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*Iso 13485 Documents
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Provides practical guidance for the optimal organization and management of an IVF laboratory for successful embryo culture.

Four years into the current version of ISO 9001, the new edition of this essential book incorporates the hard

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won experiences of working with the standard. This book, together with its accompanying free Quality Management System (QMS), contains all the information that small and medium enterprises need when developing a QMS for ISO

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9001:2000 accreditation.

Good Manufacturing Practice (GMP) ensures medicinal products are produced consistently and controlled to the quality standards appropriate for their intended use and as required by product

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specifications or marketing authorization. Annex 11 details the European Medicines Agency (EMA) GMP requirements for computer systems. The purpose of Annex 11 is Iso 13485 En 46000 Documentation Quality Manual And

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36 Operational ProceduresA
Practical Field Guide For ISO
13485:2016Medical Devices -
Quality Management Systems -
Requirements for Regulatory
PurposesQuality Press
Both synthetic and natural latices

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were covered in this conference, including natural rubber latex, high volume synthetic emulsions, such as SBR, as well as specialty products, such as acrylics. Application markets addressed included adhesives and sealants, carpet

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backing, paper coatings, construction, fabrics, foamed articles, medical gloves, medical devices, textile threads, condoms and others. The latex industry is in dynamic flux at the present time. The supply side has undergone

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major restructuring. Inter-materials competition has intensified as improved materials become capable of challenging incumbent materials. Many serious issues face the latex industry, such as continuing price depression in some sectors, rising

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technical demands as well as substantial legislative and environmental pressure. Despite the challenging times facing the industry, the overall prospects for latex are very positive. Substitution of solvent based products continues,

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the performances of latices continues to improve in such applications as adhesives and the glove industry is responding positively to the setbacks of the allergy controversy. 9 million dry tons and has spread across a wide

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range of industrial and consumer markets. Growing demand in medical and strong prospects in construction are just two of the positive trends that will continue to fuel the market growth of both natural and synthetic latices. As last

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year's conference demonstrated, the Rapra International Latex Conference is an unparalleled forum for developing understanding of the latex industry, technical trends and market driving forces, such as new legislation. The 2002 event provided

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a vital meeting point for the synthetic and natural latex communities of Europe, Asia and America. This conference will be of interest to all latex stakeholders, including: feedstock suppliers, latex producers, compounders,

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fabricators of consumer, medical and industrial articles based on latex, traders and distributors, machine and equipment suppliers, legislators, healthcare professionals and users of latex based products. This well-known QA manual has

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been updated to provide the guidance readers need to assess their compliance with standard regulations. This Volume 2 of a three-part package contains the full text on: * FDA regulations* EC and IPEC guidelines* ISO/BSI

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standards referenced in the checklists furnished in volume 1 Easy-to-read and organized to provide fa For the past decade, process validation issues ranked within the top six of Food and Drug Administration (FDA) form 483

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observation findings issued each year. This poses a substantial problem for the medical device industry and is the reason why the authors wanted to write this book. The authors will share their collective knowledge: to help

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organizations improve patient safety and increase profitability while maintaining a state of compliance with regulations and standards. The intent of this book is to provide manufacturing quality professionals working in virtually any industry a

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quick, convenient, and comprehensive guide to properly conduct process validations that meet regulatory and certification requirements. It will aid quality technicians, engineers, managers, and others that need to plan,

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conduct, and monitor validation activities.

Medical Devices and Regulations: Standards and Practices will shed light on the importance of regulations and standards among all stakeholders, bioengineering

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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

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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

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to design medical devices to ensure they meet regulations and standards
Includes a useful case study demonstrating the design and approval process

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[Mastering and Managing the FDA](#)

[Maze, Second Edition](#)

[MDD Compliance Using Quality](#)

[Management Techniques](#)

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Documentation Practices
GMP/ISO Quality Audit Manual for
Healthcare Manufacturers and
Their Suppliers, \(Volume 2 -
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Guidelines\)](#)

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[Traceability](#)
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[Medical Device Overview](#)
[Medical Device](#)

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This book is intended to serve as a reference for professionals in the medical device industry, particularly those seeking to learn from practical examples and case

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studies. Medical devices, like pharmaceuticals, are highly regulated, and the bar is raised constantly as patients and consumers expect the best-quality healthcare and safe and

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effective medical technologies. Obtaining marketing authorization is the first major hurdle that med techs need to overcome in their pursuit of commercial success.

