Presented by EduQuest in cooperation with FDAnews

The experts who offer Compliance Boot Camp are now adding two intensive medical device training courses!

MEDICAL DEVICE QUALITY & COMPLIANCE Institute 2014

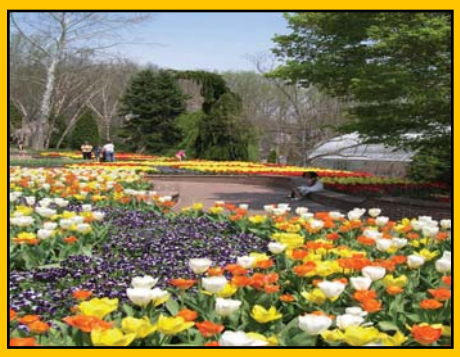
Quality Systems and Design Control Training

Now you can get real-world, step-by-step compliance information. Through plain-English instruction, detailed course materials, and interactive exercises that reinforce the lessons (not to mention making the classroom more fun and interesting), you learn to cost-effectively comply with FDA's QSR rules and related international standards.

Specifically targeted to device manufacturers and suppliers, now you can gain a thorough understanding of the massive 21 CFR 820 Quality Systems Regulation requirements. Know what it takes to stay in compliance and avoid the risk of your product not getting to market or being removed from the market once it's there! And discover how to overcome one of the biggest obstacles device manufacturers face — how the FDA expects you to develop, implement and manage design control and transfer product design to manufacturing operations. With three days of intensive training, you can walk away with the compliance guidance and insight you need to meet FDA standards with confidence. Here's how …

Enroll in these two new courses — offered separately or as an integrated three-day learning package — and discover how to develop a by-the-book quality management program so you stop spinning your wheels with non-essential activities that waste time and money.

Hilton Garden Inn Frederick
Frederick, MD
Nov. 3–6, 2014



"EduQuest seminars are excellent! If you can attend, you should. I've been to several of your seminars over the years, enjoy them, and always leave with a pile of new information."
– Doug Finner, Elbit Systems

Send Your Compliance Team for Maximum Benefit

Send four team members to the same course/s and your fifth member is free.

Get three and a half days of hands-on, interactive training!

FDA training now available to the medical device industry! Get two intensive courses in three and a half days:

- QSR Compliance Basics: Complying with the FDA's Medical Device 21 CFR 820 Quality Systems Regulation
- Design Control for Medical Devices: Meeting the FDA's 21 CFR 820.30 Rules for Quality Design and Manufacturing

www.mdcomplianceinstitute.com
(888) 838-5578 • +1 (703) 538-7600

Get three and a half days of hands-on, interactive training!

Benefits of Attending

- ✓ Fully understand your company's obligations under 21 CFR 820.
- ✓ Receive practical, actionable compliance advice straight from the source – former FDA inspectors, rulemakers, and trainers.
- ✓ Identify best practices for device design control and transfer
- ✓ Hear "lessons learned" by other device companies who have been cited by the FDA for deficient quality management.
- ✓ Hurdle the biggest obstacle facing device companies — translating product design into real-world manufacturing conditions.
- ✓ See how FDA rules relate to ISO and ICH standards — and save time and money with an integrated compliance blueprint.
- ✓ Learn to quickly capture feedback — both internal and external — to fine-tune your quality system and avoid product seizures and recalls.
- ✓ Compare notes with other device manufacturers who face challenges similar to yours.
- ✓ Receive EduQuest's **QSR Compliance Resource CD** with electronic copies of the FDA's latest quality regulations and guidance.
- ✓ Receive a Certificate of Completion to document your training to senior management and FDA inspectors.
- ✓ Save $493 and maximize your time and travel investment by attending both courses, offered back-to-back for your convenience.

Training Course #1

QSR Compliance Basics: Complying with the FDA's Medical Device 21 CFR 820 Quality Systems Regulation

(12 Course Hours)

Compliance with the FDA's quality systems approach is recognized globally as a prerequisite not only for getting your product on the market but — just as importantly — keeping it there.

This day-and-a-half, device-specific course walks you through the requirements of 21 CFR 820, discusses how the FDA's rules correlate with ISO standards and ICH guidance, and examines current FDA inspection and enforcement priorities.

