www.fdaconsulting.com

# Noblitt & Rueland

New Data!

## Important Medical Industry Training Programs:

**-attend one or more, select one course per day, mix & match courses, create your own track-**

| | | |
|---|---|---|
| Monday<br>July 10 | *or* | • FDA Quality System Regulation (QSR/GMP) & FDA Inspections<br>• Design Control Compliance for FDA & ISO |
| Tuesday<br>July 11 | *or* | • Auditing Quality Systems for FDA & ISO Compliance<br>• Risk Management, ISO 14971 & FDA Requirements |
| New Course<br>Wednesday<br>July 12 | *or* | • ISO 13485:2016 Towards a Global Quality System<br>• Software Verification & Validation Compliance Strategies |
| Major Changes<br>Thursday<br>July 13 | *or* | • Complaint Handling, MDRs, & CAPA for Devices<br>• CE Marking: Medical Devices, IVDs & AIMDs (prepare now!) |
| Friday<br>July 14 | *or* | • Process Validation for Medical Device Compliance<br>• 510(k) Submissions: How to get FDA Clearance for Devices |

**July 10-14, 2017**
**Disneyland Resort, Anaheim, California**

Photo: Newport Beach, CA

***These courses provide:***

-How to comply with FDA QSR, **new ISO 13485:2016** & Canadian Quality Regulations.
-Preparation for your FDA inspection, or ISO/EN, CMDCAS / MDSAP audits.
-Latest information & guidance (**risk mgmt, software, design control, Part 11, 510(k), CE Mark, quality systems, auditing, process validation, APPS / AGILE / Cybersecurity, etc.**).
-Current FDA Policies, enforcement activities & methods of prevention.
-Learn how to comply with Complaint Handling, MDR & CAPA requirements
-Strategic information for planning, esp. FDA QSR. ISO 13485:2016, Software, CE & 510(k)s
-Reduced liability risk of Product Safety issues & FDA Enforcement.
-Efficient implementation of Design Control, Risk Management, MDR, Complaint Handling, Software Processes, Part 11, Process Validation & Quality Systems (FDA &ISO).
...and much more! ***See website for complete course information.***

Downtown Disney©

© Disney Disneyland

View of Catalina Island from Corona Del Mar State Beach

***FDA and International Regulations Will Impact You!***
***Be Prepared for additional enforcement and coming changes.***
***Join us this summer in Southern California!***

## In-house Training Available

call or e-mail for a quote

- Have 5 or more people needing training?
- All courses offered for training at your site
- Save travel expenses and time away from job
- Train multiple employees and across disciplines
- Implement concepts immediately
- Discuss confidential or sensitive issues openly

## Consulting Services-Globally

U.S. Office locations:
- California: So. Cal & Bay areas -
- North Carolina -
- Texas -

- **FDA GMP/ISO Audits & Consulting**
- **Design Control Compliance Audits**
- **Software Compliance Audits**
- **Risk Management & EN/ISO 14971**
- **Risk & Hazard Analysis**
- **Electronic Recordkeeping Audits**
- **E-Record System Validation & Doc.**
- **510(k)/PMA/IDE/CE Submissions**
- **Software 510(k) Submissions**
- **Software Verification & Validation**
- **ISO 13485:2003 & 2016 & MDSAP**
- **IEC 60601-1 & IEC 62366-1 Consulting**
- **483 & Warning Letters, MDRs, Recalls**
- **Strategic Regulatory Planning**
- **Software Development & Apps**
- **In-house Training**

**Call for more info: 888-892-4664**
**info@fdaconsulting.com**

### Noblitt & Rueland

**Noblitt & Rueland** provides over 25 years experience as the "Go To" professional technical-regulatory consulting & training firm specializing in FDA and international regulatory compliance and implementations. The company is highly regarded for its expertise in medical device regulatory compliance & development activities per FDA QSR/GMP and ISO including regulatory submissions such as 510(k), IDE, PMA & CE Marking. Noblitt & Rueland consulting services include: FDA QSR/GMP & ISO 13485 Audits, Design Control Audits, Software Audits, Quality System & procedures creation & implementation, Independent Software Verification & Validation, Validation of manufacturing software, Validation of quality system software including ERP/MRP systems, Validation of Off-the-Shelf (OTS) software, testing, Risk Management & Hazard Analysis, IEC 60601-1 Device Safety, Product & Software Development, and associated documentation preparation. Noblitt & Rueland has memberships with the ASQ, IEEE, RAPS, AAMI, and OCRA.

