#### PROCEDURE FOR CONTROL OF DOCUMENTED INFORMATION

Procedure No: XX/PRO/01 Rev No: 1.0 Rev. Date: DD/MM/YYYY

#### 1. SCOPE

To ensure that the documented information. Including all documents of internal & external origin, is controlled with respect to approval, distribution, change etc.

#### 2. PURPOSE

To establish a consistent process for controlling the documented information required to maintain QNP's quality management system.

#### 3. REFERENCE DOCUMENTS

3.1 Best Enterprises Quality Manual,
3.2 Document Master List with Revision History
3.3 External Document Control List
3.4 Quality Plan

#### 4. TERMS & DEFINITIONS

Documented Information - Records and Documents
Maintained Documented Information - Document
Retained Documented Information - Record
WI- Work Instruction
F- Format
QM - Quality Manual
QMS- Quality Management System
SOP- Standard Operating System
CEO - Chief Executive Officer
MR - Management Representative
QNP - Quality Name Plate

#### 5. RESPONSIBILITY AND AUTHORITY

5.1 The Management Representative (MR) and In-charges of all departments are responsible for the effective implementation of this procedure.

5.2 CEO gives final approval on all QNP quality system documents

5.3 Quality Assurance In-charge, manager & MR

- Ensure that QNP quality system documents are formatted, identified and issued per the requirements of this operating procedure.
- Ensure that revisions to quality system documents are reviewed and approved by the same functions that performed the original review and approval.
- Ensure that the necessary documents are accessible to appropriate personnel.

PREPARED BY APPROVED BY

## **Iso 900document Control Procedure Sample**

**David John Seear** 

#### **Iso 900document Control Procedure Sample:**

How to Establish a Document Control System for Compliance with ISO 9001:2015, ISO 13485:2016, and FDA Requirements Stephanie L. Skipper, 2015-10-14 This book explains the requirements for compliance with FDA regulations and ISO standards 9001 13485 for documented information controls and presents a methodology for compliance The document control system DCS or documented information control system DICS is the foundation of a quality management system It is the first quality system element that must be implemented because the establishment and control of documented processes and information in a quality controlled environment is dependent on the ability to proactively manage access to documents and the movement of documents through the document life cycle A well developed document control system benefits business by Improving knowledge retention and knowledge transfer within and across business units Improving access to knowledge based information Improving employee performance by providing standardized processes and communicating clear expectations Improving customer communication and satisfaction by providing documented information from which common understanding can be achieved Providing traceability of activities and documentation throughout the organization Improving organization of and access to documents and data Sample documents are included in the appendixes of this book to help clarify explanations and a full set of formatted procedures and document templates are available for download to get you off to an even faster start This book provides a process based approach that can be used for controlling all forms of documented information that are required to be managed under the quality management system Fertilization Zsolt Peter Nagy, Alex C. Varghese, Ashok Agarwal, 2019-07-03 Now in its revised and expanded second edition including over 20 new chapters this comprehensive textbook remains a unique and accessible description of the current and developing diagnostic and treatment techniques and technologies comprising in vitro fertilization IVF Arranged thematically in sections each chapter covers a key topic in IVF in a sensible presentation Parts one and two describe the planning design and organization of an ART unit and IVF laboratory and equipment and systems respectively The sections that follow provide detailed descriptions of IVF techniques embryo culture methods sperm processing and selection insemination procedures micromanipulation embryo evaluation cryopreservation and embryo transfer Concluding sections address issues of management and regulation of ART labs across the globe as well as special topics and emerging techniques and devices Chapter authors all experts in the field contribute their expertise from around the world With the addition of learning key points and review questions at the beginning and end of each chapter this new edition of In Vitro Fertilization is a readily accessible high quality instructional resource for reproductive medicine trainees at all levels Practicing reproductive endocrinologists urologists and embryologists also will find value in the book as will infertility researchers

**Environmental and Quality Systems Integration** William C. Culley,2019-09-17 Global competition corporate downsizing and corporate restructuring have forced many firms to reevaluate their operating methods Today corporations

