MAISI – The Translation of Complex Medical Devices from Early Designs to Clinical Evaluation using Novel Technologies and Innovation

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The realisation of Medical Devices, from early research phase to delivering patient benefits, is inherently challenging. One of the most significant challenges is the gap between academic laboratory prototyping and manufacture of devices suitable for first use in human [1, 2]. This translational gap is attributable to the absence of specialised manufacturing facilities and insufficient understanding of regulatory requirements for performance and safety [3].

The facility for the Manufacture of Active Implants and Surgical Instruments (MAISI), embedded within the St Thomas' MedTech Hub at KCL, will be fully staffed, equipped, and specialised to deliver medical devices (Class II and III) suitable for first use in humans and clinical evaluation. MAISI will be equipped with a large range of state-of-the-art manufacturing processes creating a versatile environment for the manufacture of novel medical device prototypes and components. MAISI's capabilities will extend to include the manufacture of active implantable devices utilising various technologies for hermetically sealed packages, whether ceramic based encapsulated in silicone rubber or titanium cases with metal in glass feedthroughs, or innovative multi-component ceramic-titanium diffusion bonded solutions. The agile manufacturing suite will also offer sub-micron, high precision micromachining and additive manufacturing for both metals and polymers. In addition to the development of implantable medical device prototypes, this will also enable the production of specialised surgical instruments including those with patient specific tailored components and multimodal robotic assistant surgical instruments.

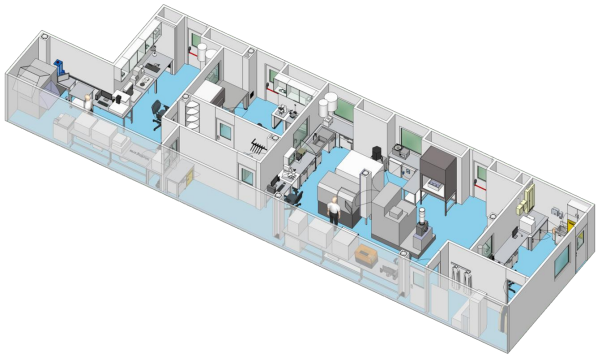

Figure 1: The MAISI facility, a suite of cleanrooms embedded within St Thomas' hospital, dedicated to the manufacture of Class II and III Medical Devices for first use in human.

To streamline the development of new medical devices, the facility will be integrated within a robust Quality Management System (QMS) developed to comply with the relevant standards including ISO 13485 (QMS), ISO 14791 (Risk Management), UK Medical Device Regulations (2002) and EU Medical Device Regulations (2017/475).

MAISI's flexibility also extends through to its pragmatic incremental validation strategy, that will not only facilitate the translation of a device to clinical evaluation, but also create a knowledge base for subsequent projects. This will accelerate process validations and reduce overall translation costs to the projects, hence to the funders, supporting medical research to achieve its full impact and improve people's lives.

The MAISI facility will provide a unique capability within the field of medical device research to accelerate the translation of new devices from conceptualisation through to clinical evaluation. It will revolutionise engagement with clinical, industrial and academic partners to accelerate medical device development and increase the uptake of innovative technologies that will ultimately improve health outcomes and promote the reputation of UK academic research worldwide.

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