



Training Workshop Agenda

Workshop Title	Good Manufacturing Practices for Pharmaceuticals and Pharmaceutical Ingredients
Duration	1 day
Venue	Worldwide, in company or public
Presenter	Aidan Madden BSc MSc Qualified Person, Certified Auditor, European Union Pharmaceutical Best Practices Expert
Training Company	www.fivepharma.com
Target Audience	Pharmaceutical Industry staff including technicians, supervisors and managers

Workshop
Contents

General Content

- The history of Pharmaceuticals and Medicine and the emerging need for regulations
- Historical and current disasters and their impact on the development of rules and regulations
- 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
- EU Guide Volume IV Parts I and II
- FDA Legislation and the CFR
- FDA Expectations
- IMB Expectations
- Emerging Regulatory Initiatives (including PAT, Risk Analysis, FMEA)
- Personnel Responsibilities
- The increased role of Management, Management Responsibility and Corporate Governance
- Premises layout and Equipment
- Current Controlled Documentation best practices
- Key aspects of production systems
- IMB Hot Topics

Critical Quality Systems

- Change Control
- Validation of Products, processes, instrumentation, utilities and Equipment
- Deviation Management
- Testing

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.