

THE MODULES

DAY 1

Introduction to Application of Software in Medical Devices and Healthcare

Introduction to application of software in medical device.

- Overview SiMD and SaMD in healthcare.
- Key applications and market trends.

AI and Machine Learning in Medical Devices and Healthcare

- Introduction to AI and machine learning principles.
- The role of AI in diagnostics, decision support, and patient management.
- Case studies of AI-driven medical device innovations.

Regulatory Landscape for SaMD and AI in Medical Devices

- Global regulatory frameworks: FDA, EU MDR, and other regional requirements.
- Regulatory pathways for SaMD and AI technology.
- Documentation and submission requirements for software and AI technologies

Risk Management and Safety for Software and AI in Medical Devices

Key risk associated with integration of software and AI technologies in medical devices.

- Implementing quality management systems in software and AI development.
- Implementing ISO 14971 for effective risk management
- Best practices for ensuring software safety and reliability.
- Software verification and validation

DAY 2

Cybersecurity, Data Privacy, and Compliance

- Managing cybersecurity risks in software-powered and AI-based medical devices
- Best practices for ensuring patient data privacy (GDPR, HIPAA, etc.)
- Cybersecurity threats in connected medical devices
- Strategies to secure AI models and protect sensitive health data

Clinical and Ethical Considerations of AI in Medical Devices

- Ethical concerns surrounding AI-driven healthcare solutions.
- Clinical evaluation and validation of AI-based diagnostics and treatments.
- Best practices for integrating AI into clinical workflows

Future of AI and Software in Medical Devices and Healthcare

- Emerging trends in AI technology and medical device innovation
- AI in wearable devices and remote monitoring
- Regulatory evolution: the future of compliance for AI-powered medical devices
- The impact of AI and software on the global healthcare landscape



Registration fees: RM 2400pax

For HRDF claimable process, kindly liaise with Ms. Kiru

(0122683818)

kiru.mddev@gmail.com or info@mddev.com.my