

Scientific/Educational Workshop

Workshop information

Workshop responsible:

Nick Donaldson

Workshop title:

The medical device regulations limit innovation in rehabilitation

Workshop goals:

The aim of this workshop is to investigate to what extent the regulations are limiting the introduction of innovative methods in rehabilitation. Commercialising new products for rehabilitation is often difficult for several reasons: the number of customers may be small, the time taken to prove efficacy may be long, provision of technical support may be expensive, and so on. The added increasing cost and delay caused by the regulations is probably deterring companies from developing new products.

The speakers will describe case studies with the emphasis on the business. The difficulty will depend on the risk class for the products, and there are speakers to describe all classes from 1 to 3. After the presentations, we will have a round-table discussion to consider the common themes, what researchers can do to improve the situation, and what changes might be recommended to increase the clinical and commercial benefits from R & D without jeopardising patient safety.

This workshop is relevant to those who want to start companies, researchers who want to understand how to get their new devices to patients, those from companies that want to improve their product development, and those who would like to see changes to the medical device regulations.

Speakers:

Nick Donaldson, Steven Crook, Alan Johnson, Lise Pape, Patrick Hall, John H Spensley, Conor Mulrooney

Start Time	Speaker	Title	Device Class
10.00	Prof. Nick Donaldson, UCL Implanted Devices Group	Introduction	
10.15	Steven Crook Odstock Medical Ltd	Regulations applied to surface electrode stimulators: changes over the years	2
10.45	Alan Johnson, Technical Director, Tactiq Limited	Optimising development for regulation Minimising the regulatory burden by considering the intended use, or phasing intended uses.	
11.15	Break		
11.30	Lise Pape, Walk with Path	A case study: medical wearables for walking	1
12.00	Patrick Hall, Development Director, Maddison Product Design	Decision making in medical device design – a product designers perspective	
12.30	Lunch		
13.30	John H Spensley, Managing Director, Finetech Medical Ltd.	Implants for small patient groups Simple implants can improve quality of life after spinal cord injury but there are barely enough patients to keep up with the demands from the regulators.	3
14.00	Conor Mulrooney, Chief Operating Officer, Phagenesis Limited	From Bench to Bedside - the Role of Regulations The role of regulatory review and design control infrastructure within academic research, start-ups and spin-outs: planning new business.	2
14.30	Break		
14.45	Discussion: all		
15.45	Prof. Nick Donaldson	Concluding remarks: recommendations	