



FivePharma Presents

Workshop Title	Importing pharmaceutical products into the EU from third countries
Workshop Code	IMPORT400
Duration	2 days
Venue	Vilnius
Presenter	Aidan Madden BSc MSc Qualified Person, Certified Auditor, European Union Pharmaceutical best practices Expert
Company	FivePharma Kilkenny Ireland fivepharma.com
Target Audience	Quality Assurance Quality Control Supply Chain Buyers Compliance Regulators
Workshop Contents	<p>Day 1</p> <ul style="list-style-type: none"> ● The history of Pharmaceuticals and Medicine and the emerging need for regulations ● Historical and recent disasters and their impact on the development of Global and EU rules and regulations ● Global and EU Legislative and Regulatory Framework for Pharmaceutical and Healthcare products Manufacturing ● Interrelationship between ISO, EMEA, FDA, ICH, WHO, Ph Eur, USP and PIC/S ● EU GMP Guide, CE Marking, FDA Pharmaceutical Regulations, FDA Devices Regulations ● The relationship between GMP and Good Distribution Practices (from raw materials to the patient) ● ICH Q7A

- ICH Q9
- ICH Q10
- EU Guide Volume IV Parts I and II
- FDA Legislation and the CFR
- FDA Expectations
- EU Regulatory Inspectors Expectations
- Emerging Regulatory Initiatives (including PAT, Risk Analysis, FMEA)
- Personnel Responsibilities
- The increased role of Management, Management Responsibility and Corporate Governance
- History of Regulatory Affairs
- Regulatory Legislation and Guidance
- EU and other Regulatory Bodies
 - EMEA
 - Medicines and Healthcare Regulatory Authority (UK)
 - Irish Medicines Board (Ireland)
 - EDQM
 - ICH
- Regulatory Strategies
- Regulatory Considerations
- Dossier Components
- Clinical Trials
 - IMP Manufacture
 - IMP Dossier
 - EU IMP Qualified person Batch Release
 - EU Clinical Trials

Day 2

- Commercial Batch Release
 - Considerations for the Active Ingredient
 - Considerations for the finished dosage form
 - Assessment of Manufacturing Site
 - Auditing the Manufacturing Site
 - The meaning of 'Equivalence' within EC GMP
 - Mutual Recognition Agreements
 - EC/EU/EMEA interrelationship explained
 - EU batch Testing
 - Test Methods Validation
 - QP Certification and the Manufacturing Licence establishment
 - QP Responsibilities
 - Pharmacovigilance
 - Product Quality Review
 - Batch Recall

● Stability Studies

Workshop Team Exercises:

- A series of scenarios are presented to the delegates. Each scenario describes a problem(s) identified in an EU based manufacturing operation by either a self inspection or a regulatory audit.

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.