturing Federation" and mail to: 2985, Jalan Bukit Merah S159457)
Please indicate "FOR MTIG Seminar – ASEAN, Australian Updates and Software Control" at the back of the cheque.

Signature (With Company Stamp):

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*Registration is on a first-come, first-served basis and will be confirmed upon receipt of full payment. For fax registrations, please ensure that your cheque reaches us before the event. No refund will be made for any cancellation but replacements are welcome. The Organiser reserves the right to postpone or cancel the seminar due to unforeseen circumstances.

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Singapore Manufacturing Federation
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