Internal and External Auditors for the Pharmaceutical Industry Course

Syllabus, Rev.1

Day 1 – Regulatory Framework and ISO 19011 Principles	
Module	Topics
Session Kick-Off	• Introductions • Course objectives and expectations

Regulatory framework (FDA and EU)	• Internal Audits requirements according to:
	  ○ FDA Guidance for Industry Quality Systems Approach to Pharmaceutical CGMP Regulations
	  ○ EudraLex Vol 4
	• Introduction to Q7A
	• Excipient applicable requirements

Auditing Basics and ISO 19011:2018	• Definitions • Principles of Auditing • The auditees responsibilities • Auditor/Lead Auditor Responsibilities • Auditor Training • Initiating Audit • Preparing Audit Activities • Conducting Audit Activities • Preparing and Distributing Audit Report • Completing Audit • Conducting Audit follow-up
Preparing Audit Activities	• Pre-Audit planning • Applicable resources • Preparing checklists or working documents • examples from actual Internal/external audits
Conducting Audit Activities	• Communicating During Audit • Communication - Difficult Situations • Reviewing Documented Information • Note Taking
Conducting Audit Activities	• Collecting and verifying information – Interviewing • Interviewing Techniques • Interview Mistakes

Day 2 –ISO 19011 Principles - Continuation	
Module	Topics
Determining audit conclusions	• Generating audit findings • Evaluating and recording audit findings and non-conformities (examples from Internal and external audits in the Pharmaceutical Industry)
Audit Findings	• Finalize Audit Findings • Determining audit conclusions • Recording and presenting audit result • Escalation of findings in a global organization
Audit Closure	• Audit report writing • Preparing and Distributing Audit Report • Completing the Audit • Follow-up and corrective action

Day 2 – Special focus areas for an API/Excipient Audit	
Module	Topics
API Audit	• Agenda preparation • Special focus areas during the tour • Special focus areas during document review
Excipient Manufacturer	• What to expect and how to prepare? • Special focus areas during the tour • Special focus areas during document review
Session Wrap-Up	• Feedback • Final Exam instructions
Final Exam	Exam • Delegates must attend the 2 days training and pass the exam to receive a Certificate of Attendance

Academic hours: 19