INTERNAL AUDITING

Ref. Standard ISO19011:2018

Guidelines for Auditing Management Systems

RENAISSANCE

DEFINITIONS

- **Audit** *systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled*
- **Audit Criteria** *set of policies, procedures or requirements*
- **Audit Findings** *results of the evaluation of the collected audit evidence against audit criteria*
- **Audit Conclusion** *outcome of an audit, provided by the audit team after consideration of the audit objectives and all audit findings.*
- **Audit Client** *organization or person requesting an audit.*
- **Auditee** *organization being audited*

DEFINITIONS

- **Auditor** *person with the competence to conduct an audit*
- **Audit team** *one or more auditors conducting an audit , supported if needed by technical experts*
- **Audit Programme** *set of one or more audits planned for a specific time frame and directed towards a specific purpose*
- **Audit Plan** *description of the activities and arrangements for an audit*
- **Audit Scope** *extent and boundaries of an audit*
- **Competence** *demonstrated personal attributes and demonstrated ability to apply knowledge and skills*

DEFINITIONS

- ***Technical Expert*** *person who provides specific knowledge or expertise to the audit team*
- **Observer** *person who accompanies the audit team but does not audit*
- **Guide** *person appointed by the auditee to assist the audit team*
- **Audit Evidence** *records, statements of fact or other information which are relevant to the audit criteria and verifiable*
- **Risk** *effect of uncertainty on objectives*
- **Conformity** *fulfillment of a requirement*
- **Non-Conformity** *non-fulfillment of a requirement*
- **Management System** *system to establish policy and objectives and to achieve those objectives*

AUDIT PRINCIPLES

- Integrity (Ethical Care)
- Fair presentation
- Due professional care
- Confidentiality
- Independence
- Evidence-based approach

AUDIT TYPES

1. Improvement
2. Management system
3. Regulatory Compliance
4. Product Audit

1. 1st Party Audit – Internal Audit
2. 2nd Party Audit – External provider Audit
3. 3rd Party Audit – Certification, accreditation, statutory or regulatory Audit

INTERNAL OR 1ST PARTY AUDITS

- *Auditors* - organization's own staff.
- *Beneficiaries* – organization itself.
- *Style* – generally more relaxed & friendly.
- *Planning* – less demanding as site(s) & process(s) known.
- *Depth* – more detailed audits.
- *Follow-up* – internal issue.

SUPPLIER OR 2ND PARTY AUDIT

- *Purpose – To control over outsourced processes*
- *Auditors* – Supplier's Auditor
- *Style* – Normally critical.
- *Depth* – Specific
- *Follow-up* – compliance the requirement

INDEPENDENT / CERTIFICATION OR 3RD PARTY AUDIT

- *Purpose – To certify the system against the international standard*
- *Beneficiaries* – organization itself.
- *Auditors – A*re qualified Lead Assessor
- Style – Friendly and Positive
- Depth – **Compliance Or Documentation Review** *(Desktop Audit);* An audit to determine the extent to which the documents system meets the requirement of a specific Standards &
- **CONFORMANCE OR SITE AUDIT:** An audit conducted to determine that the quality system is being implemented against the documentation

AUDIT METHODOLOGY

1. Audit Objective, Scope and Criteria
2. Audit program
3. Audit Planning
4. Preparing Work Documents

Conducting On-site audit activities

5. Opening Meeting
6. Collecting & verifying Information
7. Source Verification
8. Generating Audit Findings
9. Nonconformance Report
10. Corrective & Preventive Actions
11. Preparing the Audit Report
12. Closing Meeting

AUDIT OBJECTIVES

The audit objectives define what is to be accomplished by the audit and may include the following:

- Determination of the extent of conformity of the auditee's management system
- Evaluation of the capability of the management system to ensure compliance with statutory, regulatory and contractual requirements;
- Evaluation of the effectiveness of the management system in meeting its specified objectives;
- Identification of areas for potential improvement of the management system.