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Most books on regulatory affairs present regulations in each jurisdiction separately: European Union, USA, Australia, Canada, and Japan. This book proposes

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***practical solutions for a
coherent, one-size-fits-all
(or most) set of systems
and processes in
compliance with
regulations in all key
markets, throughout the***

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life cycle of a medical device. It also contains key information about international harmonization efforts and recent regulatory trends in emerging markets;

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***important terminology
needed to understand the
regulators' language; and
examples, case studies,
and practical
recommendations that
bridge the gap between***

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***regulatory theory and
practice.***

***The Biomedical Quality
Auditor Handbook was
developed by the ASQ
Biomedical Division in
support of its mission to***

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***promote the awareness
and use of quality
principles, concepts, and
technologies in the
biomedical community.
This third edition
correlates to the 2013***

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***exam Body of Knowledge
(BoK) and reference list
for ASQ's Certified
Biomedical Auditor
program. It includes
updates and corrections
to errors and omissions in***

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the second edition. Most notably it has been re-organized to align more closely with the BoK. Many companies limp along from day-to-day treating the quality side

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***of the business as a
necessary evil, and doing
only what is minimally
necessary for compliance
to regulations. This kind
of approach to
compliance almost always***

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***results in inefficiencies
and sometimes can result
in a curious kind of
noncompliance.***

***Documentation created
with compliance as the
sole consideration often***

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ends up confusing the employees who must use the documentation. This book looks beyond what is necessary for compliance alone to address what makes a quality

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***management system
(QMS) both effective and
efficient. This book also
never forgets that real
people must make any
QMS work; the book
provides a blueprint for***

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***creating a QMS that real
people will find useful.***

***After a review of the
challenges that any
medical device company
faces in the world of
today—the multiple***

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sources of QMS

requirements—the book poses a question: are we satisfied with the QMS we have now, or could we do better? If we want to do better, this book can

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***help. This book offers:
Advice that will lead to an
effective and efficient
QMS. Detailed guidance
on the key decisions to be
made regarding the
quality system being***

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established. Detailed ideas on how to execute those decisions. Up-to-date information on compliance to current regulations and standards and guidance on staying

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***up to date. Specific
examples of procedures.
Information regarding
requirements for
combination products,
such as a drug + device
combination. Advice on***

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***incorporating risk
management in the QMS.
This book explains all of
the stages involved in
developing medical
devices; from concept to
medical approval***

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***including
systemengineering,
bioinstrumentation
design, signal
processing,electronics,
software and ICT with
Cloud and e-***

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***Healthdevelopment.
Medical Instrument
Design and Development
offers a
comprehensivetheoretical
background with
extensive use of***

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***diagrams, graphics
and tables (around 400
throughout the book).
The book explains how
the theory is translated
into industrial medical
products using a market-***

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sold Electrocardiograph disclosed in its design by the GammaCardio Soft manufacturer. The sequence of the chapters reflects the product development lifecycle.

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Each chapter is focused on a specific University course and is divided into two sections: theory and implementation. The theory sections explain the main concepts

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***and principles
which remain valid across
technological evolutions
of
medical instrumentation.
The Implementation
sections show how the***

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***theory istranslated into a
medical product. The
Electrocardiograph(ECG
or EKG) is used as an
example as it is a suitable
device to explore to fully
understand medical***

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***instrumentation since it
issufficiently simple but
encompasses all the main
areas involved
indeveloping medical
electronic equipment.
Key Features: Introduces***

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***a system-level approach
to product design Covers
topics such as
bioinstrumentation,
signal
processing, information
theory, electronics,***

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***software, firmware,
telemedicine, e-Health
and medical device
certification Explains how
to use theory to
implement a market
product (using ECG as an***

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example) Examines the design and applications of main medical instruments Details the additional know-how required for product implementation:

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business context, system design, project management, intellectual property rights, product life cycle, etc. Includes an accompanying website

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***with the design of
thecertified ECG product
([http://www.gamm
acardiosoft.it/book](http://www.gamm
acardiosoft.it/book)
[www.gamm
acardiosoft.it/book/a](http://www.gamm
acardiosoft.it/book/a)
) Discloses the details of a
marketed ECG Product***

