
QF4.2.3-1	Master Document Index
QF4.2.3-2	Document Issue Sheet
QF4.2.3-3	Document Change Request

4.2.4 Control of Records

Similarly, Clause 4.2.4 demands that an organization must implement a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records and that these records must remain legible and identifiable throughout their retention period.

This because records are an important organizational asset; they provide the primary route for evidence based verification and traceability, and are able to demonstrate compliance with customer requirements. Records also prove the efficacy of the quality management system.

- Use your records to prove that requirements have been met
- Develop a procedure to control your records (QSP4.2.4)
- Ensure that your records are useable

Records Required By ISO 9001

Implementing a compliant document management system could mean keeping certain records that your organization might not be already keeping. Some of these records may seem a little confusing until you become more familiar with the quality standard.

Of course, you might decide to keep more records than those listed below, if you feel your organization needs them, but as we always preach, keep your system simple. The fewer documents and records you keep, the fewer things that will be audited, and the more time you will have to actually run your business.

Ref	Definition
5.6.1	Management review minutes, &c
6.2.2 (e)	Education, training, skills and experience
7.1 (d)	Evidence that realization process and resulting products fulfil requirements
7.2.2	Results of review of requirements relating to the product and actions arising
7.3.2	Design and development inputs
7.3.4	Results of design and development reviews and any necessary actions
7.3.5	Results of design and development verification and any necessary actions
7.3.6	Results of design and development validation and any necessary actions
7.3.7	Results of the review of design & development changes and any necessary actions
7.4.1	Results of supplier evaluations and actions arising from the evaluations
7.5.2 (d)	Validation of processes where the output cannot be verified by 8.2
7.5.3	The unique identification of the product, where traceability is a requirement.

Guidance Writing Quality Manual

World Health Organization



Guidance Writing Quality Manual:

Guide to Preparing the Corporate Quality Manual Bernard Froman,1997-04-15 Utilizes advanced concepts guidelines and requirements from the latest ISO 9000 and 10000 series of standards as well as other models including TQM Total Quality Management The text shows how to define a policy and explain it clearly It offers procedures for developing a quality manual to be used by personnel performing quality related functions and for external auditors and customers *Quality management guidelines for the implementation of the ISO standards of the 9000 series in the construction industry* FIB - International Federation for Structural Concrete,1997-04-01 *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 **Guidance on**

implementation of a quality system in food establishments World Health Organization,2024-02-23 *Quality Management Systems for the Food Industry: A Guide to ISO 9001/2* A. Bolton,1997-07-31 The ISO 9001 2 series of standards for Quality Management Systems is of increasing importance to the food and drink industry it functions as an outward and visible sign to customers that the industry has a defined quality management system that has been independently appraised and is regularly audited ISO 9001 2 certification can enable a company to reduce the audit burden from a multitude of customers and can also help the manufacturer or distributor involved in auditing its own suppliers Above all it may improve the effectiveness of its own operation and profits Quality Management Systems for the Food Industry describes what the standards are what they mean and how to achieve them and identifies both the potential benefits and limitations It discusses choice of assessment house whether to use consultants or not and particularly points out the detail that assessors will be looking for Guidance is given on the basic format for a suitable quality management system **Guidance for Preparing**

Standard Operating Procedures (SOPs). ,2001 **The Quality Improvement Field Guide** Matthew A. Barsalou,2017-09-28 The Quality Improvement Field Guide Achieving and Maintaining Value in Your Organization covers the key aspects that quality professionals must know to attain mastery in their field After reading this book readers will not only gain an understanding of the key quality improvement concepts but will gain the practical insight required to implemen