AUDIT SCOPE

- **The audit scope describes the extent and boundaries of the audit, such as physical locations, organizational units, activities and processes to be audited, as well as the time period covered by the audit.**

AUDIT CRITERIA

- The audit criteria are used as a reference against which conformity is determined and may include applicable policies, procedures, standards, laws and regulations, management system requirements, contractual requirements or industry/business sector codes of conduct.
- e.g. ISO 9001:2015

AUDIT PROGRAMME

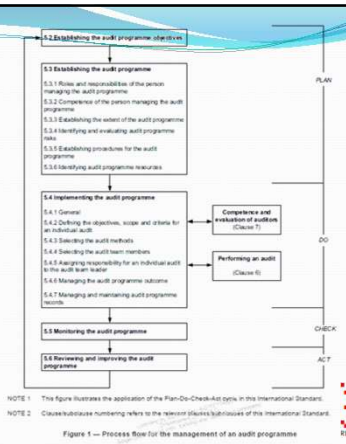


Figure 1 — Process flow for the management of an audit programme

Xyz Co.

MR/4/001
ISSUE 01

A U D I T P r o g r a m

Criteria: ISO 9001:2008 — Audit Year:2009

Prepared by: Mr. Ahmed Ali — Date: 07Jan 2009

Approved by: Mr. Omer

Department	MONTHS OF THE YEAR											
	Jan.	Feb.	Mar.	Apr.	May	Jun.	Jul.	Aug.	Sep.	Oct.	Nov.	Dec.
Management Representative	■					▣						
Marketing			▣									
Store	▣					■						
Production			■									
Packing	▣											
Finished store			■									
Q.C.												

KEY

- Audit Date Planned
- Audit Carried Out And Reported
- Non-Conformities Agreed
- Non-Conformities Stated To Be Corrected
- Closed Out By Follow - up
- Audit Carried Out & Reported No Non-Conformities

AUDIT PLANNING

-The Audit plan shall be prepared by the Auditor

-The Audit plan should cover the following:

a) the audit objectives;

b) the audit criteria

c) the audit scope

d) the dates and places where the on-site audit activities are to be conducted;

e) the expected time and duration of on-site audit activities, including meetings with the auditee's management and audit team meetings;

Continue.....

AUDIT PLANNING

f) The roles and responsibilities of the audit team members and accompanying persons;

g) Logistic arrangements (travel, on-site facilities, etc.);

h) Matters related to confidentiality;

i) Any audit follow-up actions.

XYZ & Co.

INTERNAL AUDIT PLANING

Objective	:	Improve quality management system and compliance as per customer COC
Criteria	:	ISO 9001:2008
Date	:	21-Jan-2009 — Audit No: 05/IQA/09

Date	Time		Scope		Auditee / Person	Auditor
	From	To	Dept.	Requirements		
21-jan-09	9.30	11.00	Marketing	Customer Order Review Customer compliant system Customer feedbacks	Mr. Asif	Mr. Ali
23-Jan	10.00	12.00	Store	Inventory system Traceability Stock taking	Mr. Ali	Mr. Asif
28-Jan	10.00	13.00	Production	Production controls Planning Operating procedures Calibration	Mr. Ali Mr. Asif	Mr. Fahim Mr. Asif
28- Jan	10.00	12.00	Purchasing	Supplier assessment Supplier monitoring Purchase operations	Mr. Saleem	Mr. Asif
02-Feb	14.00	16.00	Management	Documents control IQA MRM Objectives	Mr. Asif	Mr. Fahim

Prepared By : Mr. Ali — Approved By : Mr. Asif

Signature : _____ — Signature : _____

FOR # 19 : Rev # 00

PREPARING WORK DOCUMENTS

- The audit team leader and members should review the information relevant to their audit assignments according to the audit plan and prepare work documents as necessary for reference and for recording audit proceedings. Such work documents may include;

CHECKLISTS: Prepared based on criteria and as per the scope of activities

- To help the auditor safe time & to remember to cover all the main points
- During audit, auditor can note his observation under the checklist which will help him in evaluating the company compliances

