

# DETAILED REQUIREMENTS FOR AUDITOR/LEAD AUDITOR PHARMACEUTICALS/MEDICAL DEVICES

## 1. Auditing techniques

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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 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, including sampling
- 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**

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### **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 (full quality system, quality system with exclusion of certain requirements, limited quality system with mainly document control and procedures for complaints)
- 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 the role of the organization, i.e. manufacturer, contract manufacturer, supplier etc.
- 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 regulatory requirements applicable for the auditee
- 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 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**