DETAILED REQUIREMENTS FOR AUDITOR/LEAD AUDITOR PHARMACEUTICALS/MEDICAL DEVICES

1. Auditing techniques

Requirements related to auditing techniques are based on ISO 19011

1.1 General

1.1.1 Describe the management process of the auditing program in accordance with ISO 19011

1.1.2 Define, differentiate and analyze various audit techniques/methods (product, process, document review, department, function, system.)

1.1.3 Define, differentiate and analyze between different auditor-auditee relationships (internal, external, first party, second party, third party)

1.1.4 Define, differentiate and analyze between different audit purposes:

Pharma: surveillance revision/inspection and for cause revision/inspection

Medical device: revision for certification, follow-up revision, revision for re-certification ,

1.1.5 Describe and determine how the audit purpose may affect the scope of the audit

1.1.6 Analyze how audits can be used to improve system effectiveness and efficiency

1.1.7 Define and differentiate between different auditing criteria (company internal requirements, standards, regulatory requirements, customer expectations/requirements)

1.1.8 Define and describe roles and responsibilities in the audit process

1.1.9 Identify and describe the auditing principles behind professional conduct and responsibilities – (according to ISO 19011)

1.1.10 Identify connections between requirements in the organization and regulatory requirements related to product authorization/clearance/approval.

1.2 Audit program management

1.2.1 Identify how the objective of the audit program relates to the overall company objectives for quality

1.2.2 Identify and explain the role of management as support to the audit program

1.2.3 Identify how allocation of staff and resources for audits need to be related to budget

1.2.4 Identify minimum requirements for auditor competence

1.2.5 Identify suitable methods to evaluate the audit program

1.2.6 Evaluate and summarize how results from audits will become input to management review

1.3 Audit process

1.3.1 Identify how objectives for an audit relates to the overall audit program

1.3.2 Identify and apply how various audit techniques can be applied in the audit planning

1.3.3 Identify and analyze how various risks may impact audits

1.3.4 Identify and apply different criteria for choosing auditor

1.3.5 Identify and evaluate different types of documentation in the preparation of an audit

1.3.6 Choose and prepare audit tools and aids – checklists and similar

1.3.7 Identify and apply different strategies for audits

1.3.8 Identify and evaluate situations that can affect the scheduling of an audit

1.3.9 Manage the opening meeting

1.3.10 Use various techniques for collection and analysis of data

1.3.11 Identify and differentiate characteristics of objective evidence

1.3.12 Classify evidence in terms of significance and severity

1.3.13 Group and document observations and audit findings and evaluate against audit criteria

1.3.14 Develop and compile an audit summary

1.3.15 Present audit results at closing meeting

1.3.16 Organize and summarize results in the audit report – design and content, effective for organizational use, approved final version

1.3.17 Identify and evaluate different follow-up activities – responsibilities and actions, plans for activities, verification and follow-up of the effectiveness of actions

1.3.18 Identify and apply criteria for closing of the audit

1.3.19 Be knowledgeable about and able to use different models for grading of audit findings

1.4 Auditor competencies

1.4.1 Identify relevant discipline specific knowledge and skills

1.4.2 Identify and apply techniques to handle an audit team

1.4.3 Identify typical conflict situations during an audit

1.4.4 Select and use relevant communication techniques for presentations during audits

1.4.5 Select and use relevant interviewing techniques

2. Regulatory knowledge

2.1 Regulatory requirements for pharmaceuticals and medical devices in EU and US

2.1.1 Identify relation between directive/regulations and quality system requirements

2.1.2 Identify correlation and hierarchy between different regulatory requirements, guidance and standards

2.1.3 Evaluate how patient risk relates to quality system scope (comprehensive, documented, certified etc)

2.1.4 Evaluate how the scope of the organization will affect the requirements that are applicable to the organization.

2.1.5 Apply correct regulatory level related to type of organisation.

2.1.6 Identify and use different interpretation tools and guidance

2.1.7 Identify the product specific quality system objectives

2.1.8 Define differences in regional requirements

2.1.9 Identify how regulatory requirements impact on the scope of the quality system

2.1.10 Analyze and evaluate compliance with regulatory requirements

2.1.11 Define essential requirements

2.1.12 Define and analyze the role of harmonized standards

2.1.13 Define, differentiate and analyze the regulatory responsibilities for different roles (manufacturer, supplier, distributor etc)

2.1.14 Analyze and evaluate the mandatory elements in a quality system

2.1.15 Evaluate and interpret major quality system requirement

2.1.16 Identify documentation requirements and principles

2.1.17 Define and describe how risk management shall be integrated in the quality system

2.1.18 Identify mechanisms for international harmonization (IMDRF, ICH and WHO)

2.1.19 Evaluate the significance of audit findings in relation to regulatory requirements

2.1.20 Evaluate the relevance of corrective actions – case study

2.1.21 Identify techniques for root cause analysis

2.1.22 Define and describe characteristics of true root causes – case study

2.1.23 Identify the basis from an organization to be evaluated that is representative and can be used as the foundation for an audit conclusion

For further details, see Annex 5