**Past Participants:** Noblitt & Rueland has trained over 5000 representatives from over 800 medical device manufacturers, as well as, the U.S. FDA and state regulatory agencies. A very abbreviated list includes:3M Divisions, Abbott Labs Divisions, Adv. Cardiovascular Sys., Alcon Surgical, Allergan Divisions, American Cyanamid, American Red Cross, Amoco Laser Company, Ansell Inc., AT&T Network Sys., Baxter Divisions, Beckman Coulter, Becton Dickinson Divs., PPG Biomedical Sys., Procter & Gamble Inc., Puritan-Bennett, Radiant Systems, Radiation Sterilizers, Schering-Plough, Plexus Corp., Sherwood Medical, Siemens Divisions, Smith & Nephew Divs., St. Jude Medical, Underwriters Laboratories (UL), United Medical Mfg., U.S. FDA, Ventritex Inc, bioMerieux, W.L. Gore & Assoc., Zimmer, Zoll, and many, many others.

**MONDAY, JULY 10**

## FDA QSR/GMP & FDA Inspections

FDA enforcement actions; such as, Warning Letters & Consent Decrees for Quality System violations have a devastatingly negative impact both financially, competitively, and emotionally on a company. This course will provide an understanding of FDA's Quality System Regulation (QSR), 21 CFR 820, for medical device manufacturers and how it impacts all departments and personnel throughout an organization. The burden of complying with the QSR does not all fall on the Regulatory or Quality department. It is important that all departments throughout a company understand that they must fulfill their Quality System obligation in order for a Quality System to be compliant with the law. Understanding how you and your department's role fits into the QSR puzzle is essential in complying with the Quality System regulation and not causing an FDA enforcement nightmare. This course will also explain how FDA conducts inspections, how to properly prepare, what can happen, and what to do if the inspection does not go well. This course will be beneficial to ***all*** employees of medical device manufacturers and their vendors. **Jim Kozick, previous Director of Domestic Investigations, FDA L.A. District will be a featured instructor.**

**What you will learn:**

- Understanding of the elements of FDA QSR (21 CFR 820) and rationale.
- **What is required and expected to comply with FDA QSR (21 CFR Part 820).**
- What Quality System information is needed for PMAs, 510(k)s, IDEs.
- Executive Management's critical role in QSR compliance and inspections.
- Concepts & considerations when implementing QSR along with ISO 13485.
- **How to prepare & handle an FDA Inspection to avoid a 483 or Warning Letter.**
- Examples of non-conformances found by FDA.
- FDA's current hot buttons & how to interact with FDA during an inspection.
- Knowing when and what to do if your inspection has problems!

**Course Instructors:** Jim Kozick, Corrine Bonfiglio, Rich Basler

***or***

**MONDAY, JULY 10**

## Design Control Compliance for FDA & ISO

***FDA investigators are inspecting and pursuing enforcement activities for non-compliant Design Control violations.*** FDA has published that 68% of firms inspected had potential design control deviations and 55% of Warning letters cited Design Control. As one of the four major subsystems within FDA's QSIT inspection program, **expect your Design Control System to be inspected**. This training discusses Design Control, the regulatory requirements (U.S. & International ***including the new ISO 13485:2016 requirements***), and methods for implementing and maintaining a successful Design Control process. **Design Control Flowcharts will be provided to assist with modeling of Design Control procedures and the implementation of an efficient Design Control program.** This course is applicable to R&D and RA/QA personnel who are responsible for their company's Design Control program. It is very beneficial for R&D engineers, QA engineers, RA, Management, Marketing, and Manufacturing personnel who participate in the design control process or may be members of a design team.

**What you will learn:**

- **How to comply with FDA & ISO (including ISO 13485:2016) requirements for Design Control.**
- FDA expectations and requests during your Design Control Inspection.
- Design Control process requirements, Guidance, & implementation concepts.
- FDA's required Design History File (DHF), its content & level of detail.
- How to overcome the biggest problems in implementing Design Control.
- **How to implement Design Control and Design Reviews that shorten the development cycle rather than waste time and create internal friction.**
- How design control compliance will impact your 510k, PMA & IDE submissions.
- Implication of ISO 13485:2016 on your Design Control process.