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***(from GammaCardio Soft)
compliant with the ANSI
standard AAMI EC
11 under open licenses
(GNU GPL, Creative
Common) This book is
written for biomedical***

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engineering

courses(upper-level

undergraduate and

graduate students) and

for engineersinterested in

medical

instrumentation/device

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***design with
acomprehensive and
interdisciplinary system
perspective.
A Practical Roadmap to
IPT Integration From
baby formula and peanut***

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***butter, to E. coli-tainted
peppers and salmonella-
tainted pistachios, no
food product or means of
its production is immune
to risks. And while these
risks may never be fully***

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***eliminated, identity
preservation and
traceability (IPT) systems
make it easier to
determine the source and
extent of contamination,
thereby reducing the***

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***often deadly
consequences. With a
core emphasis on grain,
this encyclopedic
reference documents the
state-of-the-science
throughout the entire***

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***food chain in both
domestic and
international markets as
it relates to food safety
and economics. The book
provides a cohesive
introduction to IPT***

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***systems and summarizes
the programs currently
available, in effect
developing a conceptual
model of IPT at the
producer level. Addresses
the History, Theory, and***

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***Design Components
Beginning with an
informative history of
IPT, the book continues
with examples of IPT
programs and standards
of official seed***

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organizations. It then provides a sampling of government, industry, and company approaches toward IPT systems throughout the past two decades. For ease of use

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as a reference, most chapters begin with a brief description of the essentials necessary to understand the chapter's contents allowing readers to jump right in, rather

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than having to read chapters in sequential order. Providing an in-depth understanding of the complexity of IPT systems, the rules they function under, and how

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they are shaped and modified, this valuable resource effectively demonstrates why IPT is a critical practice for food safety.

Small and medium-sized

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***companies face many
challenges today
including the demand by
larger customers for ISO
9000 compliance. Four
years into the current
version of ISO 9000, the***

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new edition of this life-saving book incorporates the hard-won field experience of actually working with the standard. Along with a thoroughly updated and

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***customisable generic
Quality Manual with audit
checklists for developing
a complete Quality
Management System, the
book provides valuable
advice on: Compatibility***

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***and Inter-Relationship
between other
Management Standards;
Basic Requirements to
Set Up an Integrated
Management System;
and, The Eight Principles***

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***of Management, among
others.***

***The Medical Devices
Directive (MDD) is an all-
encompassing document
legislating for the
manufacture of any***

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medical device or material used either temporarily or permanently on or in the human body. To achieve its main objectives the MDD requires the

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***manufacturer of all
products covered by the
Directive to possess a
fully auditable Quality
Management System
consisting of Quality
Policies, Quality***

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***Procedures and Work
Instructions, based on the
ISO 9000 standard. The
book is based on the
sound principles of ISO
9000 and will guide to the
reader, if required, to***

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***eventually set up an ISO
9000 fully compliant
system. MDD-Compliance
using Quality
Management Techniques
consists of the following:
* A brief guide to the***

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***Medical Devices Directive
- explaining the main
requirements of the
directive, translating
legal "Eurospeak" into
everyday language * An
overview of ISO 9000 and***

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***how the MDD links in
with these international
requirements. * A Quality
Manual - will provide a
template for a complete
Quality Management
System that can be used***

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***by any product being
produced under the
requirements of the MDD
* CD ROM containing a
software copy of the
Quality Manual * A User
manual consisting of***

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***clear instructions and
flow charts on how to set
up and use the Quality
Management System
described in the Quality
Manual
Discover the latest ICH***

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***news from international
experts in the
pharmaceutical industry,
academia, and regulatory
bodies. The recent
International Conference
on Harmonisation (ICH)***

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revisions of regulatory requirements for quality, nonclinical, and clinical pharmaceutical product registration are the focus of this timely update. This cutting-edge resource

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includes the major headings in the modular structure of the Common Technical Document (CTD), which is now the agreed format for product information submission.

