

Preliminary API Q1 9th edition audit checklist Spec Q1, 9<sup>th</sup> Edition

Yellow field indicates Soft requirement (as applicable, if necessary)

Orange field indicates NEW (9th edition) requirement

4.1	<b>Quality Management System</b>		
4.1.1	<b>General</b>		
4.1.1	Establish, document, implement and maintain QMS at all times		
4.1.1	Measure effectiveness and improve QMS		
4.1.2	<b>Quality Policy</b>		
4.1.2	Top Management identifies, documents and approves policy		
4.1.2	Policy appropriate and basis for quality objectives		
4.1.2	Communicated, understood, implemented, and maintained		
4.1.2	Statement of commitment to comply and improve QMS		
4.1.3	<b>Quality Objectives</b>		
4.1.3	Management and top management establish		
4.1.3	Established at relevant functions and levels		
4.1.3	Measurable and consistent with quality policy		
4.1.4	<b>Planning</b>		
4.1.4	a. Criteria and methods of QMS determined and effective		
4.1.4	b. Planning of QMS carried out to meet requirements		
4.1.5	<b>Communication</b>		
4.1.5.1	<b>Internal</b>		
4.1.5.1	Communication processes established		
4.1.5.1	Effectiveness of QMS communicated		
4.1.5.1	a. Requirements communicated within the organization		
4.1.5.1	<b>b. Data analysis results communicated within organization</b>	NEW	
4.1.5.2	<b>External</b>		
4.1.5.2	Determine, document & implement external communication process		
4.1.5.2	a. for execution of inquiries, contracts, amendments		
4.1.5.2	b. for product information and nonconformities		
4.1.5.2	c. for addressing feedback and complaints		
4.1.5.2	<b>d. quality plans and changes</b>	Soft	
4.2	<b>Management Responsibility</b>		
4.2.1	<b>Organization Structure</b>		
4.2.1	Top management ensures availability of resources		
4.2.1	Management commitment to QMS and its improvement		
4.2.1	a. Management ensures objects established including KPIs		
4.2.1	b. Management conducts management reviews		
4.2.2	<b>Responsibility and Authority</b>		
4.2.2	Roles and responsibilities defined		
4.2.3	<b>Management Representative</b>		
4.2.3	Top management appoints management representative who:		
4.2.3	a. Ensures processes established, implemented and maintained		
4.2.3	b. Reports to top management on performance of QMS		
4.2.3	<b>c. Initiates actions to minimize nonconformances</b>	NEW	
4.2.3	d. Ensure promotion of awareness of customer requirements		
4.3	<b>Organization Capability</b>		
4.3.1	<b>Provision of Resources</b>		
4.3.1	Determine and provide resources needed for QMS		

# Api Q1 9th Edition Audit Checklist

**Gerardus Blokdyk**

## **Api Q1 9th Edition Audit Checklist:**

*How to Audit the Process-Based Qms* Dennis R. Arter,Charles A. Cianfrani,Jack West,2003-02-01 This book is intended to help individuals involved in managing and conducting audits to ISO 9001 2000 it focuses on auditing as a management process as well as a key driver of continual improvement within an organization an excellent resource for internal auditors it is perfect for novice auditors or those who need a refresher on the fundamentals of auditing This book can be used as a guide to establishing a new audit program or updating one that has been operational for some time the authors participated in integrating the process approach into ISO 9001 2000 and thoroughly understand its implications for auditing a QMS The three main areas of focus in this book include the basics of process based auditing the requirements for establishing and managing an internal quality auditing process and conducting audits One of its best features is the section on auditing worksheets forms checklists and questions Included are useful and adaptable examples from every aspect of auditing such as developing an audit schedule planning an audit writing findings documenting positive and best practices writing an audit report and requesting corrective action the book contains a comprehensive list of questions that auditors can use when conducting quality audits and features this information on the accompanying CD ROM