You'll learn:

- The FDA's Evolving Approach to Quality Systems
  - Scientific foundations of quality systems
  - Key quality system elements according to ISO and the FDA
  - Speaking the lingo: important cGMP terms and definitions
- An Introduction to the FDA's Quality Rules for Medical Devices
  - Core principles
  - Quality and compliance: two sides of the same coin
  - Seven FDA-recognized subsystems of your quality system
- ISO/ICH Approaches to Quality Systems
  - Comparison of international standards to FDA expectations
  - ISO 9001:2008 quality system requirements
  - Relationship to ISO 13485: 2003
- QSR Management Review and Control (Subpart B)
  - Management and executive responsibilities
  - Developing a quality policy
  - Allocating adequate resources
- QSR Design Controls and System Development (Subpart C)
  - Tools for design control
  - Research vs. design
  - Design verification and validation
- QSR Production and Process Controls (Subparts G, O)
  - Tools for controlling and monitoring processes
  - Process validation
  - Computerized system validation, including validating off-the-shelf software
- QSR Corrective and Preventive Actions — CAPA (Subparts J, I, N)
  - Difference between correction vs. corrective action
  - Examples of preventive action
  - Evaluating CAPA sources
- The Yin and Yang of Design/CAPA
  - FDA's trending requirement
  - ISO 9001:2008 trending requirement
- Laboratory Controls for Combination Products (21 CFR Part 211 Subpart I)
  - Process tasks for laboratory controls
  - Documenting laboratory operations
  - Validating laboratory test methods
- Conducting Failure Investigations
  - Importance of identifying root cause
  - Seven basic investigation tools you should know
  - Best practices for reducing failures
- QSR Documents, Records and Change Control (Subparts D,M)
  - Assuring changes are reviewed and approved
  - Tools for change control
- QSR Facility and Equipment Controls (Portions of Subpart G)
  - Minimizing adverse impacts of manufacturing environment
  - Tools for facility and equipment control
  - Key environmental controls
- QSR Material Controls (Subparts E, F, H, K, L)
  - Evaluating suppliers, contractors and consultants
  - Tools for material controls
- How to Prepare for an FDA QSR Inspection
  - Understanding FDA's Quality System Inspection Technique (QSIT)
  - Quality system objective evidence the inspector will want to see
  - Examples of systems-based questions to use to prepare
- FDA Enforcement Priorities
  - Understanding the FDA's mindset
  - Inspection observations and reports
  - Consequences of noncompliance
  - Recent trends in FDA 483 observations
  - Practical suggestions surviving an inspection

To register online, visit www.mdcomplianceinstitute.com or call (888) 838-5578

Who Should Attend?

These courses are designed specifically to help:

- ✓ Device industry managers
- ✓ QA/QC specialists
- ✓ Regulatory affairs professionals
- ✓ R&D specialists
- ✓ Scientists
- ✓ Medical professionals
- ✓ IT engineers
- ✓ Manufacturing engineers

The scope of FDA's Quality Systems Regulation (QSR) is huge — more than 500 pages of rules and guidance — and noncompliance is not an option. Recently, 27 medical device companies received warning letters for deficient quality management programs, and several were threatened with removal of their products from the market.

Training Course #2

Design Control for Medical Devices: Meeting the FDA's 21 CFR 820.30 Rules for Quality Design and Manufacturing

(16 Course Hours)

Design control is required for all medical devices sold in the U.S., EU, Japan and several other countries. In addition, there's relentless pressure from both the FDA and Congress to improve device design control and manufacturing.

By registering for the new Design Control course, you learn how the FDA expects you to develop, implement and manage design control. You'll also learn how to overcome one of the biggest obstacles that regularly confounds device companies – accurate and consistent transfer of product design to actual manufacturing operations. Moreover, you will learn how the FDA's design control rules relate to product quality standards established in ISO 9001:2008 and ISO 13485.

