

Logo	XXXX ISO9001:2015 Quality Manual	Reviewed by: Approved by: Version:
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1. Scope

XXXX establish, implement and maintain this ISO9001:2015 QMS to consistently provide products that meet customer and applicable legal requirements, and to continuously improve customer's satisfaction and the performance of QMS. We strive to understand the dynamic external and internal context, and the changing need & expectation of relevant interesting parties, to identify and address the risks & opportunities, by utilizing process approach, PDCA and risk-based thinking, data analysis and quality management principles.

2. Normative reference

ISO 9000:2015, Quality management systems – Fundamentals and vocabulary

- **Characteristic** - A characteristic is a distinctive feature or property of something.
- **Context of the organization** – all of the internal and external factors and conditions that affect its products and services, have an influence on its QMS, and are relevant to its purpose and strategic direction.
- **Correction** – any action that is taken to eliminate a nonconformity, but to address root causes.
- **Corrective action** – steps that are taken to eliminate the causes of existing nonconformities in order to prevent recurrence of the existing nonconformities and potentially undesirable situations.
- **Interested party** – anyone who can affect, be affected by, or believe that they are affected by a decision or activity. It is a person, group, or organization that has an interest or a stake in a decision or activity.
- **Outsource** – when an outside organization to perform part of a function or process of organization.
- **Process approach** – manage and control the processes that make up their organization, the interaction between these processes, and the inputs and outputs that tie these processes together.
- **Process-based quality management system** – using process approach to manage and control how its quality policy is implemented and how its quality objectives are achieved. A process-based QMS is a network of interrelated and interconnected processes.
- **Quality** - the degree to which a set of inherent characteristics fulfills a set of requirements of an objective.
- **Risk** – the “effect of uncertainty on an expected result” and an effect is a positive or negative deviation from what is expected.
- **Risk-based thinking** refers to a coordinated set of activities and methods that organizations use to manage and control the many risks that affect its ability to achieve objectives.

3. Terms and definitions

‘Purchased Product’ is replaced by ‘Externally Provided Processes, Products and Services’

Quality is about processes and data

Quality is shared responsibility within an organization

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Ying-Ying Zheng



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Implementing ISO 9000:2000 Matt Seaver, 2001 This text is aimed at the busy manager or proprietor who needs to implement ISO 9001 It consists of a commentary against each clause of ISO 9004 guidelines for performance improvements explaining the practical benefits of implementing the guidance that is given in the standard **Quality Procedures for**

Hardware and Software D.J. Smith, J.S. Edge, 2012-12-06 How to Use This Book The primary purpose of this book is to assist small companies involved in both hardware and software to devise and evolve their own quality systems There are a number of national and now international standards which outline the activities for which procedures and records need to be specified They are described and compared in Chapter 2 and the subsequent guidance in the book is intended to assist in meeting them Although at first sight the operations of a hardware equipment developer may seem very different from those of a software house the basic requirements of a quality system such as the BS 5750 and ISO 1987 series of documents are the same For this reason the same standard can be called for in both areas and it will be seen in Part 2 that suitable procedures can be derived to meet both types of operation Quality standards BS 5750 AQAP ISO 9000 series distinguish between companies carrying out on the one hand both design and manufacturing fixed functions and on the other hand those who only manufacture to specifications In practice the lesser requirements those applying to manufacture to fixed specifications are common to both levels of standard and the additional controls pertaining to design are added to obtain the higher standard Chapter 2 explains the differences in detail **Automotive Manufacturing & Production**, 1997

RIBA Architect's Handbook of Practice Management Nigel Ostone, 2019-07-25 The professional architect's business management bible now encompasses the RIBA Plan of Work 2013 to reflect the very latest practice in today's cutting edge architectural environment With an emphasis on the practical aspects of working as an architect the 9th edition combines clear and comprehensive guidance with a focus on new directions in practice management which will give a modern practice that vital commercial edge Topics range from starting up a practice and developing a business strategy to how to win clients manage people and handle fees It includes new sections on topics such as knowledge management QA IT and project management too With its clear accessible layout and no nonsense style aimed at busy architects this is a must read for practices of all sizes and the ideal companion to the RIBA Job Book 9th edition

