

ISO 9001:2015 Required Documents Matrix

REQUIRED RECORDS - *Documented information needed to be retained* — providing evidence.

#	Clause	Shortcut	Requirement	Title	Doc #	Rev.	Date	Distribution Location(s)
1	4.4	CONFIDENCE (AS NEEDED)	Documented information to the extent necessary to have confidence that the processes are being carried out as planned.					
2	7.1.5.1	ACCURATE MEASUREMENT RESOURCES	Evidence of fitness for purpose of monitoring and measuring resources.					
3	7.1.5.2	BASIS USED FOR CALIBRATION	Evidence of the basis used for calibration of the monitoring and measurement resources (when no international or national standards exist).					
4	7.2	COMPETENCE OF PEOPLE	Evidence of competence of person(s) doing work under the control of the organization that affects the performance and effectiveness of the QMS.					
5	8.2.3	REQUIREMENTS REVIEW	Results of the review and any new requirements for the products and services.					
6	8.3.2	D&D REQUIREMENTS MET	Records needed to demonstrate that design and development requirements have been met.					
7	8.3.3	D&D INPUTS	Records on design and development inputs.					
8	8.3.4	D&D CONTROLS	Records of the activities of design and development controls.					
9	8.3.5	D&D OUTPUTS	Records of design and development outputs.					
10	8.3.6	D&D CHANGES	Design and development changes, including the results of the review and the authorization of the changes and necessary actions.					
11	8.4.1	EXTERNAL PROVIDER (SUPPLIER) MONITORING	Records of the evaluation, selection, monitoring of performance and re-evaluation of external providers and any actions arising from these activities.					
12	8.5.2	UNIQUE ID	Evidence of the unique identification of the outputs when traceability is a requirement.					
13	8.5.3	UNSUITABLE CUSTOMER PROPERTY	Records of property of the customer or external provider that is lost, damaged or otherwise found to be unsuitable for use and of its communication to the owner.					
14	8.5.6	CHANGES TO PRODUCT OR SERVICE	Results of the review of changes for production or service provision, the persons authorizing the change, and necessary actions taken.					
15	8.6	AUTHORIZED RELEASE	Records of the authorized release of products and services for delivery to the customer including acceptance criteria and traceability to the authorizing person(s).					
16	8.7	N/C & ACTION AUTHORITY	Records of nonconformities, the actions taken, concessions obtained and the identification of the authority deciding the action in respect of the nonconformity.					
17	9.1.1	QMS PERFORMANCE EVALUATION	Results of the evaluation of the performance and the effectiveness of the QMS.					
18	9.2.2	AUDIT PROGRAM RESULTS	Evidence of the implementation of the audit programme and the audit results.					
19	9.3.3	MANAGEMENT REVIEW	Evidence of the results of management reviews.					
20	10.2.2	NATURE & ACTION OF N/Cs	Evidence of the nature of the nonconformities and any subsequent actions taken.					
21	10.2.2	CORRECTIVE ACTION RESULTS	Results of any corrective action.					

