Drug Device Combinations and Other Technologies (Module 18)

About the Module Leader

Jason Collins BSc (Hons), MSc MTOPRA, Director, Regulatory Affairs, ESPL Regulatory

He has been in consultancy since 2011 during which time he has provided support to clients across a variety of regulatory activities involving both medicines and medical devices, including clinical development, scientific advice (EMA, FDA, and EU national) and Regulatory Agency negotiation right the way through to product authorisation and life cycle management. Jason has been responsible for preparation and submission of briefing documents (to support Scientific Advice Meetings), orphan designation applications, documentation for CTAs, including IBs and IMPDs, as well as preparation of documentation and management of EU MAA submissions (inc. national and DCP submissions) and US NDA and INDs. In addition, he has prepared regulatory strategies and documentation for Medical Device technical files, as well as conducted training strategies on medical devices and drug device combination products. Jason has also been responsible for a Quality Management System (QMS), including reviewing, updating, maintaining and training staff on the quality procedures, and managing external contractors. He also has responsibility for managing patient information leaflet user testing and has conducted numerous user tests which have supported national, decentralised and centralised applications in the EU. Jason has an eye for electronic/technical documentation and has written templates and databases for the company and clients.

After degree and postgraduate studies, Jason began his regulatory career at Stiefel Laboratories in 1999, servicing the export markets (Ireland, Eastern Europe, Middle East and Africa). In 2004 he moved to Allergy Therapeutics as Regulatory Affairs Officer, later becoming Regulatory Affairs Manager, responsible for all regulatory affairs activities including new product development, life cycle management and regulatory operations across the company.

During his time as a regulatory consultant, Jason has provided support across a broad range of projects covering both medicinal products (including several biologicals) and medical devices, supporting numerous clients in relation to preparing documentation, managing projects (strategy, early phase development, INDs, MAAS), scientific advice meetings and has conducted regulatory training for clients.