FINAL DOCUMENT

Title: Training Requirements for Auditors

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GLOBAL HARMONISATION TASK FORCE

GUIDELINES FOR REGULATORY AUDITING OF QUALITY SYSTEMS OF MEDICAL DEVICE MANUFACTURERS

SUPPLEMENT No. 3

TRAINING REQUIREMENTS FOR AUDITORS: 2000

FINAL DOCUMENT

1.   Introduction

This document has been written to provide assistance in the application of the 'Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers; general requirements' and should be read in conjunction with that document, [section 10.2.3(b)].

Note: Terms written in italics in the main body of the document are defined in section 3 Definitions

2.   Scope

The document describes in more detail *training elements* required to:

         i   prepare an individual to be an *auditor*;

         ii   qualify *auditors* to conduct regulatory *audits* of medical device *manufacturers' quality systems*; and

         iii   maintain their qualifications.

3.   Definitions

Reference should be made to the definitions given in 'Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers: General requirements'.

3.1 Training elements

Training elements are topics within a training programme that describe the content for addressing a particular training need. The topic may contain information, *regulatory requirements*, policies and technical data used for learning and developing skills and competencies as listed in clause 10.2.3 (b) of the 'Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers: general requirements' .

4.   General Principles

The purpose of *auditor* training is to facilitate the transfer of the information described in section 10.2.3 of the 'Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers: general requirements' and 5.1 below.

Based on the principle that auditing may be team activity, training should be split into a number of *training elements*. Some of these elements will be applicable to all trainees while other elements will be applicable only to some trainees, depending on their level of experience.

Training needs should be identified and monitored for each individual *auditor*. A training record should be maintained for each *auditor*. The effectiveness of training should be evaluated.

Team leaders also need *audit* training as well as training in their role of leading an *audit* team.

5.   Training program for auditors

5.1 Basic training elements for auditors

5.1.1 The following are suggested as basic *training elements* for individuals to become *auditors*:

    (a)   Principles and applications of *quality systems* and auditing;

    (b)   Auditing techniques, including interviewing, collection, documentation and reporting of *quality audit observations* and non-conformities;

    (c)   Policies and procedures of the *auditing organisation*.

5.1.2 The following are suggested to qualify *auditor*s to conduct regulatory *audit*s of medical device *manufacturer'*s *quality systems*:

(a)   The legal framework, including the *regulatory requirements*, their enforcement, and the role of the *auditing organisation*;

(b)   Understanding and application of laws and *regulatory requirements*;

(c)   Principles and applications of *quality systems* and auditing for medical device *manufacturer*s;

(e)   Overview of medical devices, their intended use(s), safety and risks (see GHTF SG1 document on essential principles);

(f)   Overview of processes commonly used in the design and manufacture of medical devices;

5.1.3 There are some medical devices and their related technologies where the *auditors* will need special knowledge and training in order to carry out their functions. Examples include sterilisation processes, in–vitro diagnostics and tissue processing.

5.2 On–the-job (practical) training

In addition to the classroom training on-the-job or practical training plays an important role in developing competence in conducting *audit*s. Actual experience in conducting *audit*s is essential to developing the ability and expertise to conduct efficient and effective *audit*s.

Some typical methods for on-the-job training in conducting *audit*s include:

    (a)   Having an experienced *auditor* coach and guide the trainee in conducting *audits*;

    (b)   Allowing the trainee to observe one or more *audit*s conducted by an experienced *auditor*;

    (c)   Having the trainee participate in one or more *audit*s with the experienced *auditor*;

    (d)   Having the trainee conduct one or more *audits* with the experienced *auditor* observing and evaluating the *auditor*-trainee, and

    (e)   Having an experienced *auditor* as a mentor who provides on-going coaching and guidance to the trainee throughout the training process.

The rate at which the trainee passes through the stages of observing and participating in *audits* and being observed conducting *audits* should be governed by the trainee's readiness to progress to the next step as agreed by the trainee and the experienced *auditor* evaluating the trainee's progress

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5.3 Continuous Professional Development

Most professional bodies impose requirements for Continuous Professional Development (CPD). All *auditors* should undertake CPD activities including training, participation in scientific meetings, and self-study. Such activities should ensure timely awareness of new or modified *regulatory requirements*, policies, procedures, etc., as well as emerging technologies. Training in emerging technologies may be provided through co-operation with *manufacturer*s developing or using the concepts. Knowledge is also gained from experience in enforcing *regulatory requirements*, implementing procedures, and applying policies and interpretations.

It is recognised that medical device manufacturing constitutes a highly specialised, technology driven and fast evolving sector. Additionally, new *regulatory requirements*, standards, policies, and procedures are introduced, and existing ones are modified from time to time. It is therefore necessary that *auditing organisation*s ensure maintenance of the knowledge and skills of *auditor*s appropriate to cover the scope of regulatory *audit*s of medical device *manufacturer*s, through appropriate and timely training and encouraging Continuous Professional Development.

Auditing organisations may employ different strategies to maintain knowledge and skills of teams conducting regulatory *audit*s, depending on their development policy. Such strategies should comply with the basic principles and criteria for *audit* team competency set out in section 10.2.1(a) and (b) of the 'Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers: general requirements'.

5.5 Advanced training elements for auditors

As *auditor*s gain competence in conducting regulatory *audit*s, advanced and specialised training is recommended. The *auditor*'s needs, weaknesses, and desires for career development may influence specific advanced training courses selected by an *auditor*. Subjects suggested for advanced training include:

(a)   Risk management, including risk analysis;

(b)   Process validation;

(c)   Sterilisation and related processes;

(d)   Electronics manufacture;

(e)   Plastics manufacturing processes;

(f)   Development and validation of software or hardware for devices and manufacturing processes;

(g)   In-depth knowledge of specific medical devices and/or technologies.

5.6 Auditor qualification

The trainee should be evaluated by an experienced *auditor* who is independent from the training programme and who observes the trainee conducting one or more *audit*s. Trainees should be judged competent to conduct *audit*s before they are allowed to work without supervision.   Similarly, *auditor*s should be judged competent to audit highly specialised technologies before working without supervision.