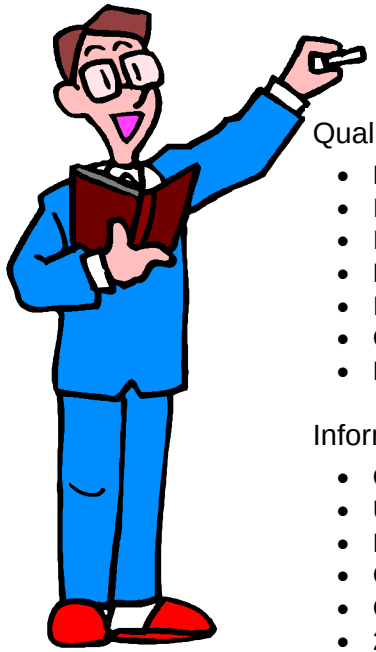
QA RA Compliance Connection, Inc.
P.O. Box 448 * Odessa, Florida 33556 * (813) 784-8457

2006 Product Catalog



Highlighted Products:

Quality System Training Modules

- FDA QSR (GMP)
- ISO 13485:2003
- ISO 9000:2000
- Design Controls
- Internal Auditing
- Compliant & MDR Requirements
- Root Cause Analysis & CAPA

Informational Handbooks

- QSR Companion
- Understanding ISO 9000:2000
- Medical Device Regulation Basics
- Conducting Design Reviews
- Cosmetic Regulation Handbook
- 21 CFR Part 820

Quality System Templates

- QSR Quality Manual
- QSR Audit Checklist

Who are we?

QARA Compliance Connection is a first class Quality Assurance and Regulatory Affairs consulting company offering a wide range of regulatory and quality system consulting services and training to the manufacturing and other industries. We are excited to offer a number of quality products, including highly effective quality system CD-ROM training modules, informational handbooks, and quality system documentation templates.

With QARA Compliance Connection, you secure experienced and knowledgeable professionals with a proven track record of successful results in both the commercial and regulated industries. Our personnel have hands-on experience in developing, implementing, training and auditing organizations to the requirements of ISO 9001, EN 46001, ISO 13485, ISO 17025, FDA QSR (21 CFR 820), 21 CFR 211 and the Medical Device Directive 93/42/EEC.

QARA Compliance Connection is dedicated and committed to working with you to achieve your goals.

For more information about our products and services visit our website at *www.qaracc.com* or Email us at: info@qaracc.com

Table of Contents

QARACC Informational Handbooks

Informational Handbooks

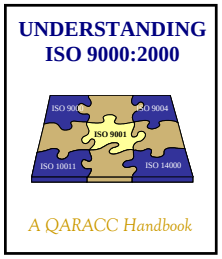
QARA Compliance Connection offers a number of informational handbooks on various topics. These books are either 5 1/2 in x 8 1/2 in or 8 1/2 in x 11 in. QARACC Handbooks are the ideal quick reference guide and a cost effective supplement to any training program. These guides provide the information you need on a particular subject in easy to understand language. Get a copy today for all members of your organization or regulatory compliance team.

We currently offer the following handbooks:

- Understanding ISO 9000:2000
- Medical Device Regulation Basics
- Conducting Effective Design Reviews
- Cosmetic Regulation Handbook
- QSR Companion
- 21 CFR Part 820

Visit our website at http:\\www.qaracc.com to view a Table of Contents for each of our handbooks!

QARACC Informational Handbooks



Understanding ISO 9000:2000

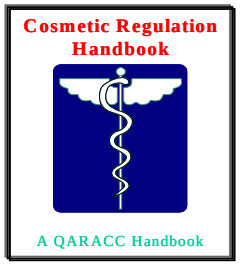
This handbook provides employees with a basic review of ISO 9001:2000 requirements and the basic principles from which the standard was founded. It serves as an effective supplement to your ISO 9000 training program and is the perfect handout for every employee in the organization.

Price: $9.95
Order #: ISOHK
Type: 5 1/2" x 8 1/2" Handbook

Medical Device Regulation Basics

This handbook is packed with information on FDA medical device regulation requirements. It is a must have for any quality or regulatory professional or medical device manufacturer.

Price: $6.95
Order #: MDHK
Type: 5 1/2" x 8 1/2" Handbook



Cosmetic Regulation Handbook

This handbook provides the regulatory professional with all of the information needed to comply with FDA Cosmetic Regulations. It is a must have for any organization that manufactures cosmetics.

