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Requirements for
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Statistical Concepts of
Process Validation 5
steps to create your
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Jason Lim ISO
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| Equipment
Qualification | Medical
Devices ISO 14971 :
2019 (Medical Device
Risk management) |
Detailed explanation
Clause by Clause ISO
9001 IN A
NUTSHELL | How it

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Quality and How it
Can Work For You
~~What Is ISO 9001 ?~~

~~System Medical~~
Best ISO 13485:2016
Starter Video [For
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What is ISO 13485 for
medical devices? Total
Quality Management
The Seven basic
quality tools Risk
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of the IAASB's
Quality Management
Standards Medical
Devices - ISO 14971 :
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Theranos Aftershock
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Regulatory/Investment
Changes on the
Horizon

Introduction to ISO
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Requirements Benefits
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(quality management
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~~Expectations for~~
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and Services
Obtained from
Suppliers Authoring
Group: GHTF Study
Group 3 Endorsed by:
The Global
Harmonization Task
Force Date:
December 11, 2008
Dr. Roland Rotter,
GHTF Chair

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processes . Authoring
Group: Study Group
3. Date: 4 November
2010 . Dr. Larry Kelly,
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2.3 Quality

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system to direct and

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Control an organization with regard to quality. (ISO 9000:2005, 3.2.3) 3.0

References GHTF
SG4/N28R4:2008 -
Guidelines for
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Systems of Medical
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obtain data, record

data, and interpret

data. These activities

may be considered to

fall into three phases:

1) an initial

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Qualification of the
equipment used and
provision of
necessary services ☐
also

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Process Validation
Guidance -January
2004

SG3/N99-10. That
standard was updated
in 2004 to reflect the
new validation

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requirements of
ISO13485:2003,
Medical devices □
Quality management
systems, which was
itself updated to
harmonize with the
more general
ISO9001:2000
standard. FDA
provided input into the
current 13485
standard, so it is
fitting that CDRH will

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utilize SG3/N99-10.

This whitepaper will
examine the

SG3/N99-10:2004

standard to evaluate
how it compares to
U.S.

GHTF and FDA

Validation Guidance:

A Comparison

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to direct and control

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regard to quality. (ISO

9000:2005, 3.2.3) 3.0

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and GTHF
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□ January 2004

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originally finalized in

1999 and re-

published as □GHTF/

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(Edition 2) □ after

revisions due to the

changes in ISO

13485:2003, which is

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published through
IMDRF and utilized in
some regulatory
systems.

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Regulation Process
Validation FDA Small
Business Regulatory
Education for Industry
(REdI) Silver Spring

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MD September 30,
2015 Joseph Tartal

Quality System
Regulation Process
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GHTF.SG3.N15-R8:
Implementation of
Risk Management
Principles and
Activities Within a
Quality Management
System. Presented by
Carolyn Albertson

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Gunter Frey Member,
SG3 NEMA Medical
device manufacturers
are generally required
to have a quality
management system
as well as ... □

PowerPoint PPT
presentation.

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Implementation of
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author according to
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T 0287-2003 quality
management system
for medical device
regulatory
requirements, and
process validation
guidance document G
HTF-
SG3-N99-10-2004,
combined with the
actual implementation
process in the

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enterprise, detailed
the process and
applications of
process validation.

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preventive action and
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processes; SG3; 2010
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Quality System
Regulation Overview
Study Group 3 is
concerned with
examining and
harmonizing current
quality systems
requirements.

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Examples of documents put out by Study Group 3 include Implementation of Risk Management Principles and Activities Within a Quality Management System and Quality Management Systems - Process Validation Guidance. Study Group 4

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Management
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Devices: Properties,
Requirements, and
Applications, Third
Edition provides a
comprehensive
overview on the main
types of plastics used
in medical device
applications. The
book focuses on the
applications and

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properties that are most important in medical device design, such as chemical resistance, sterilization capability and biocompatibility. The roles of additives, stabilizers and fillers as well as the synthesis and production of polymers are covered and backed up with a

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wealth of data tables.