Claues	Questions	Yes	No	Notes
4	**Quality Management System**			
4.1	**General Requirements**			
Q1	Processes needed for the quality management system and their application throughout Swiss Pharma has been determined.			
Q2	The sequence and interaction of these processes have been determined.			
Q3	Criteria and methods needed to ensure that both the operation and control of these processes are effective have been determined.			
Q4	The availability of resources and information necessary to support the operation and monitoring of these processes are ensured.			
Q5	processes are monitored, measured and analysed. Actions necessary to achieve planned results and continual improvement of these processes are implemented.			
4.2	**Documentation Requirements**			
4.2.2	**Quality Manual**			
Q6	A quality manual has been established and is maintained.			
Q7	The scope of the manual includes details of and justificationfor any exclusions (exclusions are limited to clause 7). The manual contains or references the documented procedures established for the quality management system. The manual contains a description of the interaction between the processes of the quality management system.			
4.2.3	**Control Of Documents**			
	All QMS documents are controlled.			
Q8	A documented procedure is established to define the controls needed to: Approve documents for adequacy prior to issue. Review and update as necessary and re-approve documents.			
Q9	Ensure that changes and the current revision status of documents are identified.			
Q10	Ensure that relevant versions of applicable documents are available at points of use.			
Q11	Ensure that documents remain legible and readily identifiable.			

CCP/cl 10: Internal Audit Checklist

Audit No6/12 .

Location: Date: Auditor:

Personal Hygiene and Uniforms

	Yes	No	Corrective action		Yes	No	Corrective action
Employees wear proper uniform including proper shoes	☐	☐		Hands are washed thoroughly using proper hand washing procedures at critical points	☐	☐	
Hair restraint is worn	☐	☐		Smoking is observed only in designated areas away from preparation, service, storage and ware washing areas	☐	☐	
Fingernails are short, unpolished and clean	☐	☐		Eating, drinking or chewing gum are observed only in designated areas away from work areas	☐	☐	
Jewelry is limited to simple ring and earrings	☐	☐		Employees take appropriate action when coughing or sneezing	☐	☐	
Hands are washed or gloves are changed at critical points	☐	☐		Disposable tissues are used and disposed of when coughing/blowing nose	☐	☐	
Open sores, cuts or splints and bandages on hands are completely covered while handling food	☐	☐		Hand washing facilities are maintained and provided with hot water, soap and paper towel	☐	☐	

Food Storage and Dry Storage

	Yes	No	Corrective action		Yes	No	Corrective action
Temperature is between 20°C and 22°C	☐	☐		There are no bulging or leaking canned goods in storage	☐	☐	
All food and paper supplies are 6 to 8 inches off the floor	☐	☐		Food is protected from contamination	☐	☐	
All food is labeled with name and delivery date	☐	☐		All surfaces and floors are clean and maintained	☐	☐	
The FIFO (First In, First Out) method of inventory is being practiced	☐	☐		Chemicals are stored away from food and other food related supplies	☐	☐	

Large Equipment

	Yes	No	Corrective action		Yes	No	Corrective action
Food slicer is clean to sight and touch	☐	☐		All other pieces of equipment are clean to sight and touch – equipment on serving lines, storage shelves, cabinets, ovens, ranges, fryers and steam equipment	☐	☐	
Food slicer is sanitized between uses when used with potentially hazardous foods	☐	☐		Exhaust hood and filters are clean	☐	☐	

Refrigerator and Freezer

	Yes	No	Corrective action		Yes	No	Corrective action
Thermometer is conspicuous and accurate	☐	☐		Proper chilling procedures have been practiced	☐	☐	
Temperature is accurate for piece of equipment	☐	☐		All food is properly wrapped, labeled and dated	☐	☐	
Food is stored 6 inches off floor in walk – in	☐	☐		The FIFO (First In – First Out) method of inventory is being practiced	☐	☐	
Unit is clean	☐	☐					

CONDUCTING ON-SITE AUDIT ACTIVITIES

OPENING MEETING

Should be held with the auditee's management.