User-Driven Healthcare: Concepts, Methodologies, Tools, and Applications Management Association, Information Resources, 2013-01-31 User Driven Healthcare Concepts Methodologies Tools and Applications provides a global discussion on the practice of user driven learning in healthcare and connected disciplines and its influence on learning through clinical problem solving This book brings together different perspectives for researchers and practitioners to develop a comprehensive framework of user driven healthcare **The Changing Politics of Organic Food in North America** Lisa F. Clark, 2015-08-28 The Changing Politics of Organic Food in North America explores the political dynamics of the remarkable transition of organic food from a

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Handbook of Footwear Design and Manufacture A. Luximon,2013-09-30 Understanding footwear design and manufacture is vital for improving the functionality aesthetics and marketability of a product The Handbook of footwear design and manufacture provides a comprehensive review of footwear production and design and explores how these processes are used across a variety of application areas Part one an introductory section reviews the fundamentals of footwear anatomy chapters discuss the anatomy of the human foot biomechanics and gait foot models and measurements the development of the foot in childhood and adolescence and foot problems and their implications for footwear design Part two examines footwear design including the development of shoe design foot sketch templates and footwear drawing templates Aspects of footwear manufacture are highlighted in part three including the design manufacture and sizing and grading of shoe lasts Further chapters focus on the footwear business advertising and the environmental impact of footwear manufacture Part four explores the design and manufacture of footwear for specific applications and includes chapters on footwear for cold weather textiles and other materials used in the production of protective military and orthopaedic footwear and design issues in geriatric footwear The Handbook of footwear design and manufacture is a wide ranging and technical resource for footwear designers materials scientists and researchers involved in the production of footwear and professionals in the footwear industry looking to expand their knowledge of design and manufacture processes Discusses foot anatomy in detail and considers its implications for footwear design Looks at design issues from foot and footwear drawing templates to shoe last design and footwear manufacture Specific chapters focus on the footwear business advertising and the environmental impact of footwear manufacture *A Practical Guide to Quality Management in Clinical Trial Research*

Graham Ogg, 2005-11-01 Setting up a GXP environment where none existed previously is a very daunting task. Getting staff to write down what they do for every task is a correspondingly difficult and time consuming exercise. Examining how to maintain quality control in clinical trial research. A Practical Guide to Quality Management in Clinical Trial Research provides a co

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Medical Devices Seeram Ramakrishna, Lingling Tian, Charlene Wang, Susan Liao, Wee Eong Teo, 2015-08-18 Medical Devices and Regulations Standards and Practices will shed light on the importance of regulations and standards among all stakeholders: bioengineering designers, biomaterial scientists and researchers to enable development of future medical devices. Based on the authors' practical experience, this book provides a concise practical guide on key issues and processes in developing new medical devices to meet international regulatory requirements and standards. Provides readers with a global perspective on medical device regulations. Concise and comprehensive information on how to design medical devices to ensure they meet regulations and standards. Includes a useful case study demonstrating the design and approval process.

A Manual for the Chemical Analysis of Metals, **Laboratory Auditing for Quality and Regulatory Compliance** Donald C. Singer, Raluca-Ioana Stefan, Jacobus F. van Staden, 2005-07-25 Identifying current tools, techniques and approaches for the evaluation of laboratory operations, this reference reviews the latest regulatory standards and auditing practices to test laboratory safety, quality and performance.