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***The format, specification,
and technical
requirements of the e-
CTD, the electronic
version of CTD, are also
thoroughly discussed. The
book is organized into six***

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***highly practical
segments: Part I: CTD,
eCTD, Module 1, and
Environmental Risk
Assessment Part II: CTD
Summaries Part III:
Quality Topics Part IV:***

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***Nonclinical Topics Part V:
Clinical Topics Part VI:
Other Topics (including
drug-device combination
products) This text is a
must-have for those in
the pharmaceutical***

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***industry determining
regulatory requirements
for the major world
markets in Europe, the
US, Canada, and Japan.
International
Pharmaceutical Product***

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**Registration, Second
Edition**

**How to Establish a
Document Control System
for Compliance with ISO
9001:2015, ISO
13485:2016, and FDA**

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Requirements

Write It Down

Medical Instrument

Design and Development

ISO 9001:2015 in Plain

English

Regulatory Affairs for

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***Biomaterials and Medical
Devices***

Safer Grains

Medical Product

Regulatory Affairs

Technical Writing One

Hundred One

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***Medical Devices - Quality
Management Systems -
Requirements for
Regulatory Purposes
A Comprehensive Guide
to Designing a Process-
Based Document Control***

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System

ISO 9001:2000 Quality

Management System

Design

An International

Perspective

Recognize market opportunities,

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master the design process, and develop business acumen with this 'how-to' guide to medical technology innovation. A three-step, proven approach to the biodesign innovation process - identify, invent, implement - provides a practical

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formula for innovation. The experiences of hundreds of innovators and companies, in the form of case studies, quotes and practical advice, offer a realistic, action-orientated roadmap for successful biodesign innovation.

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Real-world examples, end-of-chapter projects, and Getting Started sections guide the reader through each of the key stages of the process and provide a template to create their own new medical devices.

Addressing common medical,

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engineering, and business challenges to develop well-rounded expertise, this book is the complete package for any biodesign entrepreneur. The text is supported by valuable resources, including up-to-date industry changes: found at

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ebiodesign.org.

The number of FDA regulations and the agency's increased expectations is staggering and their content tedious, creating a regulated industry need for compliance insight and appropriate detail. This book is

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the reference needed to successfully
navigate through the FDA maze!

The target audiences for this desk
reference include: Regulatory
professionals, who know their
responsibility to keep their firm's
employees trained and competent on

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FDA device regulations and who need a preliminary desk reference that can be used throughout their enterprise to help train and ensure compliance Neophytes, who know nothing about FDA but need a resource that provides both broad

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and specific information in
sufficient detail to be useful

Beginners, who know a little about
FDA, need to know more, and need
a reference tool to help them be
more effective and productive on the
job Intermediates, who knows

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enough about FDA to know they need to know more and who need a reference tool that provides them with both more basics and executable detail Busy managers, who need to know regulatory requirements and FDA expectations

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in order to manage compliance in their specific activity Busy executives (CEOs, COOs, and operations managers, whom FDA holds responsible for all regulatory compliance), who also need a desk reference with specific information

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to quickly assess regulatory compliance, identify potential noncompliance, and review corrective, preventive, and compliance actions

This book constitutes the proceedings of the 18th International

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Conference on Computer
Information Systems and Industrial
Management Applications, CISIM
2019, held in Belgrade, Serbia, in
September 2019. The 43 full papers
presented together with 3 abstracts
of keynotes were carefully reviewed

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and selected from 70 submissions.

The main topics covered by the chapters in this book are biometrics, security systems, multimedia, classification and clustering, industrial management. Besides these, the reader will find interesting

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papers on computer information systems as applied to wireless networks, computer graphics, and intelligent systems. The papers are organized in the following topical sections: biometrics and pattern recognition applications; computer

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information systems; industrial management and other applications; machine learning and high performance computing; modelling and optimization; various aspects of computer security.

Medical device regulation in Asia

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has gained more importance than ever. Governments and regulatory bodies across the region have put in place new regulatory systems or refined the existing ones. A registered product requires a lot of technical documentation to prove its

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efficacy, safety, and quality. A smooth and successful registration process demands soft skills for dealing with various key stakeholders in the government, testing centers, and hospitals and among doctors. Handbook of

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Medical Device Regulatory Affairs in Asia covers medical device regulatory systems in different countries, ISO standards for medical devices, clinical trial and regulatory requirements, and documentation for application. Government bodies, the

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medical device industry, and academics and students will find this book immensely useful in understanding the global regulatory environment and in their research and development projects.