**Course Instructors:** David MacKenzie. Dennis Rubenacker

- Two courses offered each day
- Mix & Match courses to your interest
- Multiple course discounts available
- Multiple attendee discounts available

Noblitt & Rueland

**TUESDAY, JULY 11**

## Auditing Quality Systems for FDA & ISO

Internal auditing and vendor auditing are critical compliance requirements & activities in avoiding FDA enforcement actions and are cited repeatedly in FDA Warning Letters to manufacturers. Notified bodies also verify that internal and vendor audits are taking place when inspecting for ISO registration, CE Mark approval, or the requirements of Health Canada including MDSAP. This course will teach auditing concepts and techniques when auditing medical device manufacturers for compliance to quality systems such as FDA QSR (21 CFR Part 820), ISO 13485 (2003 or 2016) and CMDCAS. Vendor auditing and MDSAP will also be discussed. Training will cover auditing techniques & case studies for quality systems designed to meet FDA & ISO requirements. This course will be beneficial to new auditors, audit teams, experienced auditors wishing a refresher; as well as, companies anticipating or expecting to be audited or inspected. This course is recommended for all audit team members, QA, RA, R&D, and management of both device manufacturers and their vendors.

### What you will learn:

- **Auditing Techniques, pre-audit, during the audit, post-audit.**
- How to report audit observations so deficiencies can be corrected.
- Writing accurate audit reports that minimize company liability exposure.
- **How to conduct an audit & report it without negatively polarizing an organization.**
- What Management should look for and review in an audit report.
- Role of checklists in an audit and how to create an effective checklist.
- Differences when auditing to FDA QSR , ISO 13485 (2003 or 2016) & CMDCAS.
- Auditing vs. FDA Inspections (esp. QSIT) vs. Notified Body Inspections.
- Auditing specific elements, i.e. CAPA, Design Control, Production, etc.
- Auditing the quality system itself vs. its implementation.
- Vendor Audits, internal audits, and MDSAP discussion.

**Course Instructors:** Ray Pizinger, Corrine Bonfiglio, Rich Basler

**WEDNESDAY, JULY 12**

## ISO 13485:2016 Towards a Global Quality System

Prepare now for implementation or transition to the newly released ISO 13485:2016. This course will explain the differences between ISO 13485:2016, ISO 13485:2003, and what needs to be modified in a FDA (21 CFR Part 820) compliant Quality System in order to be compliant with the requirements of ISO 13485:2016 including the additional requirements for compliance in Canada and the European Union (MDD / new MDR); thereby, substantial increasing market potential.Europe (EU), Canada, Australia, Asia, and Central & South America either accept ISO 13485 or a modified version of it (i.e. nationalized to their own needs)...in all that's a huge global market! This course will be beneficial to ***all*** employees of medical device manufacturers; as well as, vendors/suppliers/ contract manufacturers that will benefit by marketing their quality commitment and reduced customer audits. *One of the goals of this course is to teach how to integrate ISO 13485:2016, Canadian MDRs, and EU MDD requirements into an FDA QSR/GMP compliant quality system; individuals not familiar with the FDA Quality System Regulation (21 CFR Part 820) or needing a refresher will find it beneficial to also attend the FDA QSR/GMP course on Monday.*

### What you will learn:

- Global marketing benefits of complying with FDA, ISO 13485:2016, Canadian, and EU MDD & MDR quality system requirements.
- Understand the differences between ISO 13485:2016, ISO 13485:2003, Canadian, U.S., and EU MDD quality regulations.
- How to integrate ISO 13485:2016, US FDA, Canadian, and EU MDD quality system regulations so that only one (1) quality system needs to be maintained.
- How to get certified and maintain compliance, including an overview of the Medical Device Single Audit Program (MDSAP).
- Simplicity is key.