The purpose of an opening meeting is:

- To confirm the audit plan,
- To provide a short summary of how the audit activities will be undertaken,
- To confirm communication channels, and
- To provide an opportunity for the auditee to ask questions.

COLLECTING AND VERIFYING INFORMATION

- During the audit, information relevant to the audit objectives, scope and criteria, including information relating to interfaces between functions, activities and processes, should be collected by appropriate sampling and should be verified.

SOURCES OF INFORMATION

- Interviews with employees and other persons;
- Observations of activities and the surrounding work environment and conditions;
- Documents, such as policy, objectives, plans, procedures, standards, instructions, contracts and orders;
- Records, such as inspection records, minutes of meetings, audit reports, records of monitoring programmes and the results of measurements. analysis;
- Information on the auditee's sampling programmes and on procedures for the control of sampling and measurement processes;
- Reports from other sources, for example, customer feedback, other relevant information from external parties and supplier ratings;

GENERATING AUDIT FINDINGS

- Audit evidence should be evaluated against the audit criteria to generate the audit findings.
- Audit findings can indicate either **conformity or nonconformity** with audit criteria. When specified by the audit objectives, audit findings can identify an opportunity for improvement.
- The audit team should meet as needed to review the audit findings at appropriate stages during the audit.
- Conformity with audit criteria should be summarized to indicate locations, functions or processes that were audited.

NON-CONFORMANCE REPORTS

The Non-Fulfillment of a Requirement

MINOR NON-CONFORMITY:

May be either a failure in some part of the MS or a single observed lapse in following one item of a company's system.

MAJOR NON-CONFORMITY:

Absence of total breakdown of a system to meet a requirement of a standard or a number of minor nonconformities against one requirement can represent the total breakdown of the system.

OBSERVATION /RECOMMENDATION

Auditor's suggestions / judgments to improve the overall status and effectiveness of QMS.

CORRECTION & CORRECTIVE OR PREVENTIVE ACTION

1. **Correction**

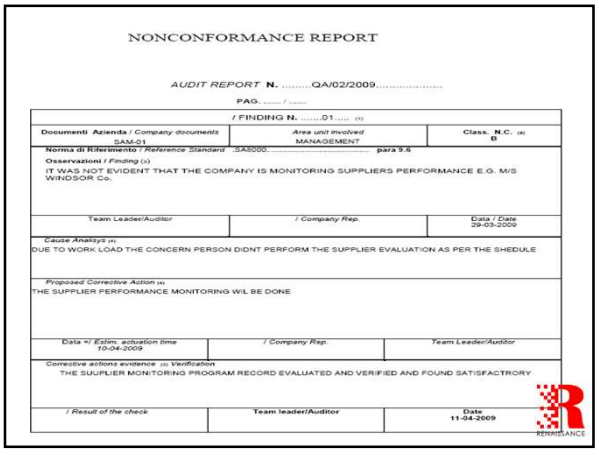
A correction to be done for the in hand problem

2. **Corrective Action**

To eliminate the cause of nonconformities to prevent recurrence.

3. **Preventive Action**

To eliminate the cause of nonconformities to prevent occurrence.



NONCONFORMANCE REPORT

AUDIT REPORT N. .....QA/02/2009.....

PAG. ..... / .....

/ FINDING N. .....01..... (1)

Documenti Azienda / Company documents	Area unit involved	Class. N.C. (3)
SAM-01	MANAGEMENT	B

Norma di Riferimento / Reference Standard SAS000..... para 9.6

Osservazioni / Finding (2)

IT WAS NOT EVIDENT THAT THE COMPANY IS MONITORING SUPPLIERS PERFORMANCE E.G. M/S WINDSOR Co.