Medical Devices Quality

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Management Systems: Strategy and Techniques for Improving Efficiency and Effectiveness is written for the needs of quality, compliance, and regulatory professionals in medical device companies. It includes secrets for

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developing an effective, yet efficient, Quality Management System (QMS) and explains how to create a vision, strategy, and tactical plans. Author Manz shares lessons on leadership, key roles and responsibilities within a medical

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device company, while also exploring the concepts of process ownership, individual accountability, and how to cultivate a culture of quality and compliance. This book is useful for all executive, functional leaders, and organizations

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in the highly regulated medical device industry. Provides practical, real-world guidance on developing an effective and efficient Quality Management System Presents a roadmap for QMS development Covers techniques to assess current

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state Includes discussions on tools, such as CAPA and Six Sigma that help define vision, strategy and quality plans

Although complex and lengthy, the process of certification for the ISO 13485 can be easily mastered using

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the simple method outlined in ISO 13485: A Complete Guide to Quality Management in the Medical Device Industry. Written by an experienced industry professional, this practical book provides a complete guide to the ISO 13485

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Standard certification for medical device manufacturing. Filled with examples drawn from the author's experience and spanning different sectors and fields of the medical device industry, the book translates the extra ordinary requirements and

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objectives of the standard into feasible activities and tasks. The book provides a full analysis of each clause and sub clause through quality perspectives: the implications on an organization, its processes, management, human

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resources, infrastructures, work environment, control and effectiveness, documentations and records. The book is organized like the standard itself — the table of contents is identical to the ISO 13485 Standard's table of contents

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— making it user friendly, familiar, and unintimidating. You can use the book as a consulting session — read it, explore it ,extract ideas — and draw on the information and knowledge that suits you and your organization, and then apply it

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effectively to your quality management system and processes. The Manual of Commercial Methods in Clinical Microbiology 2nd Edition, International Edition reviews in detail the current state of the art in each of the disciplines of

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clinical microbiology, and reviews the sensitivities, specificities and predictive values, and subsequently the effectiveness, of commercially available methods – both manual and automated. This text allows the user to easily summarize the

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available methods in any particular field, or for a specific pathogen – for example, what to use for an Influenza test, a Legionella test, or what instrument to use for identification or for an antibiotic susceptibility test. The Manual of

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Commercial Methods in Clinical Microbiology, 2nd Edition, International Edition presents a wealth of relevant information to clinical pathologists, directors and supervisors of clinical microbiology, infectious disease physicians, point-

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of-care laboratories, professionals using industrial applications of diagnostic microbiology and other healthcare providers. The content will allow professionals to analyze all commercially available methods to determine which works best in

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their particular laboratory, hospital, clinic, or setting. Updated to appeal to an international audience, The Manual of Commercial Methods in Clinical Microbiology, 2nd Edition, International Edition is an invaluable reference to those in the

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health science and medical fields.

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

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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

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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

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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

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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

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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

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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

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managed under the quality
management system.

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CISIM 2019, Belgrade, Serbia,
September 19–21, 2019,
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Regulations, Standards, and Guidelines Latex 2002

*"The book describes the
design rules required to
document, implement, and
demonstrate quality*

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*management system
effectiveness in
compliance with the latest
version of the ISO 9000
International Standard.
This systematic and
engineering approach*

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simplifies the many complexities in maintaining compliance with ISO standards. This hands-on guide is packed with tips and insights the author has garnered from

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*personally designing
quality management systems
that integrate
organizational strategy
with quality management.
Moreover, the book helps
professionals create*

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*meaningful documentation
and a user-friendly,
informative quality manual
that together form the
core of an effective and
responsive quality
management*

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system."--Jacket.

*Due to the direct health
and safety effects they
have on users, medical
devices are subject to
many regulations and must
undergo extensive*

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*validation procedures
before they are allowed on
the market. Requirements
formulation is one of the
most important aspects of
the design process because
it lays the foundation for*

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*the rest of the design.
ISO 9001 hasn't changed
much in the last 15
years... until now! ISO
9001:2015 is a MAJOR
revision. A LOT has
changed. Requirements have*

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*been added and removed.
Content has shifted to
different sections and
clauses. ISO 9001:2015 is
built upon a completely
different structure with
the adoption of Annex SL.*

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This may seem like a lot to take in, and it is. Fortunately, bestselling author Craig Cochran has translated ISO 9001:2015 into plain English that anyone can understand.