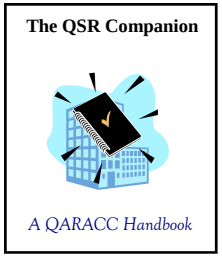
Price: $19.95
Order #: CRHB
Type: 8 1/2" x 11 " Handbook

Design Reviews

This handbook is designed to assist personnel responsible for establishing formal design review programs and/or conducting effective formal design reviews to help meet FDA QSR, ISO 9001 or other industry or organizational requirements. It is the ideal quick reference guide for any project team in any size organization.

Price: $6.95
Order #: DRHB
Type: 5 1/2" x 8 1/2" Handbook

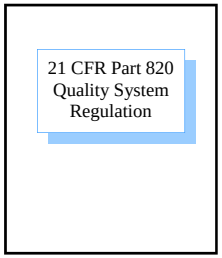
QARACC Informational Handbooks



The QSR Companion

This handbook reviews the four major subsystems of the FDA Quality System Inspection Technique (QSIT) in clear and easy to understand language, and provides a reference for compliance. This handbook is essential to employees who may be involved in an FDA QSIT inspection.

Price: $15.95
Order #: QSRHK
Type: 5 1/2” x 8 1/2” **or** 8 1/2” x 11” Handbook



21 CFR Part 820—Quality System Regulation

This handbook is simply the Quality System Regulation, 21 CFR Part 820 printed in a convenient handbook form. It serves as a great handout for employees as part of any QSR training program.

Price: $5.95
Order #: 820HK
Type: 5 1/2” x 8 1/2” Handbook

New handbooks are added periodically, so be sure to regularly check our site out!

http:\\www.qaracc.com

QARACC CD-ROM Training

Quality System Training Modules

QARA Compliance Connection offers a number of highly effective quality system training modules for the medical device and manufacturing industries. These modules are designed to reduce the time, expense and scheduling difficulties associated with off-site employee training and provide organizations with the scheduling flexibility and convenience they require. The training modules are ideal for both large and small companies and are used by many well known medical device manufacturing companies worldwide.

Each module includes a CD-ROM of the Adobe Acrobat® formatted presentation, an Instructor's/Training Manual (includes presentation notes pages to assist the trainer in explaining or emphasizing the information or concepts presented), a comprehension exam, and a master 3-per-page presentation handout for participants.

We currently offer the following CD-ROM training modules:

- FDA QSR Training
- FDA QSR Executive Overview
- FDA QSR Employee Overview
- Complaint & MDR Requirements
- Root Cause Analysis & CAPA
- ISO 13485:2003 Overview
- ISO 9000:2000 Overview
- Design Controls
- Internal Auditor Training

Visit our website at http:\\www.qaracc.com to see a preview of some of the presentation pages for each module or email us at: *info@qaracc.com* for a brochure. Check out our website to view the FAQ page on our training modules.

Quality System Training Modules

FDA QSR Training

This module was designed to provide personnel with a knowledge and understanding of the FDA's Quality System Regulation, 21 CFR Part 820. It is a must for any organization required to implement and comply with the regulation.

Price: $1095.00 Order #: QSRO-001
Type: CD ROM Training w/Instructor's Manual

FDA QSR Executive Overview

This module was designed to provide executives with a basic understanding of the QSR requirements and their impact on the organization. It presents the QSIT approach to an FDA facility inspection and is ideal for executives mandated to implement a compliant quality management system.

Price: $695.00 Order #: QSRE-002
Type: CD ROM Training w/Instructor's Manual

FDA QSR Employee Overview

This module was designed to provide personnel with a basic understanding of the FDA's QSR in simple, easy to understand language. It is ideal for training employees who work in the industry and who are responsible for implementing and/or complying with the regulation.

Price: $595.00 Order #: QSRE-003
Type: CD ROM Training w/Instructor's Manual

Design Controls—An In-Depth Perspective

This module is essential to those companies looking to comply with mandated ISO 9001, ISO 13485 and FDA QSR design control requirements. This module provides personnel with the knowledge needed to implement an effective design control program.

Price: $895.00 Order #: DC-01
Type: CD ROM Training w/Instructor's Manual

Quality System Training Modules

ISO 13485:2003 Overview

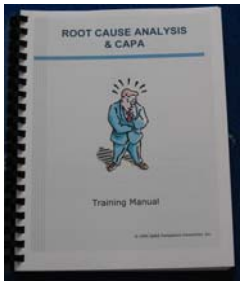
This module was designed to provide personnel with a knowledge and understanding of the ISO 13485 Quality Management System Requirements for Medical Devices. It is a must for any medical device manufacturer looking for global quality management system compliance.

