Submodule Benchtop Simulation Systems

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STEP4NAMs

Module No.		Lecture Title	Content / Educational Objective	Expert Lecturer
1	**Preclinical evaluation and Bench top test systems**		Introduction to preclinical evaluation of medical technologies and the role of bench top test systems and NAMs	Dr Joaquin Penide
2	**Basic processes for preclinical evaluation of endovascular medical devices**		The key steps in preclinical evaluation of endovascular devices, from bench testing and animal models to safety and performance validation prior to clinical translation.	Dr Janice O'Sullivan
	2.1	Principles of Safety and Efficacy	Principles of Safety and Efficacy for medical technologies, related standards and their application for the development of new medical devices	Dr Joaquin Penide
	2.2	Bench top testing	Bench top testing to bring a new medical technology to the market	Dr Janice O'Sullivan
	2.3	User testing		Dr Joaquin Penide
	2.4	Design Control and Risk management	Design control for medical devices and risk minimizing approach for preclinical evaluation	Gerardine Timoney
	2.5	Regulations and bench top test systems	The role of the regulatory approval process on bench-top test system requirements. EMA and FDA overview	Niamh Nolan
	2.6	GLP	Introduction to Good Laboratory Practice	Dr Janice O'Sullivan
	2.7	Biocompatibility testing	To understand the principles and regulatory framework of biocompatibility testing for med devices	Dr Janice O'Sullivan
3	**Bench top test systems**		Principles for the validation of bench top test systems	Dr Kohyar Yazdanpanahardakani
	3.1	Vascular models	Introduction to the design of bespoke vascular models for testing cerebrovascular devices	Dr Kohyar Yazdanpanahardakani
	3.2	Imaging technologies	Role of imaging technologies in the creation and validation of bench top test system. Practical activity with 3D Slicer	Dr Kohyar Yazdanpanahardakani
	3.3	Validation of bench top test systems	Various validation methods for bench top test systems aimed to test endovascular devices	Dr Kohyar Yazdanpanahardakani
	3.4	Blood analogues	Fundamentals of replication of blood clots to simulate acute ischemic stroke	Dr Sharon Duffy