CSMD 2024

Workshop:
Clinical Evidence Requirements and Data Management over the Medtech Product Lifecycle

28 May 2024 | London, UK

Preliminary Program

13:00	Welcome Coffee
13:10	Welcome Address & Introduction Helene Quie *(CSMD2024 Conference Chair)* Amie Smirthwaite *(Pre-Conference Workshop Lead)*
13:30	**Interactive Workshops, 1st Round** (30 min each, attendees pick 2 out of 4 topics) **Stream 1: New Product Development - Defining Clinical Evidence Requirements Based on "State of the Art"** **Facilitators**: Sally Sennitt *(Medical Director, RQM+ Trial Services)* Dirk Steenmans *(Global Head, Clinical and Post Market Practice)* Tunvez Boulic *(Product Manager, Giotto.ai)* *Attendees will explore tools and techniques to define clinical evidence requirements based on user needs and state of the art treatment options. Includes hands-on use of AI literature search tools to optimize efficiency.* **Stream 2: Clinical Study Design for Regulatory Approvals and Market Access** **Facilitators:** Danielle Giroud *(CEO, MDClinicals)* Helene Quie *(CEO, QMed Consulting)* *Strategies to ensure clinical investigations meet requirements for regulatory and market access purposes, based on example case studies* **Stream 3: Enhanced Clinical Evidence Generation Through PMCF Studies** **Facilitators:** Rich Holborow *(Global Head of Clinical Compliance, BSI Notified Body)* Amie Smirthwaite *(SVP, Scientific Affairs, RQM+)* *Using PMCF as an opportunity to answer key research questions to addressed residual risks and unanswered questions arising from the clinical evaluation.* **Stream 4: Post Market Surveillance, Reporting and Risk Management** **Facilitators:** Ashley Stratton Powell (*Expert Assessor in Benefit-Risk Evaluation, Medicines and Healthcare Products Regulatory Agency (MHRA)* Sarah Contu *(Product Manager, Giotto.ai)* *Designing and managing an effective system for postmarket surveillance, adverse event reporting, and risk management for medical devices to ensure patient safety and regulatory compliance.*
15:00	Coffee Break (Delegates Change Stations)
15:30	**Interactive Workshops, 2nd Round**
17:00	Panel Discussion with the Leaders of the Workshop Summarizing the Results / Key Points
17:45	Closing Remarks
18:00	Drinks Reception
19:00	Dinner Event with Keynote Speaker Danielle Giroud (not included in the Pre-Conference Workshop fee)