



APPENDIX 1 COURSE PROGRAMME

Day 1

08.30 – 09.00 Registration

'Company Audit Programming'

09.00 – 09.45 Session 1: Course Introduction and Objectives

09.45 – 10.30 Session 2: Audit Scene Setting

10.30 – 10.45 Refreshment Break

10.45 – 11.00 Session 3: Teamwork: What I Want to Know Is

11.00 – 12.00 Session 4: Audits and the Quality System
Session 4: Teamwork: Different Types of Audit

12.00 – 12.30 Session 5: The Use of Risk Management in Auditing

12.30 – 13.15 Lunch

13.15 – 13.45 Session 6: Exam and Certification Process Briefing

13.45 – 14.15 Session 7: Teamwork: Introduction to Terminology

14.15 – 15.00 Session 8: Teamwork: The Difference Between External Audits and Internal Audits

15.00 – 15.45 Session 9: Teamwork: The Audit Process

15.45 – 16.00 Refreshment Break

16.00 – 16.30 Session 10: Teamwork: Auditing the Audit System

16.30 – 17.00 Session 11: Teamwork: Evaluating the Audit System

17.00 – 17.30 Session 12: PIC/S, EU, FDA Audit Standards and Procedures

17.30 – 18.15 Session 13: Technical Standards and Guidelines

18.15 – 18.30 Tutor Meeting with Tutees for Continual Assessment

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Day 2

08.00 – 08.30 Specimen Exam Paper and Feedback

'Auditor Skills and Competencies'

08.30 – 09.10 Session 14: The Principles of Auditing

09.10 – 09.45 Session 15: Teamwork: What Makes a Good Auditor?

09.45 – 10.15 Session 16: Teamwork: How do you Assess the Competence of an Auditor?

10.15 – 10.30 Refreshment Break

10.30 – 11.30 Session 17: Communication Skills

11.30 – 12.00 Session 18: Cultural Differences and Body Language

12.00 – 12.30 Session 19: Teamwork: Self-Assessment

12.30 – 13.15 Lunch

13.15 – 13.45 Session 20: Developing and Using Aide-Mémoires

13.45 – 14.45 Session 21: Other Useful Techniques and Advice

14.45 – 14.55 Session 22: Introduction to Systems Auditing

14.55 – 15.15 Session 23: Teamwork: Pharmaceutical Quality Systems Audits – What to Look For

15.15 – 15.30 Refreshment Break

15.30 – 16.20 Session 24: ICH Q10 Pharmaceutical Quality Systems

16.20 – 16.50 Session 25: The Detailed Planning of the Audit

16.50 – 17.10 Session 26: Teamwork: Gathering Information

17.10 – 17.35 Session 27: Teamwork: Selecting the Team

17.35 – 18.00 Session 28: Teamwork: Audit Logistics

18.00 – 18.30 Tutor Meeting with Tutees for Continual Assessment

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Day 3

08.00 – 08.30 Review of Homework

'Conducting the Audit Including ICH Q10'

08.30 – 09.15 Session 29: Teamwork: Create an Audit Plan

09.15 – 10.00 Session 30: The Introductory Meeting

10.00 – 10.15 Session 31: Auditing Materials Management

10.15 – 10.30 Refreshment Break

10.30 – 11.30 Session 32: Teamwork: Materials Management Audit
Session 32: Teamwork: Audit Observations

11.30 – 12.30 Session 33: Teamwork: Auditing the PQS (ICH Q10) and Elements of the PQS

12.30 – 13.15 Lunch

13.15 – 14.30 Session 33: *(continued)*

14.30 – 15.15 Session 34: Teamwork: Ranking the PQS Observations

15.15 – 15.30 Refreshment Break

15.30 – 18.15 Session 35: Teamwork: Topic of Choice

18.15 – 18.30 Tutor Meeting with Tutees for Continual Assessment

Day 4

08.00 – 08.30 Specimen Exam Paper and Feedback and Review of Homework

08.30 – 09.30 Session 36: Writing Audit Observations

09.30 – 10.00 Session 37: The Close-Out Meeting

10.00 – 10.15 Refreshment Break

10.15 – 11.15 Session 38: Teamwork: Sharing Best Practice on Report Writing

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11.15 – 12.30 Session 39: Close-Out Meeting Role Play Exercise

12.30 – 13.15 Lunch

13.15 – 15.15 Session 40: Close-Out Meeting Role Play Exercise

15.15 – 15.30 Refreshment Break

15.30 – 16.00 Session 41: Audit Follow Up

16.00 – 16.30 Session 42: New Developments for Auditors

16.30 – 16.45 Session 43: Final Questions and Answers

16.45 – 17.15 Session 44: Key Messages and Close of Course

17.15 – 17.30 Tutor Meeting with Tutees for Continual Assessment

Day 5

IRCA Examination

08.30 – 10.00 Tutors' Open Discussion and Exam Preparation Self-Study

10.00 – 10.15 Break

10.15 – 10.30 Exam Briefing

10.30 – 13.00 2 hour IRCA Exam

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