**Regulation of Software as a Medical Device**

25 - 26 October 2022
**Mode**: Face to Face

**WORKSHOP PROGRAMME**

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**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 as a medical device
- 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

## 25 – 26 October 2022

**Programme**

**Day 1 (25th October)**

| Time | Agenda | Speaker/Facilitator |
|---|---|---|
| 8.00 am | **Registration** | **Attendees** |
| 8.30 am | **Welcome Address** | **Prof John Lim**<br>Executive Director<br>Centre of Regulatory Excellence (CoRE)<br>Duke-NUS Medical School |
| 8.40 am | **Workshop Briefing and Introduction to SaMD** | **Mr Sheikh Muhd**<br>Senior Education Associate<br>Centre of Regulatory Excellence (CoRE)<br>Duke-NUS Medical School |
| 9.00 am | **Overcoming Challenges in the Medical Device Regulatory Environment** | **Mr Nichol Lim**<br>Head of Consulting<br>(Singapore)<br>Stendard, ISO SMART Champion<br>(APAC) |
| 9.30 am | **Regulation of SaMD** | **Ms Maria Cecilia C. Matienzo**<br>Director IV, Center for Device Regulation,<br>Radiation Health and Research<br>Food and Drug Administration<br>The Philippines |
| **10.15 am** | **Tea Break** | |
| 10.30 am | **Overview of SaMD regulation (Part I)** | **Ms Maria Cecilia C. Matienzo**<br>Director IV, Center for Device Regulation,<br>Radiation Health and Research,<br>Food and Drug Administration<br>The Philippines |
| 11.30 pm | **Overview of SaMD regulation (Part II)**<br>• US FDA / EU | **Dr Lesley Maloney**<br>Regulatory Policy Lead - Digital Health<br>International Regulatory Policy Product Development Regulatory<br>Genentech |
| **12.30 pm** | **Lunch** | |
| 1.30 pm | **Technical documentary requirements for regulatory submission**<br>• Pre-clinical<br>• Clinical<br>• QMS | **Mr Aufar Rahadiandy**<br>Country Manager (Indonesia)<br>Stendard, ISO SMART Champion<br>(APAC ) |
| 2.30 pm | **Overview of SaMD Design Verification and Validation** | **Dr John Thornback**<br>Senior Advisor<br>Diagnostics Development (DxD) Hub |

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| **3.45 pm** | **Tea Break** | |
| 4.00 pm | **Team activity**<br>• Risk classification and regulatory requirements | **Attendees / CoRE** |
| **5.30 pm** | **End of Day 1** | |

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**Day 2 (26th October)**

| Time | Agenda | Speaker/Facilitator |
|---|---|---|
| 8.30 am | **Clinical evidence in SamD**<br>• Clinical investigation data<br>• IMDRF guideline on SaMD clinical evaluation | **Dr Reni Yohannan**<br>Quality Engineer<br>Rook Quality Systems |
| 9.15 am | **Software testing**<br>• Testing targets ( unit, integration and system test )<br>• IEC 62304 and Software for Unknown Provenance | **Mr Nichol Lim**<br>Head of Consulting (Singapore)<br>Stendard, ISO SMART Champion (APAC) |
| 10.00 am | **Brainstorming for panel discussion & Networking Session** | **Attendees** |
| **10.45 am** | **Break** | |
| 11.00 am | **Addressing cybersecurity concerns for SaMD**<br>• Principles and practices for SaMD | **Mr Paul Chua**<br>Cyber Security officer<br>Greater Asia<br>BD |
| 11.45am | **Change Management – Life Cycle Management for SaMD**<br>• Key considerations in software design change<br>• Version controls and regulatory clearance | **Mr Nichol Lim**<br>Head of Consulting (Singapore)<br>Stendard, ISO SMART Champion (APAC) |
| **12.30 pm** | **Lunch** | |
| 1.30 pm | **Trends in SaMD Development in Asia-Pacific** | **Mr Allen Chen**<br>Senior Software Quality Engineer<br>Project Manager<br>Rook Quality Systems |
| 2.15 pm | **Regulation of AI products (EU)**<br>• Challenges and opportunities | **Mr Roland Shum**<br>Software Engineer<br>Software Consultant<br>Rook Quality Systems |
| **3.15 pm** | **Tea Break** | |
| 3.30 pm | **Product on AI in Healthcare** | **Mr Andrew Wu**<br>General Manager<br>Lead Software Consultant<br>Rook Quality Systems |
| **4.15 pm** | **Photo taking Session** | |
| 4.20 pm | **Panel session**<br>• Enabling innovations beyond regulatory.<br>  • Trial and experimentation of innovation complying with individual market regulations<br>  • Minimizing failure, no-go decision for market access.<br>  • Global/local collaboration and partnership to spearhead successful adoption. | **Moderator**<br><br>**Mr Sheikh Muhd**<br>Senior Education Associate<br>Centre of Regulatory Excellence (CoRE)<br>Duke-NUS Medical School |

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| | | **Panelist**<br>**Mr Jason Lim**<br>CEO and CO-Founder<br>Stendard, ISO SMART Champion (APAC)<br><br>**Mr Andrew Wu**<br>General Manager<br>Lead Software Consultant<br>Rook Quality Systems<br><br>**Mr Monir El Azzouzi**<br>Founder & CEO<br>Easy Medical Device |
| 5.20 pm | **Workshop Conclusion** | **A/Prof Silke Vogel**<br>Deputy Director, CoRE<br>Senior Associate Dean<br>Graduate Studies<br>Duke-NUS Medical School |
| **5.30 pm** | **End of Workshop** | |

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