The book also covers other key aspects in detail, including

regulations,

compliance,

purchasing controls

and supplier controls,

and process

validation. This

updated edition has

been thoroughly

revised with regard to

new plastic materials,

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applications and requirements. This is a valuable resource for engineers, scientists and managers involved in the design and manufacture of medical devices. Presents detailed coverage of commercially available plastics used in medical

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Quality applications,
organized by polymer
type and supported by
data Includes up-to-
date regulatory
requirements and
practical information
on purchasing and
supplier controls,
process validation
and risk management
Supports the
development,
marketing and

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The Biomedical
Quality Auditor
Handbook was
developed by the
ASQ Biomedical
Division in support of
its mission to promote
the awareness and
use of quality

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principles, concepts, and technologies in the biomedical community. This third edition correlates to the 2013 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 the

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second edition. Most notably it has been re-organized to align more closely with the BoK.

This handbook covers medical device regulatory systems in different countries, ISO standards for medical devices, clinical trial and regulatory

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requirements, and documentation for application. It is the first to cover the medical device regulatory affairs in Asia. Experts from influential international regulatory bodies, including the US Food and Drug Administration (FDA), UK Medicines and

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Healthcare Products
Regulatory Agency,
Japan
Pharmaceuticals and
Medical Devices
Agency, Saudi Food
and Drug Authority,
Korea Testing
Laboratory, Taiwan
FDA, World Health
Organization, Asian
Harmonization
Working Party,
Regulatory Affairs

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Professionals Society, and British Standards Institution, have contributed to the book. Government bodies, the medical device industry, academics, students, and general readers will find the book immensely useful for understanding the global regulatory environment and in

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Quality Management
their research and
development projects.

System Medical
Devices
This report presents
the recommendations
of a WHO Expert
Committee
commissioned to
coordinate activities
leading to the
adoption of
international
recommendations for
the production and

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Control of vaccines and other biological substances, and the establishment of international biological reference materials. Following a brief introduction, the report summarizes a number of general issues brought to the attention of the Committee. The next part of the report, of

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particular relevance to manufacturers and national regulatory authorities, outlines the discussions held on the development and adoption of new and revised WHO Recommendations, Guidelines, and guidance documents. Following these discussions, WHO Guidelines on the

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quality, safety and efficacy of Ebola vaccines, and WHO Guidelines on procedures and data requirements for changes to approved biotherapeutic products were adopted on the recommendation of the Committee. In addition, the following two WHO guidance

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documents on the
WHO prequalification
of in vitro diagnostic
medical devices were

also adopted: (a)

Technical

Specifications Series

(TSS) for WHO

Prequalification -

Diagnostic

Assessment: Human

immunodeficiency

virus (HIV) rapid

diagnostic tests for

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professional use
and/or self-testing;
and (b) Technical
Guidance Series
(TGS) for WHO
Prequalification -
Diagnostic
Assessment:
Establishing stability
of in vitro diagnostic
medical devices.
Subsequent sections
of the report provide
information on the

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current status,
proposed
development and
establishment of
international
reference materials in
the areas of:
antibiotics,
biotherapeutics other
than blood products;
blood products and
related substances; in
vitro diagnostics; and
vaccines and related

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substances. A series of annexes are then presented which include an updated list of all WHO Recommendations, Guidelines, and other documents on biological substances used in medicine (Annex 1). The above four WHO documents adopted on the advice of the Committee are

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then published as part of this report (Annexes 2-5).

Finally, all additions and discontinuations made during the 2017 meeting to the list of International Standards, Reference Reagents and Reference Panels for biological substances maintained by WHO are summarized in

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Annex 6. The updated full catalog of WHO International Reference Preparations is

available at: <http://www.who.int/bloodproducts/catalogue/en/>.

Risk management principles are effectively utilized in many areas of business and

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government, including
finance, insurance,
occupational safety,
and public health, and
by agencies

regulating these
industries. The U.S.
Food and Drug
Administration (FDA)
and its worldwide
counterparts are
responsible for
protecting public
health by ensuring the

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safety and effectiveness of the drugs and medical devices. Regulators must decide whether the benefits of a specific product for patients and users outweigh its risk, while recognizing that "absolute safety" (or zero risk) is not achievable. Every product and every

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process has an associated risk. Although there are some examples of the use of quality risk management in the FDA-regulated industry today, they are limited and do not represent the full contribution that risk management has to offer. The present FDA focus on risk-

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Quality determination is requiring that the regulated industries improve dramatically their understanding and capability of hazard control concepts. In addition, the importance of quality systems has been recognized in the life sciences industry, and it is becoming evident that

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quality risk

management is a valuable component of an effective quality system. The purpose of this book is to offer a systematic and very comprehensive approach to quality risk management. It will assist medical and food product manufacturers with the integration of a

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risk management system or risk management principles and activities into their existing quality management system by providing practical explanations and examples. The appropriate use of quality risk management can facilitate compliance

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with regulatory requirements such as good manufacturing practices or good laboratory practices.