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Just as he did with the bestselling ISO 9001 in Plain English Cochran has written a comprehensive yet easily understandable guide to ISO 9001:2015. ISO 9001:2015 in Plain

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English was written so that anyone at any level of the organization can get to the heart of the standard's requirements and how they apply to the organization quickly and

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simply. Plus, Cochran shows what has changed between the 2008 and 2015 version. This straightforward book is ideal for people who are new to ISO 9001:2015,

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experienced ISO coordinators who want to get more out of an established system as they transition to the new standard, and for employees who just need a

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*basic understanding of
what ISO 9001:2015 is and
how it applies to them.
Cochran explains each of
ISO 9001:2015's sections
and clauses using real-
world examples and*

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*frequently asked
questions.*

*Documentation Practices
demystifies the
documentation process and
provides an accurate and
meaningful understanding*

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*of manual document
management requiremenst
for FDA, GMP, QSR, ISO
13485 regulated medical
product industries.*

*The focus of this book is
to demystify the*

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*requirements delineated
within ISO/IEC 17025:2017,
while providing a road map
for organizations wishing
to receive accreditation
for their laboratories.
AS9100, ISO 9001:2015, and*

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ISO 13485:2016 are standards that have been created to support the development and implementation of effective approaches to quality management, and

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are recognized blueprints for the establishment of a quality management system (QMS) for many diverse industries. Similar to these recognized QMS standards, ISO/IEC

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17025:2017 for laboratory accreditation serves a unique purpose. It is not unusual for laboratories to retain dual certification in ISO 9001:2015 and ISO/IEC

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*17025:2017. However,
ISO/IEC 17025:2017
contains requirements
specific to the laboratory
environment that are not
addressed by ISO
9001:2015. This book*

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highlights those differences between ISO 9001:2015 and ISO/IEC 17025:2017, while providing practical insight and tools needed for laboratories wishing

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to achieve or sustain accreditation to ISO/IEC 17025:2017. For those currently or formerly accredited to the 2005 version of ISO/IEC 17025, an appendix outlines the

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*changes between the 2005
and 2017 versions of the
standard.*

*Written in a clear and
concise style by an
experienced author, this
attractively-priced book*

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*covers regulatory affairs
in all major global
markets for
pharmaceuticals and
medical devices, making it
the most comprehensive in
its field. Following a*

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*look at drug development,
complete sections are
devoted to national and EU
regulatory issues,
manufacturing license
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and regulation in the USA.*

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Other topics dealt with include CDER, CBER and marketing and manufacturing licenses, the ICH process and Good Laboratory/Clinical/Manufacturing Practices.

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*Everything
pharmacologists,
bioengineers, pharma
engineers, students in
pharmacy and those working
in the pharmaceutical
industry need to know*

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*about medical regulatory
affairs.*

*Gillespie includes all the
necessary procedures for
documenting and
implementing the process,
detailed information on*

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*preparing for registration
and audit, case studies,
and interviews with
executives in industry.
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The purpose of this expanded field

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guide is to assist organizations, step by-step, in implementing a quality management system (QMS) in conformance with ISO 13485:2016, whether "from scratch" or by transitioning from variations of the ISO 13485 family. In keeping with

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ISO 9000:2015's definition of quality as the "degree to which a set of inherent characteristics fulfills requirements," Myhrberg, Raciti, and Myhrberg have identified the requirements and inherent characteristics

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(distinguishing features) for this expanded field guide. Within the guide, each subclause containing requirements is the focus of a two-page visual spread that consistently presents features that fulfill the requirements listed below. This

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guide will: -Provide a user-friendly guide to ISO 13485:2016's requirements for implementation purposes -Identify the documents/documentation required, along with recommendations on what to

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consider retaining/adding to a QMS during ISO 13485:2016 implementation -Guide internal auditor(s) regarding what to ask to verify that a conforming and effective QMS exists -Direct management on what it must do

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and should consider to satisfy ISO 13485:2016's enhanced requirements, as well as on the responsibilities for top management

- Depict step-by-step in flowchart form what must occur to create an effective, conforming QMS

