Software as Medical Device Training:
Translating research into products

Translation Manchester and The Christabel Pankhurst Institute, Translation Theme are pleased to announce a training opportunity for researchers interested in developing Software as Medical Device (SaMDs).

Hardian Health
Clinical | Digital | Consulting

This training is funded by the Wellcome Trust via the Translational Partnership Award and delivered by clinical digital consultancy firm Hardian Health. Hardian Health is the UK's leading SaMD consultancy, with a track record of regulatory approvals in all major global jurisdictions.

About the course:

Hardian Health will be delivering two live interactive online webinars in early 2024, designed for researchers wanting to learn more about how to commercialise their research and bring SaMDs to market in a regulatory compliant way. These sessions focus on two main aspects of regulatory compliance - technical regulatory factors and clinical evaluation. Prior to attending the webinars, participants will be given access to pre-recorded resources in the form of bitesized videos and short exercises. These resources will provide essential background to the live sessions and will equip participants to get the most out of the interactive training. You will be able to submit questions to the trainers prior to the live sessions based on what you learned from the pre-recorded resources.

Details and dates for the webinars are provided below:

Technical Regulatory webinar
23rd January 2024   10:00 – 12:00

Topics covered
- Intended use & examples of risk classification, comparing EU CE to US FDA
- Benefit risk analysis
- Software development lifecycles
- Quality management systems
- Cybersecurity

Clinical Evaluation webinar
27th February 2024   13:00 – 15:00

Topics Covered
- Clinical evaluation plans
- Literature review
- Clinical investigations
- Clinical evaluation reports
- Post market clinical follow up

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The University of Manchester

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About Translation Manchester and The Christabel Pankhurst Institute

Funded by the Wellcome trust, Translation Manchester was established in 2018 to help researchers translating their discoveries towards healthcare outcomes by providing direct support, as well as funding and training opportunities. The Christabel Pankhurst institute is a unique partnership between the University, NHS, business and local government working together to translate world-leading research into new products and services.

About the trainers

Hardian Health consultancy is committed to help researchers, industry and investors bringing digital solutions to healthcare. Hardian brings together a multidisciplinary team of experienced clinicians, regulatory experts, and specialists in intellectual property, health economics and market strategy. The following team members from Hardian will be delivering this training package.

Regulatory Team

Mike Pogose - Director of Quality Assurance & Regulatory Affairs
Mike specialises in Quality Assurance and Regulatory Affairs for medical devices, particularly SAMD. He has worked in a range of SMEs at various stages of maturity and growth.

Karandeep Badwal - Consultant, Quality Assurance & Regulatory Affairs
Karandeep's extensive experience is primarily within medical devices across a wide range of products from pacemakers to software.

Clinical Team

Dr Hugh Harvey - Managing Director
Hugh is an ex-consultant radiologist and academic. He has helped CE mark over 30 medical devices including artificial intelligence systems, and is widely published and renowned for his insight into the healthtech landscape.

Dr Ankeet Tanna - Senior Clinical Associate
Ankeet is a Cambridge-trained doctor with experience developing machine learning tools for dementia. He has a special interest in the intersection between the clinical validation and health economic value of clinical AI.