The content of this book will provide FDA-regulated manufacturers with a framework within which experience, insight, and judgment are applied systematically to

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manage the risks associated with their products.

Manufacturers in other industries may use it as an informative guidance in developing and maintaining a risk management system and process. The two appendices add even more insight:

Appendix A contains

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general examples of risk management, while Appendix B includes 10 case studies illustrating real examples of the quality risk management process across the medical product arena.

Medical device regulation in Asia has gained more

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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 efficacy, safety, and quality. A smooth and

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Successful registration process demands soft skills for dealing with various key

stakeholders in the government, testing centers, and hospitals and among doctors.

This handbook covers medical device regulatory systems in different countries, ISO standards for medical devices,

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clinical trial and regulatory requirements, and documentation for application. It is the first to cover the medical device regulatory affairs in Asia. Each chapter provides substantial background materials relevant to the particular area to have a better

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Understanding of
regulatory affairs.

This book contains
both the theory and
practice of risk
management (RM)
and provides the
background, tools,
and application of risk
in pharmaceutical and
biologics
manufacturing and
operations. It includes

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case studies and specific examples of use of RM for biological and pharmaceutical product manufacture. The book also includes useful references and a bibliography for the reader who wishes to gain additional knowledge in the subject. It aids in

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assisting both industry and regulatory agencies to implement compliant and effective risk management approaches, and includes case studies to help with understanding.

The second edition of a bestseller, Design Controls for the

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Industry provides a comprehensive review of the latest design control requirements, as well as proven tools and techniques to ensure your company's design control program evolves in accordance with current industry practice. The text

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assists in the development of an effective design control program that not only satisfies the US FDA Quality System Regulation (QSR) and ISO 9001 and 13485 standards, but also meets today's third-party auditor/investigator expectations and saves you valuable

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time and money. The author's continual participation in FDA QSR inspections and Notified Body ISO audits is reflected in updates to all chapters and appendices of the book, now bursting at the seams with: New coverage of ISO 9001 and 13485 design control requirements

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More real-world examples from the medical device industry Additional detail for greater understanding and clarity Fresh templates for practical implementation Extensive references for further study The book addresses design control elements such as

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design planning, input, output, review, verification, validation, change, transfer, and history, as well as risk management inclusive of human factors and usability, biocompatibility, the FDA Quality System Inspection Technique (QSIT) for design controls, and medical device regulations

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and classes in the
US, Canada, and
Europe.

Design, development
and life-cycle
management of any
electromechanical
product is a complex
task that requires a
cross-functional team
spanning multiple
organizations,
including design,

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manufacturing, and service. Ineffective design techniques, combined with poor communication between various teams, often leads to delays in product launches, with last minute design compromises and changes. The purpose of Design of Electromechanical

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Quality: A Systems Approach is to provide a practical set of guidelines and best practices for driving world-class design, development, and sustainability of electromechanical products. The information provided within this text is applicable across the entire span of product

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life-cycle

management, from initial concept work to the detailed design, analysis, and development stages, and through to product support and end-of-life. It is intended for professional engineers, designers, and technical managers, and

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Quality provides a gateway to developing a product's design history file ("DHF") and device aster record ("DMR").

These tools enable design engineers to communicate a product's design, manufacturability, and service procedures with various cross-functional teams.

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How have recent changes in domestic and international regulations affected quality management in the development and marketing of medical devices in the US and abroad? Consultants Daniel and Kimmelman take a close look at the Quality System

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Regulation (QsReg),
the ISO 13485: 2003
standard and the
ISO/TR 14969: 2004
guidance document
as well as a number
of US Food and Drug
Administration (FDA)
and Global
Harmonization Task
Force (GHTF)
guidance documents.
The authors provide
extensive

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Commentary and notes an update their material to include such topics as the incorporation of principles of risk management into the medical device organizations' quality management systems (QMSs) and considerations of combination products. Daniel and

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Kimelman include full coverage of the QSR requirements, descriptions of comparable requirements in the ISO documents, excerpts of the FDA's responses to the QSR preamble and excerpts from FDA guidance documents related to QMSs.

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