J E M O Ltd

HOW TO DO EFFECTIVE INTERNAL QUALITY AUDITS TO ISO 13485

INTRODUCTION

It is designed for existing auditors who require some refresher training and for people new to internal auditing and provides:

- Understanding of the requirements of ISO 9001: 2008
- Understanding of ISO 13485:2003 and CFR 820
- Instruction and practice in auditing to these standards using the guidance provided in ISO 19011: 2002 – Guidelines for quality and/ or environmental management systems auditing

The course includes live auditing of existing management systems.

Course structure

The course is structured in a series of build-up modules which provide a sound understanding of:

- ISO 9001: 2008 – the baseline quality management system
- ISO 9000: 2005 – the terminology and principles underpinning ISO 9001
- ISO 13485: 2003 and CFR 820 – the requirements for medical devices to comply with EU and US statutes applicable to Class 1 medical devices
- How to do compliance audits in a constructive and value-adding manner

An optional extra is the inclusion of a module on ISO 9004: 2000 – which provides guidance on continual improvement – not considered a part of a regulated system, but which can provide substantial cost savings and other business benefits.

LEARNING OBJECTIVES

At the conclusion of the course, attendees should be able to:

- Understand the principles and application of ISO 9001, ISO 13485 and CFR 820 for internal auditing purposes
- Use the ask-look-check-record technique for seeking the true state of the quality management system
- Use forward and trace-back techniques for auditing a process based system
- Understand the component parts of a quality management system process and how the processes inter-relate
- Establish audit checklists in the same sequence as the process
- Establish an audit plan which ensures an efficient audit
- Use the most appropriate approach for obtaining information from the auditees
- Report the audit findings in a constructive manner and categorise any nonconformities and improvement opportunities found
- Put the audit findings and possible corrective actions into a business impact matrix (cost versus benefit)

COURSE DELIVERABLES

The course should provide a number of trained auditors who can be utilised immediately to fulfil the audit programme.

It will also provide a number of completed audits arising from the practical auditing sessions

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WHAT THE DELEGATES ARE PROVIDED WITH

Each delegate is given a set of course notes which include all the PowerPoint presentations used by the tutor (a data projector is used and can be provided by us).

They are also provided with copies of relevant standards (for copyright reasons these must be returned at the end of the course), and other useful reference documents.

THE COURSE TUTOR

The course is run by Jeff Monk FCQI, CQP who is an IRCA Registered Corporate Auditor, QMS 2000 Lead Auditor and PQG listed PS 9000 Pharmaceutical Lead Auditor (Cert No A001154). He has many years experience of training auditors at all levels up to and including IRCA Lead Auditors in many parts of the world. He is an audit team leader auditing for various pharmaceutical and medical device companies in the USA and Ireland and AJA Registrars a UKAS accredited international certification body. He regularly performs audits of medical device equipment manufacturers and suppliers of components to the pharmaceutical industry.

OPTIMUM NUMBER OF DELEGATES

The course is designed for 6 people who will work in pairs during the live auditing.

THE TEACHING METHODS

We employ accelerated learning techniques which blend instructive presentations with hands-on “explore and discover”. Using carefully facilitated practical exercises our experience obtained in many countries is that this helps maintain the delegates’ interest and greatly enhances their knowledge retention. The practical auditing is carried out “real time” and the audit results are constructively reported to the responsible management if practicable.