Key: D&D = Design & Development | ID = Identification | N/C = Nonconformance

Iso 9001 Sample Document Master List

**International Organization for
Standardization**



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The ISO 9000 Quality System Debby L. Newslow, 2001-02-26 Author is a certified Quality Assurance Lead Auditor who has worked with more than 100 companies seeking ISO 9000 certification One of the only books on ISO 9000 compliance written exclusively for the food industry Examples are based on real world cases although company names and other identifying details are not included to protect privacy These examples can be invaluable to food companies who want to avoid potential pitfalls Relates ISO 9000 to other quality and safety assurance management systems **ISO 9001 for Engineers and Designers** Stephen J. Schoonmaker, 1997 This step by step guide shows engineering professionals how to successfully take advantage of the ISO 9001 standard It covers such critical processes as documentation design output design verification and design validation *International Environment Management* P. Rathnaswamy, 1998 The International Environment Management is a new Phenomena which is fast developing to make sustainable development possible and achievable The International Environment Management comprises International Management Law and institutional organisation for achieving sustainable development at global and national level The term Sustainable Development is widely accepted defining development and environment However there are contradictions and controversies To implement sustainable development it is found difficult to practise it for various reasons which are elaborately discussed in this book There are two approaches to achieve the Sustainable Development and these are through Environmental Laws Agreement Protocols Treaties Declarations and through international organizations like UNO and its agencies National Government Agencies Private Sectors etc In this book a solution is suggested by proposing a new theory of Empowerment of Sustainable Development **Implement ISO9001:2008 Quality Management System** DIVYA SINGHAL, K. R. SINGHAL, 2012-04-02 ISO 9000 series standards have changed the whole concept of quality management methods ISO 9001 2008 QMS standard has been implemented and ISO 9000 series standards have been adopted as national standards or endorsed for use in 178 countries and economies ISO 9001 2008 Quality Management System QMS is based on eight quality management principles and there are various internal and external benefits of implementing this standard whether or not an organization goes for certification This book provides the readers with an accessible and up to date introduction to the essentials of a quality management system discusses what is in the ISO 9001 2008 QMS and shows how the organizations can implement this system With the authors extensive experience in QMS audit training and advisory services the book incorporates basic information on understanding and implementing ISO 9001 2008 QMS and highlights its importance towards making quality the fundamental business principle The text contains plenty of practical tips and guidance on how to implement ISO 9001 2008 QMS in the real world It discusses sample QMS procedures emphasizes the importance of maintaining a value added internal audit system and highlights the necessity of developing the QMS documentation procedures Apart from the regular BBA MBA and diploma courses in Total Quality Management this book is also suitable for Management Development

Programmes in Quality Management and ISO 9001 offered to professionals by many of the B schools **Textbook of Assisted Reproductive Technologies** David. K Gardner, Ariel Weissman, Colin M. Howles, Zeev Shoham, 2008-11-11

Textbook of Assisted Reproductive Technologies is a truly comprehensive manual for the whole team at the IVF clinic Information is presented in a highly visual manner allowing both methods and protocols to be consulted easily The text provides clinical and scientific teams with the A to Zs of setting up an embryology laboratory gives research fellows insight into technical developments and supplies seasoned professionals with a review of the latest techniques and advances New to the Third Edition fully revised and expanded chapters with new information on single embryo transfer artificial gametes pharmacogenetics ISO 9000 Roy M. Chiulli, 2001 If you are switching from using MIL Q 9858 to ISO 9000 and don't want to become an ISO 9000 expert this book is for you Easily read in an hour or two the book provides managers and engineers with a quick basic understanding of these important international standards *Tool and Manufacturing Engineers Handbook: Continuous Improvement* Charles Wick, Ramon Bakerjian, Society of Manufacturing Engineers, 1983 Part of the renowned TMEH Series the book contains hundreds of practical new ways to make continuous improvement work and keep on working quality management guidelines quality and productivity improvement ideas cost reduction tips continuous process improvement plus how to use world class techniques such as TPM TQM benchmarking JIT activity based costing improving customer supplier relationships and more You'll also learn from best practices examples for quality training teamwork empowerment self assessment using Baldrige Quality Award criteria ISO 9000 audits and certification and more