must do more with less while still watching the bottom line and improving profitability ISO 14000 and ISO 9000 because of their similar management system requirements and auditing procedures are g ISO 9001: 2000 for Small Businesses Ray Tricker, 2012-09-10 Review of previous edition This will be of particular importance to companies that act as suppliers to larger multinational organisations whose original specifications may not translate readily into local practice Quality Today Small and medium sized companies face many challenges today not least that their larger institutional and multinational customers make demands that are difficult to meet for an organisation with limited resources One such demand is ISO 9000 compliance Fully revised and updated ISO 9001 2000 for Small Businesses explains the new requirements of ISO 9001 2000 and helps businesses draw up a quality plan that will allow them to meet the challenges of the market place For engineers and managers in small and medium sized companies and also in service industries and user groups the text will serve as a essential guide to the most important new developments in quality assurance The ISO 9001:2015 Implementation Handbook Milton P. Dentch, 2016-08-17 The handbook is structured to guide organizations new to ISO 9001 through the process necessary to connect their current practices to the requirements of ISO 9001 2015 For organizations already certified to ISO 9001 it advises how to use your upgrade to ISO 9001 2015 as an opportunity to rebuild your QMS into a helpful asset in managing your business ISO 9001:2015 for Small Businesses Ray Tricker, 2016-10-04 Small businesses face many challenges today including the increasing demand by larger companies for ISO 9001compliance a challenging task for any organisation and in particular for a small business without quality assurance experts on its payroll Ray Tricker has already guided hundreds of businesses through to ISO accreditation and this sixth edition of his life saving ISO guide provides all you need to meet the new 2015 standards ISO 9001 2015 for Small Businesses helps you understand what the new standard is all about and how to achieve compliance in a cost effective way Covering all the major changes to the standards this book provides direct accessible and straightforward guidance This edition includes down to earth explanations to help you determine what you need to enable you to work in compliance with and or achieve certification to ISO 9001 2015 a contextual explanation of ISO 9001 within the structure of ISO 9000 family of standards a detailed description of the structure of ISO 9001 2015 and its compliance with Annex SL coverage of the new requirements for Risk Management and Risk Analysis a guide to the costs involved in implementing ISO 9001 2015 and advice on how to control costs an example of a complete generic Quality Management System consisting of a Quality Manual plus a whole host of Quality Processes Quality Procedures and Word Instructions and access to a free software copy of these generic QMS files to give you a starting point from which to develop your own documentation This book is also supported with a complete bibliography containing abbreviations and acronyms as well as a glossary of terms This comprehensive text will provide you and your small business with a complete guide on your way to ISO compliance ISO 9001:2015 Internal Audits Made Easy Ann W. Phillips, 2015-09-21 Implementing the requirements of ISO 9001 can be a daunting task for many organizations. In an

attempt to develop a system that will pass the registration audit we are tempted to establish processes with the primary purpose of conforming to the requirements of ISO 9001 In doing so however it is easy to lose sight of the primary intent of the standard to continually improve the effectiveness of the quality management system QMS implemented at our organization This book is intended to help managers quality professionals internal audit coordinators and internal auditors implement a practical internal audit process that meets the requirements of ISO 9001 2015 while adding significant measurable value to the organization The tools techniques and step by step guidelines provided in this book can also be used by those organizations that have a well established internal audit process but are looking for easy ways to make that process ISO 9001 Audit Trail David John Seear, 2012 This book has been revised to coincide with the issue of the ISO 9001 Family of Standards by the same author The intention is to improve the standard of auditing especially audits carried out under the banner of the ISO 9001 standard The ISO 9001 standard is quite capable of allowing organizations certification bodies and auditors to judge if an organization is capable of consistently providing product or service that meets the customer and applicable statutory and regulatory requirements At the present time however there is no common understanding about what the ISO 9001 audit should achieve The aim of this book is to explain what auditing is capable of achieving in particular the method of carrying out audits There is however a need to improve the understanding of the ISO 9000 Family of Standards and to this end appendix C contains the first five pages of that book Auditing can be costly and time consuming and for it to be effective it needs to give tangible benefits This book will enable organizations and other interested parties to judge if their auditing activities are effective and beneficial It enables them to examine their approach to audits and compare them with the techniques used within this book ISO 9001:2008 for Small Businesses Ray Tricker, 2014-01-21 Small businesses face many challenges today including the increasing demand by larger companies for ISO compliance Compliance is a challenging task for any organisation and can often be time consuming and costly particularly for small businesses who are unlikely to have quality assurance experts on the payroll However it is still possible to achieve compliance without the need for expensive consultancy or training that takes you out of the office Ray Tricker has already guided hundreds of businesses through the challenge and this the 5th edition of his life saving ISO guide has been rewritten and refined following 5 years field use of working with the standard The one area that an organisation particularly a small business always wants to know is how much is it going to cost to implement and operate a QMS compliant with ISO 9001 2008 and is it going to be worth the trouble Due to popular demand Edition 5 now includes a brand new chapter on the cost of implementing ISO 9001 2008 This edition provides Relevant examples that put the concepts and requirements of the standard into a real life context Down to earth explanations to help you determine what you need to work in compliance with and or achieve certification to ISO 9001 2008 An example of a complete generic Quality Management System consisting of a Quality Manual plus a whole host of Quality Processes Quality Procedures and Work Instructions Access to a free software

copy of this generic QMS files available from the author to give you a starting point from which to develop your own documentation ISO 9001 2008 is the most widely followed quality management standard and the rewards can be great opening up new business opportunities as well as bringing real improvements to your processes and outputs Integrating Business Management Processes Titus De Silva, 2020-08-18 Integrating Business Management Processes Volume 3 Harmonising Quality Food Safety and Environmental Processes 978 0 367 48547 4 Shelving Guide Business Management The backbone of any organisation is its management system It must reflect the needs of the organisation and the requirements of its customers Compliance with legal requirements and ethical environmental practices contributes towards the sustainability of the management system Whatever the state of maturity of the management this book one of three provides useful guidance to design implement maintain and improve its effectiveness and is intended to provide readers with practical how to methods for integrating quality safety and environmental management processes This volume sets out procedures and flowcharts to show how the integration of these processes can be achieved Separated into management procedures core procedures support procedures and assurance procedures and complemented by practical examples this book is an invaluable resource for complete systems development and integration This book along with its two companion volumes is a practical guide for real managers designed to help them manage their business more effectively and gain competitive advantage Titus De Silva is a consultant in management skills development pharmacy practice quality management and food safety and an advisor to the newly established National Medicines Regulatory Authority NMRA in Sri Lanka

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