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All biomaterials and medical devices are subject to a long list of regulatory practises and policies which must be adhered to in order to receive clearance. This book provides readers with information on the systems in place in the USA

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and the rest of the world. Chapters focus on a series of procedures and policies including topics such as commercialization, clinical development, general good practise manufacturing and post market surveillance. Addresses global

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regulations and regulatory issues surrounding biomaterials and medical devices Especially useful for smaller companies who may not employ a full time vigilance professional Focuses on procedures and policies including

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risk management, intellectual protection, marketing authorisation, university patent licenses and general good practise manufacturing

A well-understood tenet exists among the FDA and other

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regulatory bodies: if you didn't write it down, it didn't happen. And if it didn't happen, your company stands to lose time, money, and perhaps its competitive edge. Write it Down: Guidance for Preparing Effective and Compliant

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Documentation provides you with the tools you need to put effective documentation in place. The book has a three-pronged focus: to help writers understand the why of what they must write and the current industry standards for good

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documentation practices, to provide effective examples of a broad spectrum of documents, and to supply an in-depth explanation of grammar and punctuation conventions. Substantially expanded, the second edition

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focuses on the regulations, the need to document, and the range of documentation that must be in place to support therapeutic products from discovery through market. Readers will find useful examples of good writing, many

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provided by people in the industry. Letters and memos; short reports of varied topics, including equipment evaluation, vendor audit, and trip review; standard operating procedures, laboratory methods, and training materials;

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documentation for an IQ/OQ/PQ project; a journal article; and excerpts from a development report and a dossier are among the many examples. The book also gives a thorough explanation of grammar, punctuation, and usage, with a

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strong emphasis on the components of the language that pose difficulties for non-native writers of English. This book is a must for people working in or preparing to work in environments that produce drugs, medical devices, or biologics

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for sale in countries that have stringent regulatory requirements and where the business language is English. Firmly placing the writing task in context of the existing laws and guidances, the book offers valuable insights into managing

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systems and producing documentation that meets the requirements of the binding regulations.

Having a robust and functional Quality Management system is a QSR requirement for all

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Pharmaceutical, Biomedical, and Medical Device companies. This book does the following for you:

1. It helps Managers in Startup companies design a Quality management system that meets and exceeds QSR requirements.
2. It

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helps you understand requirements for the design of a Quality Management system for Medical Device, Pharmaceutical, Tissue, and Biomedical industries 3.It provides the Quality system document structure 4.It helps you understand

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Quality system requirements for ISO 13485, and ISO 9001 5. It provides standard definitions for the Quality management system 6. It provides examples of Quality system related warning letters written by the FDA during onsite

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audits 7.It provides the reader several models of a Quality Management system

This book is meant to be a guide to all who want to learn about a highly regulated industry. My approach is to give you, the reader,

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an example of a fictitious device, and we will take it from a conceptual idea all the way to launch and beyond. My intention is to incorporate the best experiences that I and other contributors have had into this book and convert

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them into laymans terms for those who are in need. These experiences can and will be indispensable to beginners and professionals alike who are trying their hand in the medical device industry and to those who have not been out of

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their silo to help see how each of the systems relate to each as a whole. However, it should be noted that the contents of this book should be taken only as information and is not intended to demonstrate how companies can be

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In compliance. In some instances, there are multiple ways to go through the maze of regulations that are documented and made by agencies because the regulations are pretty much made and designed to be flexible and high level so that

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companies can adopt their systems, which are solely designed for their purposes. Therefore, this book will try to avoid complicated words and complex technical details of engineering and statistics. This book will strive to be an

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embodiment of the honest-to-goodness, everyday experiences and issues that folks experience while working in the medical device industry.

This book will be a substantial revision, which will reflect the new

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version of the ISO 13485:2016. This represents the standard protocols that all medical device manufacturers must follow, in the fabrication of their products. It will focus on changes in the structure of the quality management system;

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change in the documentation for quality management systems and finally, present the different methods of implementation of the standard requirements within the organization. This new version was initiated in 2016, thus all

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appropriate enterprises using the old standard must convert to the new version, now available. The Second Edition will clarify, explain and demonstrate the new version.

[A Complete Guide to Quality Management in the Medical Device](#)

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