## **Systems Development Project Audit Checklist** Mark Mitchell,MIS Training Institute (Framingham, Mass.),198?

### **Quality Audits for Improved**

**Performance** Dennis R. Arter,2003-01-01 This book is an excellent reference for learning and applying basic quality auditing principles Examples and checklists throughout the book help make this one of the best single source reference guides Quality practitioners registrars and those preparing for certification exams will find this book to be a useful tool the new edition expands on established techniques and addresses both internal and supplier auditing as it relates to any quality management system including ISO 9001 GMP automotive and others

*The Audit Checklist* ,1992 As the old saying goes If you have no objective any road will take your there So it is with the audit checklist The checklist is the primary tool for providing order to Quality Assurance audit activities With a well planned and well defined checklist success is achievable Without a checklist the auditor has a disjointed disorganized activity and no place to document his or her failed efforts A number of formal quality programs which include audits as one of their program elements require the audit to be performed using a checklist or procedures to document what the auditor reviewed and what he or she found It is the intent of this paper to provide the reader with the some insight as to the value of the checklist the varieties of checklists that can be constructed the pitfalls of improper application and the success that can be achieved when the checklist has been properly researched developed and deployed

**The ASQ Certified Quality Auditor Handbook** Lance B. Coleman,2020-02-01 The value of the ASQ Certified Quality Auditor Handbook Fifth Edition is clear It is designed to help new auditors gain an understanding of the field and prepare for the ASQ CQA exam In addition experienced auditors can refer to it as a helpful reference audit managers and quality managers can rely on it for guiding their auditing programs and trainers and educators can use it for teaching

fundamentals This in depth overview of quality auditing represents auditing practices for internal and external applications It provides practical guidance for both system and process auditors as well Many current topics have been expanded to reflect changes in auditing practices since 2012 with guidance from the recent 2017 update of ISO 19011 In addition readers will find example audit situations stories and review comments to enhance their understanding of the field Topics covered include the common elements of all types of system and process audits quality environmental safety and health Auditing fundamentals including types of quality audits purpose and scope of auditing terms and definitions roles and responsibilities of participants and professional conduct The audit process from preparation and planning to performance and reporting to follow up and closure Auditor competencies including resource management conflict resolution communication interviewing and team dynamics Audit program management and business applications including staffing training and development program evaluation organizational risk management and best practices Quality tools and techniques including problem solving tools process improvement techniques basic statistics verification and validation This book is an encyclopedia of all major bodies of information a new or experienced quality auditor would need It covers both the qualitative and the quantitative which is a strength I can t think of a quality auditor that would not find this work helpful Kim H Pries CRE CQE CSQE CSSBB CMQ OE CQA This handbook will be helpful to those who are new to auditing or require more in depth knowledge of the implementation of an audit program Boxed examples or scenarios provide some of the practical challenges encountered during auditing Govind Ramu ASQ Fellow Co Author ASQ SSGB Handbook Author ASQ CSSYB Handbook Lance B Coleman Sr has over 25 years of leadership experience in the areas of quality engineering Lean implementation quality and risk management in the Medical Device Aerospace and other regulated industries He has presented trained and consulted throughout the United States and abroad Lance is currently a Director of Quality for IDEX Health and Science LLC in Oak Harbor Washington     [Audit Checklists Standard Requirements](#) Gerardus Blokdyk,2018-11-08 Does the Audit Checklists task fit the client s priorities Do you monitor the effectiveness of your Audit Checklists activities What vendors make products that address the Audit Checklists needs How do you keep improving Audit Checklists What are the record keeping requirements of Audit Checklists activities Defining designing creating and implementing a process to solve a challenge or meet an objective is the most valuable role In EVERY group company organization and department Unless you are talking a one time single use project there should be a process Whether that process is managed and implemented by humans AI or a combination of the two it needs to be designed by someone with a complex enough perspective to ask the right questions Someone capable of asking the right questions and step back and say What are we really trying to accomplish here And is there a different way to look at it This Self Assessment empowers people to do just that whether their title is entrepreneur manager consultant Vice President CxO etc they are the people who rule the future They are the person who asks the right questions to make Audit Checklists investments work better This Audit Checklists All Inclusive Self Assessment enables You

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