**Course Instructors**: Corrine Bonfiglio, Rebecca Pine

***or***

***or***

**TUESDAY, JULY 11**

## Risk Management, ISO 14971 & FDA Requirements

FDA QSR/GMP regulations require that "Design validation shall include...risk analysis" and a FDA Reviewer's Guide requires that a Hazard Analysis be completed for the clearance of 510(k) submissions. The **new ISO 13485:2016 requires Risk Management throughout the quality system**. Impacting your ability to CE Mark, ISO 13485 specifically recommends that ISO 14971 be used to manage risk. Lack of a risk analysis will result in **submission and inspection problems (FDA & ISO)**; including possible enforcement actions. This seminar provides a complete overview of risk management needed to comply with FDA and International regulations, **including ISO 14971, ISO 13485, new IEC 60601-1 3rd Ed and EN ISO 14971:2012 Annex Z**. Risk Management methods reviewed will apply to all aspects of device design & manufacturing, including mechanical, electronics, microprocessors, software, disposables, manufacturing processes, & quality systems. **Attendees will receive templates for Risk Analysis, Fault Trees, FMECA & more.**

### What you will learn:

- **How to comply with FDA's Design Control requirement for risk analysis.**
- How to comply with FDA's requirement for hazard analysis for submissions.
- FDA & ISO 13485 Requirements (**including ISO 13485:2016**) for Risk Mgmt.
- **Understand ISO 14971** and **EN ISO 14971:2012 Annex Z requirements.**
- Methods of documentation for Risk Analysis & FMEA.
- **Fault Tree Analysis (FTA) & Failure Modes and Effects Analysis (FMEA)**.
- Risk Analysis as part of software verification and validation.
- How to identify potential hazards and sources of harm.
- How to estimate probability of risk and degree of severity.
- Generating Critical Components and Critical Process Lists.
- Fail-safe design techniques, including software/hardware trade-off strategies.

**Course Instructors**: David MacKenzie, Dennis Rubenacker

**WEDNESDAY, JULY 12**

## Software Verification & Validation Strategies

FDA and ISO both require Software Verification & Validation and it is a frequent issue of FDA Warning Letters and recalls. Software Verification and Validation (V&V) is a critically important requirement for ensuring the safety and reliability of manufacturing or device software. ***The FDA QSR/GMP states "Design validation shall include software validation and risk analysis." All devices automated with software will be subject to this regulation.*** Software validation is also required for any automated software processes that are used in production or in the quality system. FDA 510(k), PMA, & IDE submissions require software V&V information. By applying the appropriate V & V strategy **including applicability of IEC 62304**, considerable time and money can be saved. This course will provide an understanding of the software V&V strategies and requirements for Device Software & Submissions, Manufacturing Software, 3rd Party & **Off-The-Shelf** software, QC/RA statistical & clinical software. Case studies will be presented. **SVVP, SQAP and OTS Templates will be provided.**

### What you will learn:

- Software Verification & Validation requirements of the FDA and ISO.
- Latest FDA Software Guidance & **Part 11** - impact on V&V strategies.
- **How to determine & demonstrate an appropriate V & V strategy.**
- Manufacturing software & electronic recordkeeping requirements for V & V.
- How to determine & handle software for different Levels of Concern.
- Impact of **APPS/AGILE/Cybersecurity** and standards such as **IEC 62304**.
- V & V documentation and level of detail required for device submissions.
- Software Test Strategies & Methodologies.
- Retrospective V & V for Previously Released Software.
- Case studies-Devices (different levels of concern), Manufacturing, QC/ RA software, Clinical software, 3rd Party, sub-contracted & OTS software.

**Course Instructors:** Marc Goodman, Dennis Rubenacker

## Noblitt & Rueland Training Courses

- Leaders in Medical Device FDA & ISO Training
- Top instructors having years of experience
- Current hands-on experience in the field
- Team offering provides practical view points
- Course contents updated with each offering
- Ample time provided for your issues & questions

## Discounts Available

- Early & Multiple Registration Discounts
- Multiple Day Discounts
- Airline & Hotel Discounts Available
- Continuing Education Units Awarded
- Training Certificates for FDA & ISO

**See www.fdatraining.com for complete course descriptions, outlines & registration.**

**THURSDAY, JULY 13**

## Complaint Handling, MDRs & CAPA

According to FDA's published data for last year, ~90% of all Medical Device Warning letters had at least one CAPA related citation and 70% of the top seven FDA 483 inspection observations were directly related to Complaint Handling, MDRs, or CAPA. Your CAPA system **will** be scrutinized by FDA during your next inspection and you must to be prepared. Properly implemented, Complaint Handling and Medical Device Reports (MDRs) are usually a manufacturer's first alert to product issues that may result in a correction, removal or recall which is why FDA is so concerned about these activities. The majority of FDA Warning Letters and serious enforcement actions, including criminal & civil penalties have been levied on companies that failed to properly report events and take proper corrective actions. In addition, product liability and financial risks are staggering when companies fail to properly report and take corrective action when required. **Understanding what is a complaint and when & how it needs to be reported as a formal MDR is very important and will be discussed in detail with examples.** This course topic is critical to all device manufacturers and is recommended for anybody or team involved in complaint handling, MDRs, CAPA, and recall decisions. J**im Kozick, previous Director of Domestic Investigations, FDA Los Angeles District Office will be an instructor along with Christine Posin, a device expert specializing in Complaint Handling, MDR and Recall issues.**