You'll learn:

- Why Does the FDA Require Design Controls?
  - FDA's major areas of concern
  - CDRH's cradle-to-grave vision: The Total Product Life Cycle
  - Design control as part of the Quality System Regulation (QSR)
  - FDA's definition of key design terminology
- The FDA's Guidance for Design Controls
  - Defining a "substantially equivalent" production unit
  - Understanding difference between a deviation vs. nonconformance
  - Understanding difference between project design vs. product design
  - How international standards relate to the FDA's expectations
- Design and Development Planning — 21 CFR 820.30 (b)
  - Implementing top-level design control procedures
  - Elements of the general development
  - Best practices in design planning
- Design Review — 21 CFR 820.30 (e)
  - Types of review
  - Proven design review methods
- Design Input — 21 CFR 820.30 (c)
  - Understanding inputs vs. outputs
  - Typical input documents
  - Using FDA recognized standards and guidance
  - Importance of human factor considerations
  - Good and bad examples of requirements
- Design Output — 21 CFR 820.30 (d)
  - Process controls outputs
  - Other final output documents
  - Conducting design output review
- Design Verification — 21 CFR 820.30 (f)
  - Verification documents
  - Understanding difference between verification vs. validation
  - Elements of a test protocol
  - What the FDA looks for in test reports
  - What if the design fails verification and validation?
- Design Validation — 21 CFR 820.30 (g)
  - How the FDA defines validation
  - Key validation documents and methods
  - Conducting design validation review
- Design Change — 21 CFR 820.30 (i)
  - Developing a change control policy
  - Role of planned, temporary changes
  - Identifying all areas impacted by change
  - Conducting reverification and revalidation
- Design Transfer to Manufacturing — 21 CFR 820.30 (h)
  - Integrating manufacturing considerations into design
  - Key design transfer documents
  - Developing a manufacturing and transfer plan
  - Proven design transfer methods
- Lessons Learned in Design Transfer
  - Documentation reminders
  - Impacts on tooling and components
  - Conducting design transfer review
  - Importance of process control review
- Design History File (DHFs) — 21 CFR 820.30 (j)
  - FDA requirements for design history
  - Responsibilities of team leaders
  - Relationship between the DHF and the Device Master Record
  - Creating a traceable DHF index
  - Practical suggestions for maintaining compliance

To register online, visit www.mdcomplianceinstitute.com or call (888) 838-5578

Space is limited — Register today!

Three-and-a-Half-Day Device Compliance Learning Package: Save by Attending Both Back-to-Back Courses

Save $493

when you register for the full three-and-a-half-day **Device Compliance Learning Package.** Attend the one-and-a-half-day **QSR Compliance Basics** course followed by the two day **Design Control** course for the reduced tuition of $2,997, including all course materials, lunch, refreshments, and the opportunity to learn and interact with some of the top FDA compliance experts in the nation.

Receive Your Certificate of Completion

Receive documentation of your training endeavors for management and inspectors. On the last day of each course, you will be presented with a Certificate of Completion.

CONFERENCE TUITION

2014

	Training Course #1: QSR Compliance Basics: Complying with the FDA's Medical Device 21 CFR 820 Quality Systems Regulation (12 Course Hours)	Training Course #2: Design Control for Medical Devices: Meeting the FDA's 21 CFR 820.30 Rules for Quality Design and Manufacturing (16 Course Hours)
Fee	$1,495 Includes instruction, interactive participation, training materials, refreshments, breakfast and lunch.	$1,995 Includes instruction, interactive participation, training materials, refreshments, breakfasts and lunches.
Dates and Times	Monday 8:30 a.m. – 5:30 p.m. Tuesday 8:30 a.m. – 12:30 p.m.	Tuesday 1:30 p.m. – 5:30 p.m. Wednesday 8:30 a.m. – 5:30 p.m. Thursday 8:30 a.m. – 12:30 p.m.

Save $493 by registering for both courses!

Register for Both Courses and Save!

Both courses	Discounted Fee
Training Course #1: QSR Compliance Basics: Complying with the FDA's Medical Device 21 CFR 820 Quality Systems Regulation **and** **Training Course #2: Design Control for Medical Devices: Meeting the FDA's 21 CFR 820.30 Rules for Quality Design and Manufacturing**	$2,997

To register online, visit www.mdcomplianceinstitute.com or call (888) 838-5578

4 EASY WAYS TO REGISTER

Please mention priority code BROCHU when registering.