Quality Assurance Management Michael J. Fox,2013-11-27 **Quality assurance of pharmaceuticals: a compendium of guidelines and related materials, tenth edition. Volume 1. Good practices and related regulatory guidance** World Health Organization,2024-10-24 This publication represents a significant achievement in our ongoing effort to ensure that everyone can reach the highest possible level of health Over the last three decades we have seen the

transformation of the pharmaceutical industry and the increasing intricacy of the product life cycle The challenges we face today are very different from those we faced when the first edition of this Compendium was published in 1997 However our mission remains the same to promote health keep the world safe and serve the vulnerable The new edition reflects the collective knowledge and expertise of countless professionals who have worked diligently to develop revise and implement WHO guidelines for pharmaceuticals This includes experts from WHO Member States our Expert Advisory Panels and Expert Committees on Specifications for Pharmaceutical Preparations and other organizations and has undergone extensive consultation with stakeholders worldwide This Compendium covers development through manufacturing and quality control to post marketing surveillance It provides a comprehensive framework for quality assurance that is both strong and flexible capable of meeting the requirements of a rapidly changing global health landscape The 10th edition is a collection of knowledge and tools for empowerment enabling all stakeholders in the pharmaceutical industry to make informed decisions that prioritize patient safety and well being

The TickIT Guide ,2001 **Total Quality Management** Poorinma M. Charantimath,2011 **Guidance for quality assurance project plans** , *The AT&T Documentation Guide* ,1993-06

Catalog of the most often requested AT T documents *Technical Guidance Manual for Developing Total Maximum Daily Loads* ,1997 *The Quality Audit for ISO 9001:2000* David Wealleans,2017-03-02

Since the publication of the first edition of this book in 2000 the revised ISO 9001 standard has been implemented and is being used widely While the basic premise of the original book is still sound the reality of auditing the new standard has shown up various areas which require refinement this new edition addresses that need It remains a pragmatic guide covering all aspects of auditing including certification assessment supplier investigation and internal audit enabling auditors to appreciate the approaches adopted by those working in related areas With its detailed analysis of the requirements of ISO 9001 2000 this book will also be of interest to all those involved in implementing certified quality management systems as well as the auditors who are required to examine those systems A down to earth approach is taken throughout The Quality Audit for ISO 9001 2000 avoiding the impractical and nit picking methods which have so often characterized quality management audits making it an invaluable source of realistic advice It demonstrates how to produce real benefits from an audit programme rather than simply guaranteeing compliance to a documented system Everyone who sees audits as a useful tool for business improvement should read this book

TOTAL QUALITY MANAGEMENT P. N. MUKHERJEE,2006-10-30 This book presents a comprehensive view of concepts principles and practices of Total Quality Management TQM from basics through advanced tools and techniques for practical implementation It is well known that Total Organization Involvement in understanding and implementing TQM along with the integrated business strategy provided Japanese organizations with a strong platform for a meteoric rise to world class performance and global leadership in every sphere of their operation The success of TQM therefore depends a lot on the strong foundation and infrastructure of an organization This is the crux of the author s theory of Holistic Management

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Quality assurance of pharmaceuticals: a compendium of guidelines and related materials. Volume 2. Good manufacturing practices and inspection World Health Organization, 2024-01-31 The GMP Compendium for Medical Products is a valuable resource for manufacturers regulators and other stakeholders involved in producing and distributing medical products It covers various topics from quality management systems to personnel hygiene equipment validation and complaint handling The guidance provided is based on the latest scientific and technical knowledge and considers the evolving regulatory landscape and the challenges faced by the industry *Device Inspections Guide*, 2003

Chilled Foods Michael Stringer, C. Dennis, 2000 Examines aspects of the chilled food industry including the market applicable legislation variety selection refrigeration temperature control quality and safety microbiology and shelf life

Quality Assurance Implementation in Research Labs Akshay Anand, 2021-08-17 This book is a comprehensive and timely compilation of strategy methods and implementation of a proof of concept modified quality module of Good Laboratory Practices GLP This text provides a historical overview of GLP and related standards of quality assurance practices in clinical testing laboratories as well as basic research settings It specifically discusses the need and challenges in audit documentation and strategies for its implications in system dependent productivity striving research laboratories It also describes the importance of periodic training of study directors as well as the scholars for standardization in research processes This book describes different documents required at various time points of a successful Ph D and post doc tenure along with faculty training besides entire lab establishments Various other areas including academic social responsibility and quality assurance in the developing world lab orientations and communication digitization in data accuracy auditability and back traceability have also been discussed This book will be a preferred source for principal investigators research scholars and industrial research centers globally From the foreword by Ratan Tata India This book will be a guide for students and professionals alike in quality assurance practices related to clinical research labs The historical research and fundamental principles make it a good tool in clinical research environments The country has a great need for such a compilation in order to increase the application of domestic capabilities and technology

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