Centre of Regulatory Excellence
@ Duke-NUS Medical School

Regulation of Software as a Medical Device

1st – 2nd December 2020
Mode: Zoom

WORKSHOP PROGRAMME

Learning Outcomes

At the end of this workshop, participants should be able to:

- Determine key regulatory considerations in medical device software development
- Identify relevant standards and guidance required for software verification and validation
- Apply regulatory compliance requirements in medical device software development, testing and documentation

Target Audience

- Software developers, engineers, researchers, SMEs developing Medical Device software, regulatory/quality assurance professionals

Regulation of Software as a Medical Device (SaMD)

Duke-NUS Medical School

1st – 2nd December 2020

Programme

Day 1 (1 Dec 2020)

Time	Agenda	Speaker/Facilitator
8:30 am	**Zoom Briefing**	**Mr Osman Bin Mohamad** Senior Associate Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
9.00 am	**Welcome Address**	**A/Prof Silke Vogel** Deputy Director, CoRE Senior Associate Dean Graduate Studies Duke-NUS Medical School
9.10 am	**Workshop Briefing and Introduction to SaMD**	**Mr Ananda P Muthalagu** Associate II Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
9.30 am	**Regulation of SaMD** • Overview of SaMD regulation and key principles • Total product life cycle approach in regulation	**Mr Zhuang Guangyi** Senior Regulatory Specialist Medical Devices Branch Health Sciences Authority Singapore
10.00 am	**Overview of SaMD regulation in** • EU • IMDRF	**Dr Nathan Carrington** Head of Digital Health and Innovation Global Regulatory Policy and Intelligence Roche Diagnostics
11.00 am	**Break**	
11.30 am	**US FDA** • Current regulatory framework • Updates on Pre-certification	**Dr Lesley Maloney** Regulatory Policy Lead - Digital Health International Regulatory Policy Product Development Regulatory Genentech
12.30 pm	**Lunch**	
1.30 pm	**Technical documentary requirements for regulatory submission** • Pre-clinical • Clinical • QMS	**Mr Su Jinyao** Regulatory Affairs Manager Diagnostics Development (DxD) Hub
2.30 pm	**Overview of SaMD Design Verification and Validation**	**Dr John Thornback** Chief Operating Officer Diagnostics Development (DxD) Hub
3.30 pm	**Break**	
4.00 pm	**Team activity** • Risk classification and regulatory requirements	**CoRE and DxD Hub**
5.15 pm	**End of Day 1**	

**The Programme is accurate as of 27 November 2020 and may be subjected to further refinement if necessary before the actual workshop.*

Day 2 (2 Dec 2020)

Time	Agenda	Speaker/Facilitator
8.45 am	**Registration**	
9.00 am	**Clinical evidence** • Clinical investigation data • IMDRF guideline on SaMD clinical evaluation	**Dr Yuri A. Maricich** Chief Medical Officer and Head of Development Pear Therapeutics
9.45 am	**Change Management** • Key considerations in software design change • Version controls and regulatory clearance	**Mr Manan Hathi** Senior Manager Regulatory Affairs – Software Stryker
10.30 am	**Break**	
11.00 am	**Post market surveillance case studies** • AE and FSCA on SaMD	**Ms Siew Jie Yee** Senior Regulatory Specialist Medical Devices Branch Health Sciences Authority Singapore
11.45am	**Cybersecurity** • Principles and practices for SaMD	**Mr Paul Chua** Cyber Security Officer Greater Asia BD
12.30 pm	**Lunch**	
1.30 pm	**Trends in SaMD Development and Regulation in Asia-Pacific**	**Mr Varun Veigas** Regional Regulatory Affairs & Policy Lead, Asia Pacific Roche Diagnostics Asia Pacific Pte. Ltd
2.15 pm	**Regulation of AI products** • Challenges and opportunities	**Mr Lin Anle** Senior Regulatory Specialist Medical Devices Branch Health Sciences Authority Singapore
3.00 pm	**Break**	
3.15 pm	**Guideline on AI in Healthcare**	**Mr Praveen Raj Kumar** Senior Assistant Director Engagement & Strategy Health Regulation Group Ministry of Health, Singapore
3.45 pm	**Photo-Taking Session**	
3.50 pm	**Panel session** • Q&A with regulator, policy maker, developer and industry.	**Moderator** **Prof John Lim** Executive Director Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School **Panelists** **Dr Sethuraman Rama** Director Medical Devices Branch Health Sciences Authority, Singapore **Mr Praveen Raj Kumar** Ministry of Health, Singapore **Dr John Thornback** DxD

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		Dr Nathan Carrington Roche Diagnostics **Dr Roberta Sarno** Manager Digital health and Clinical & Medical affairs Asia Pacific Medical Technology Association (APACMed)
4.25 pm	**Workshop Conclusion**	**Prof John Lim** CoRE
4.30 pm	**End of Workshop**	

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