



## FivePharma Presents

Workshop Title	Drug registration in EU
Workshop Code	REGISTER500
Duration	1 days
Venue	Vilnius, Lithuania
Presenter	Aidan Madden BSc MSc Qualified Person, Certified Auditor, European Union Pharmaceutical best practices Expert
Company	FivePharma Kilkenny Ireland fivepharma.com
Target Audience	Registration Departments Medical Departments Quality Assurance Quality Control Compliance Regulatory Affairs
Workshop Contents	<p><b>Day 1</b></p> <ul style="list-style-type: none"> <li>● The history of Pharmaceuticals and Medicine and the emerging need for regulations</li> <li>● Historical and recent disasters and their impact on the development of Global and EU rules and regulations</li> <li>● The EU CTD Dossier – Discussion on the format and structure of the EU CTD dossier.</li> <li>● The EU CTD Dossier – Discussion on the Module 3 Quality section of the EU CTD Dossier.</li> <li>● Application procedures within the EU – The Decentralised Procedure</li> <li>● Application procedures within the EU – The Mutual Recognition Procedure</li> <li>● Application procedures within the EU – The Centralised Procedure</li> </ul>

	<ul style="list-style-type: none"> <li>● Application procedures within the EU – National Applications</li> <li>● Comparability protocols for Biopharmaceuticals</li> <li>● EU clinical trial submissions – content and format of EU CTA submissions.</li> <li>● The regulatory green light process in Clinical Trials.</li> <li>● Legislation governing medicinal products within the EU</li> <li>● The Scientific Advice process in the European Union</li> <li>● EU legislation for medicinal products - Operational aspects of the sunset clause</li> <li>● Product Lifecycle Maintenance within the EU</li> <li>● The new pediatric legislation within the EU.</li> <li>● Pharmacovigilance requirements within the EU.</li> <li>● Risk Management medicinal products within the EU</li> <li>● Package leaflet and labelling requirements within the EU</li> <li>● Regulatory Compliance, change control and maintaining compliance with the approved dossier.</li> <li>● An introduction to medical device directive – An introduction to the European medical device legislation. It will explain the directives and which products are covered, the involvement of Notified Bodies, how to choose one and outline what a manufacturer must do, plus the documentation necessary to apply for the CE Mark.</li> <li>● Managing the revisions to the medical device directive - assess how to anticipate how the revisions will affect you and how to adapting business practices to meet the new requirements and overcome the challenges of working within the new regulatory framework.</li> <li>● Drug Device combinations – regulation within the EU. A very important example of a drug device combination product is the drug eluting stent, which has now become the most widely used modality for coronary stent re-vascularisation. This discussion focuses on our experience in the registration of these products in EU.</li> <li>● Post marketing surveillance and vigilance for medical devices and IVD's - gain critical insights on key post market surveillance and vigilance challenges. Analyse the new med dev vigilance guideline and understand how you need to meet the requirements PMS obligations: What processes do you need to put in place? Understand PMS as an integral component of your risk and quality management systems Determine how, why and when to conduct PMS and develop PMS systems Assess vigilance requirements for clinical investigations &amp; post market clinical studies.</li> <li>● Is my product a cosmetic or drug? - Europe, the USA and the rest of the affluent West are increasingly interested in the medicinal use of cosmetics. This seminar will discuss the grey</li> </ul>
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area between cosmetics and drugs, including the latest statutory procedures and how Industry can work within the Regulations.

- Functional and medicinal Food registration within the EU – Discussion on the different categories of same.
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#### **Workshop Team Exercises:**

- A series of scenarios are presented to the delegates. Each scenario describes a registration objective, delegates are asked to devise a registration strategy and the approaches are discussed at the end.

#### **Quiz Content:**

- A series of quizzes are presented based on delivered content, delegates work in groups to answer the questions
- Questions are then discussed and corrected

#### **Assessment of Learning Outputs from this Workshop**

- The Quizzes described above will be signed by delegates and corrected and countersigned by the tutor as evidence of this requirement.