Pharmaceutical Vendors Approval Manual Erfan Syed Asif, 2021-12-12 This book provides stepwise guidance on how to evaluate audit qualify and approve an active pharmaceutical ingredient API and packaging material manufacturer and supplier to enhance the GMP within the industry The book will also be beneficial for institutions conducting pharmaceutical technology courses in terms of GMP and GLP applications The Pharmaceutical Vendors Approval Manual provides readers and front line health care products manufacturers R D management and biotech laboratories all the information they need to know to develop a GMP oriented industry with trained and skilled personnel and manufacture products that meet GMP and regulatory requirements This book provides a simple concise and easy to use reference tool covering basic quality concepts and the elements of vendor's assessment qualification and approval required by the pharmaceutical educational institutions and professional certification bodies It is equally relevant to Quality Assurance officers Quality Control Analysts Quality Auditors and other personnel involved in GMP GLP services in the company The book will also be beneficial for the institutions conducting Pharmaceutical technology study courses in terms of GMP and GLP applications This book provides readers and front line health care products manufacturers R D management and biotech laboratories all the information they need to know to develop a GMP oriented industry with trained and skilled personnel and manufacture products that meet GMP and regulatory requirements covers basic quality concepts and the elements of vendor's assessment qualification and

approval required by the pharmaceutical educational institutions and professional certification bodies provides stepwise guidance on how to evaluate audit quality and approve an API and packaging material manufacturer and supplier to enhance the GMP within the industry provides ready to use regulatory documentation e.g. letter of commitment questionnaire SOP etc required for API and Packaging Materials contract Provided material can be easily tailored to incorporate changes to add in house vendor s qualification requirements Erfan Syed Asif Ph D is a Senior Consultant at PharmEng Technology

Quality Management Comité euro-international du béton,1998 This guide has been written to provide conceptual and procedural guidance for the application of quality management systems in the field of concrete construction Modern construction requires more and more specialized expert knowledge and involves an increasing number of participants in the construction process such as architects designers material producers and contractors The quality of the construction depends on the quality of the work of each participant and in particular on the organization and flow of information at the interfaces between these participants

The Quality Auditor's Handbook Don L. Freeman,1997 The practical easy to use handbook for every quality auditor manager or trainer In this book leading ISO 9000 auditor and trainer Don Freeman gives you straight answers and practical tools for every step of the quality auditing process You ll learn how to successfully plan and conduct quality audits and report on their results And you ll discover proven solutions for the challenges faced by every quality auditor From start to finish The Quality Auditor s Handbook provides step by step methods tools matrices and forms that streamline the audit process Along the way you ll also learn the communications skills questioning listening and observation techniques that are essential to successful auditing The practices and tools you ll learn can be modified and used with any type of quality system auditing and for other types of auditing as well such as environmental auditing ISO 14000

The ISO 9000 Documentation Toolkit Janet L. Novack,1994 Enlarged revised and completely updated to include the new 1994 Revised ISO Standard this innovative book disk set is a practical toolkit designed to evoke discussion at planning meetings to be annotated and written in and to be employed in the writing of procedures Disk contains documentation templates in Microsoft Word for the PC and Mac and in WordPerfect for DOS

Quality Manager's Complete Guide to ISO 9000 Richard B. Clements,1999

ISO 9000 Quality Management System Design Jay J. Schlickman,1998

Quality Management and Quality Assurance Standards International Organization for Standardization,1993

ISO 9001 and Software Quality Assurance Darrel Ince,1994 The first book to examine the impact of ISO 9001 standards on software vendors and tell how to meet them Quality and product managers and anyone who hopes to become ISO 9001 certified will learn how to develop and maintain documented quality systems prepare valid contracts meet design and document control requirements implement product identification and traceability and more

Proceedings ,1998

ISO 9001:2000 International Organization for Standardization,International Trade Centre UNCTAD/GATT.,2005 This Workbook presents a set of questions checklists and planning guides to be used as a tool for streamlining the internal process of conformance to

the ISO 9001 2000 standard by professional service firms in developing countries The Workbook provides an overview of ISO 9001 2000 as an international quality management framework focuses on internal decisions discussions and the planning needed in applying ISO 9001 2000 concept and for creating the necessary quality management system in a small service firm Publishing Agency International Trade Centre ITC **FAO Animal Production and Health Manual** Richard A. Cowie,2013 *ISO 9000* International Organization for Standardization,1992 **Guidelines for Implementing MS ISO 9000 in the Civil Service** ,1996

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