Price: $1095.00 Order #: ISO-13485
Type: CD ROM Training w/Instructor's Manual

ISO 9000:2000 Overview

This module was designed to provide personnel with a knowledge and understanding of the ISO 9001 Quality Management System Requirements. It is a must for any organization looking to comply with ISO 9000:2000 requirements.

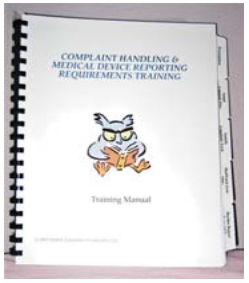
Price: $995.00 Order #: ISO-9000
Type: CD ROM Training w/Instructor's Manual



Root Cause Analysis & CAPA

This module was designed to provide personnel with a complete knowledge and understanding of the ISO 13485 and FDA QSR CAPA requirements. The requirements are presented using the FDA QSIT and Six Step approach. Methods for performing root cause analysis are reviewed to facilitate effective corrective and preventive action.

Price: $895.00 Order #: RCA-CAPA
Type: CD ROM Training w/Instructor's Manual

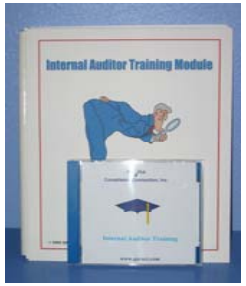


Complaint Files & MDR Requirements

This module was designed to provide personnel with a knowledge and understanding of FDA's complaint file 21 CFR 820.198 and Medical Device Reporting (MDR) 21 CFR 803 requirements. It is a must for any medical device manufacturer and applicable to those individuals involved in the complaint handling and adverse event reporting process.

Price: $395.00 Order #: CHMDR
Type: CD ROM Training w/Instructor's Manual

Quality System Training Modules



Internal Auditor Training
This module was designed to provide personnel with the techniques and skills needed to develop and implement an effective quality audit program. This module comes complete with a sample QSR audit checklist.

Price: $895.00 Order #: IA-001
Type: CD ROM Training w/Instructor's Manual

Quality System Documentation Templates

QSR Quality Manual

The objective of QARA Compliance Connection's FDA QSR Quality Manual is to provide organizations with a template that assists in writing or revising a quality manual. The manual is a Microsoft Word document and was written to satisfy the intent and requirements of FDA's Quality System Regulation codified under Title 21 CFR 820. The manual contains suggestions and comments on how to modify or supplement the manual and is organized by subpart and section, corresponding to the 15 subparts of the Quality System Regulation.

Price: $195.00 Order #: QSRQM
Type: 3 x 5 Diskette

QSR Audit Checklist

QARA Compliance Connection's FDA QSR Audit Checklist is a Microsoft Word document that addresses all of the requirements of the FDA' Quality System Regulation (QSR) in simple and easy to understand language. The checklist provides a baseline at the start of implementation to identify what needs to be done to meet the requirements of the QSR (i.e. gap analysis), and during implementation can be used as a reference to measure progress and verify compliance. The checklist also serves as an invaluable training tool for management and internal auditors by identifying the types of question or issues that need to be addressed to show compliance with the QSR.

Price: $150.00 Order #: AUDCL
Type: 3 x 5 Diskette

On-Site Training

QARA Compliance Connection offers on-site training in a number of areas including: ISO 9000, FDA QSR, Design Controls and Auditor Training. On-site training saves you the time, expense and hassle associated with off-site training. Training is conducted by certified and experienced professionals and can be tailored to meet your particular needs.

$695 each (5 person minimum)
$495 each additional

ISO 9000 or FDA QSR Overview (2 Days)

This class is recommended for those individuals responsible for developing, implementing, maintaining and/or managing the company's quality management system.

Internal Auditor Training (2 Days)

This class is recommended for anyone responsible for implementing, developing, conducting, managing, or participating in an internal or external quality system audits.

Design Controls (2-Days)

This class is recommended for those individuals responsible for managing or participating on a design project team or participating in quality system audits.

ISO 9000 or FDA QSR Training (1 Day)

ISO 9000 Executive Overview	**$2000 ≤ 5 persons**
FDA QSR Executive Overview	**+$300 ea. additional**
ISO 9000 Employee Overview	**$1800 ≤ 12 persons**
FDA QSR Employee Overview	**+$125 ea. additional**

These classes are recommended for those individuals who require a general knowledge of the requirements, their role, and/or how they will be impacted by the requirements.

Coming soon!

Quality System Documentation:
ISO 13485/QSR Audit Checklist

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