Managing the Change: Software Configuration and Change Management Michael Haug, Eric W. Olsen, Gonzalo Cuevas, Santiago Rementeria, 2001-10-23 C Amting Directorate General Information Society European Commission Brussels. Under the 4th Framework of European Research, the European Systems and Software Initiative (ESSI) was part of the ESPRIT Programme. This initiative funded more than 470 projects in the area of software and system process improvements. The majority of these projects were process improvement experiments carrying out and taking up new development processes, methods and technology within the software

development process of a company In addition nodes centres of expertise European networks organisations managing local activities training and dissemination actions complemented the process improvement experiments ESSI aimed at improving the software development capabilities of European enterprises It focused on best practice and helped European companies to develop world class skills and associated technologies to build the increasingly complex and varied systems needed to compete in the marketplace The dissemination activities were designed to build a forum at European level to exchange information and knowledge gained within process improvement experiments Their major objective was to spread the message and the results of experiments to a wider audience through a variety of different channels The European Experience Exchange tUR X project has been one of these dissemination activities within the European Systems and Software Initiative UR X has collected the results of practitioner reports from numerous workshops in Europe and presents in this series of books the results of Best Practice achievements in European Companies over the last few years

The Complete Guide to Writing & Producing Technical Manuals Leslie M. Haydon, 1995-06-23 Technical writing as a career technical manuals and handbooks planning a technical manual publishing systems layout and format manual writing style preparing a manual specification front matter and introductory material illustration table preparation operation maintenance and repair instructions illustration parts breakdown appendixes and addenda amending manuals preparing camera ready copy printing and binding the technical editor a technical handbook department appendixes capitalization rules mathematical and scientific terminology using the metric SI system numbers in technical manuals abbreviations footnotes punctuation glossary of technical terms bibliography index

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Food and Drink - Good Manufacturing Practice Institute of Food Science and Technology, Louise Manning, 2012-11-26 Good Manufacturing Practice GMP refers to advice and guidance put in place to outline the aspects of production and testing that can impact the quality and safety of a product In the case of food and drink GMP is aimed at ensuring that products are safe for the consumer and are consistently manufactured to a quality appropriate to their intended use Manufacturers have for several years been driving towards such goals as Total Quality Management TQM lean manufacturing and sustainability GMP is bound up with these issues The ever increasing interest amongst consumers retailers and enforcement authorities in the conditions and practices in food manufacture and distribution increases the need for the food manufacturer to operate within clearly defined policies such as those laid down in GMP The ability to demonstrate that Good Manufacturing Practice has been fully and effectively implemented could in the event of a consumer complaint or a legal action reduce the manufacturer s liability and protect them from prosecution First launched in 1986 IFST s Good Manufacturing Practice Guide has been widely recognized as an indispensable reference work for food scientists and technologists It sets out to ensure that food manufacturing processes deliver products that are uniform in quality free from defects and contamination and as safe as it is humanly possible to make them This 6th edition has been completely revised and updated to include all the latest standards and guidance especially with regard to legislation driven areas such as HACCP The Guide is a must have for anyone in a managerial or technical capacity concerned with the manufacture storage and distribution of food and drink It is also a valuable reference for food education training and for those involved in food safety and enforcement Food scientists in academic and industry environments will value its precision and policy makers and regulatory organizations will find it an indispensable guide to an important and multifaceted area About IFST IFST is the leading independent qualifying body for food professionals in Europe and the only professional body in the UK concerned with all aspects of food science and technology IFST members are drawn from all over the world and from all ages and backgrounds including industry manufacturing retailing and food service universities and schools government research and development quality assurance and food law enforcement IFST qualifications are internationally recognised as a sign of proficiency and integrity

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dominance of the computer that results in simplified cartographic products All three fields make use of basic components such as the Internet and databases The Springer Handbook of Geographic Information is organized in three parts Basics Geographic Information and Applications Some parts of the basics belong to the larger field of computer science However the reader gets a comprehensive view on geographic information because the topics selected from computer science have a close relation to geographic information The Springer Handbook of Geographic Information is written for scientists at universities and industry as well as advanced and PhD students *Thomas Regional Industrial Buying Guide ,2002*

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