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300 N. Washington St., Suite 200,
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LOCATION

Nov. 3–6, 2014
Hilton Garden Inn Frederick
7226 Corporate Court
Frederick, MD 21703
www.frederick.stayhgi.com
Reservations: 866-909-6090
Room rate: $119 per night, plus tax
(Please mention discount code: QUEST2)
Reservation cut-off date: Oct. 13, 2014

CANCELLATIONS AND SUBSTITUTIONS

Cancellations received before the beginning of a course will be subject to a refund according to the following schedule and rates: A 95% refund will be provided for cancellations received up to 6:00 PM EST, 10 business days in advance of the course start date. If less than 10 business days-advance notice is provided, the refund amount will be reduced to 50%. Substitutions are permitted with prior notification to **FDAnews**. Individuals requesting to change course location less than 10 business days in advance of the course will be charged a $500 administrative fee. No-shows will be charged the full amount. **FDAnews** reserves the right to cancel the courses and is not responsible for any airfare, hotel, or other costs incurred by registrants.

TEAM DISCOUNTS

Significant tuition discounts may be available for teams from the same company. Register four members and for the same course and send the fifth member for free. You must register at the same time and provide a single payment to take advantage of the discount. Call +1 (703) 538-7600 for details.

Select your choice of:

COURSE(S)

❑ **Training Course #1: QSR Compliance Basics: $1,495**
Complying with the FDA's Medical Device 21 CFR 820 Quality Systems Regulation

❑ **Nov. 3–4, 2014, Hilton Garden Inn Frederick — Frederick, MD**

❑ **Training Course #2: Design Control for Medical Devices: $1,995**
Meeting the FDA's 21 CFR 820.30 Rules for Quality Design and Manufacturing

❑ **Nov. 4–6, 2014, Hilton Garden Inn Frederick — Frederick, MD**

Save $493 by registering for both courses!

❑ **BEST DEAL! Both Training Courses: $2,997**
Training Course #1: QSR Compliance Basics:
Complying with the FDA's Medical Device 21 CFR 820 Quality Systems Regulation

Training Course #2: Design Control for Medical Devices:
Meeting the FDA's 21 CFR 820.30 Rules for Quality Design and Manufacturing

❑ **Nov. 3–6, 2014, Hilton Garden Inn Frederick — Frederick, MD**

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MEET YOUR INSTRUCTORS

Denise Dion, the course leader, is vice president of regulatory and quality services EduQuest. Ms. Dion spent 18 years with the FDA, where she served as an Office of Regulatory Affairs headquarters authority on agencywide inspections and investigations. She developed many of the FDA's inspection guidance and training materials, including serving as the primary editor of the well-known *FDA Investigations Operations Manual (IOM)*. Denise was the primary contact for interpretation and request for changes and additions to the IOM. For her EduQuest clients, Denise provides regulatory guidance with particular emphasis on cGMPs, GCPs, quality systems, CAPA systems, risk management, bioresearch monitoring, and FDA inspections and enforcement. Denise regularly performs audits to assess regulatory compliance with drug, medical device and biologics regulations.

Martin Browning, course leader, president and co-founder of EduQuest, 2004 IVT Speaker of the Year, capped a 22-year FDA career as a special assistant to the associate commissioner for regulatory affairs. As vice chair of the electronic record and signature working group, he helped draft the original 21 CFR Part 11 regulations. He also served as the chair of the U.S. government's ISO 9000 committee, and was a member of the committee that developed the medical device quality system regulation. EduQuest was hired by the FDA to train its field investigators, analysts and compliance staff on Part 11 and inspection of computerized systems.

Send Your Compliance Team for Maximum Benefit

Get your compliance team up to speed in just three days!

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Call +1 (703) 538-7600 for details.

Denise and Martin will be joined at ***Medical Device Quality & Compliance Institute 2014*** by other members of the EduQuest training team — medical device quality and compliance experts with extensive FDA experience, plus decades more experience in engineering, software, quality, validation and manufacturing positions with leading FDA-regulated companies.

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EduQuest

EduQuest is a leading provider of regulatory consulting, auditing and training services to the pharmaceutical, biologics and medical device industries.

FDANEWS

FDAnews publishes domestic and international regulatory, legislative and business news and information for executives in industries regulated by the U.S. Food and Drug Administration.

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