Team Leader/Auditor	/ Company Rep.	Data / Date
		29-03-2009

Cause Analysis (4)

DUE TO WORK LOAD THE CONCERN PERSON DIDNT PERFORM THE SUPPLIER EVALUATION AS PER THE SHEDULE

Proposed Corrective Action (4)

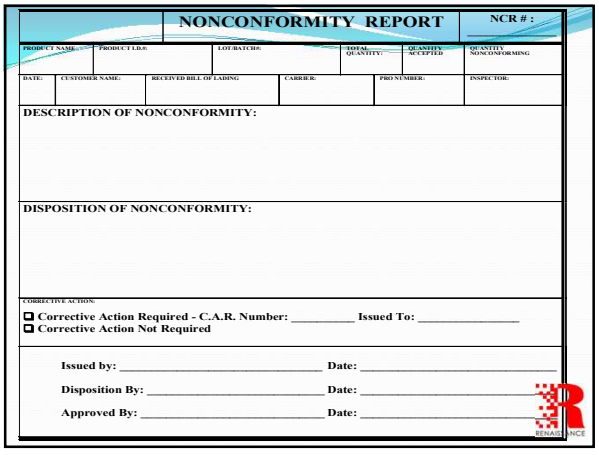
THE SUPPLIER PERFORMANCE MONITORING WIL BE DONE

Data +/ Eplm. actuation time	/ Company Rep.	Team Leader/Auditor
10-04-2009		

Corrective actions evidence (5) Verification

THE SUUPLIER MONITORING PROGRAM RECORD EVALUATED AND VERIFIED AND FOUND SATISFACTRORY

/ Result of the check	Team leader/Auditor	Date
		11-04-2009



NONCONFORMITY REPORT NCR # : _____

PRODUCT NAME:	PRODUCT I.D.#:	LOT/BATCH#:	TOTAL QUANTITY:	QUANTITY ACCEPTED:	QUANTITY NONCONFORMING:

DATE:	CUSTOMER NAME:	RECEIVED BILL OF LADING	CARRIER:	PRO NUMBER:	INSPECTOR:

DESCRIPTION OF NONCONFORMITY:

DISPOSITION OF NONCONFORMITY:

CORRECTIVE ACTION:

☐ Corrective Action Required - C.A.R. Number: _____ Issued To: _____

☐ Corrective Action Not Required

Issued by: _____ Date: _____

Disposition By: _____ Date: _____

Approved By: _____ Date: _____

PREPARING THE AUDIT REPORT

-The audit team leader should be responsible for the preparation and contents of the audit report.

-The audit report should provide a complete, accurate, concise and clear record of the audit, and should include or refer to the following:

- The audit objectives;
- The audit scope
- Audit team members name and date of audit
- Audit scope and criteria;
- Audit conclusions.
- Agreed follow-up action plans, if any;

CLOSING MEETING

- A closing meeting, chaired by the audit team leader, should be held to present the audit findings and conclusions in such a manner that they are understood and acknowledged by the auditee, and to agree, if appropriate, on the timeframe for the auditee to present a corrective and preventive action plan.
- Internal audits in a small organization, the closing meeting may consist of just communicating the audit findings and conclusions. For other audit situations, the meeting should be formal and minutes, including records of attendance, should be kept.

AUDITOR'S RESPONSIBILITIES

- An auditor's job is to:
  - Evaluate the quality system.
  - Carry out assigned audit tasks.
  - Comply with audit requirements.
  - Respect all confidentiality requirements.
  - Collect evidence about the quality system.
  - Document audit observations and conclusions.
  - Safeguard audit documents, records, and reports.
  - Determine whether quality policy is being applied.
  - Find out if the quality objectives are being achieved.
  - See whether quality procedures are being followed.
  - Detect evidence that might invalidate audit results.

POSSIBLE PROBLEM AREAS

1. Assessment of competence.
2. Applicable statutory & regulatory requirements.
3. In the absence of procedures:
   - Are all the processes covered?
   - Do all the work in uniformly?
4. Uniformity handling of storage activities.
5. Data Analysis related to supplier performance
6. MRM, IQA, Quality Objectives compliances

Thank you