### What you will learn:

- **Determining what is or is not a complaint & what is a reportable (MDR) event.**
- How to properly document complaints and MDRs.
- How and when to file Medical Device Reports (MDR) & the **eMDR** program.
- Understand the relationship of CAPA and Risk Management processes as they relate to complaints, reportable events (MDRs), and recalls.
- Key factors in implementing and maintaining compliance with the regulations.
- **What FDA expects** and requires during an Inspection of these processes.

**Course Instructors:** Jim Kozick, Christine Posin

*or*

**THURSDAY, JULY 13**

## CE Marking: Medical Devices, IVDs & AIMDs

All medical devices and IVDs must have a CE Mark in order to be sold in the European Union. And, the rules for CE marking these devices are changing. This course will delve into the details of CE Marking medical devices, active implantables, and IVDs. Topics such as product classification, Technical File construction, authorized representatives, Notified Body selection/audits, directives, & the pending regulations will be reviewed. Special focus will be given to the timing of moving from the directives to the regulations, technical file / design dossier construction including selection of standards and how to ensure that the file continues to reflect the current state of the product while providing insight into how to remain current with the ever-changing landscape of standards, guidance documents and emerging rules, including the **new MDR & IVDR** that may impact your product. This course will help you develop documentation that clearly shows a product complies with the directive/regulation and supports the CE mark. The course will be of interest to staff involved in CE Mark approvals & maintainence, related documentation processes and ISO 13485 compliance programs (also see Wednesday's ISO 13485 course).

### What you will learn:

- The CE Mark approval process for medical devices, active implantables & IVDs.
- **The roles of all parties involved: Competent Authority, new MDCG, Notified Body, authorized representative, production facility and the manufacturer.**
- Directives currently in effect as well as the pending regulations, how to achieve compliance & plan the move to the **new MDR and IVDR** regulations.
- How to classify your Medical Device or IVD and what are "routes to conformity".
- **How to create technical files & dossiers that Notified Bodies will accept.**
- How to document and show compliance to Essential Requirements.
- Standards & guidance to use in demonstrating compliance including ISO 13485.
- Use of Common Technical Specifications (CTS).
- Electronic IFU Rules – can you avoid printing? What Languages are required?

**Course Instructors:** Christine Ruther, Deborah Madsen

**FRIDAY, JULY 14**

## Process Validation for Medical Devices

Process Validation deficiencies are major quality system compliance problems found during FDA inspections. Many FDA 483s and Warning Letters cite deficiencies in Process Validation during FDA inspections. Over 349 medical device manufacturers have received Warning Letters that included process validation (21 CFR Part 820.75) deficiencies since 2005. There were 286 FDA-483 Observations in 2015 alone. A "lack of or inadequate process validation" was the **3rd highest** Warning Letter observation in 2015 right behind Complaint Handling & MDRs (see Thursday's course). This course will teach **how to comply with FDA process validation regulations** so that companies understand what is required to demonstrate compliance. It will also clarify the differences in process validation and various other validation & qualification activities. **A logical approach to process validation will be discussed** so that compliance is straight forward and easy to understand. Current FDA regulations and international guidance will be discussed. To allow for more time to focus & fully understand the requirements & approach to Process Validation, statistical math details will not be discussed.

### What you will learn:

- What is Process Validation and what are FDA and international requirements.
- **First hand FDA process validation inspection expectations from former FDA investigator and Director of Domestic Investigations at FDA Los Angeles District Office.**
- Unlocking the confusion between Process Validation and Equipment Qualification.
- How to comply with Process Validation requirements & FDA inspections.
- Understanding the benefits and how to implement a Master Validation Plan.
- How to organize & schedule qualification & validation using a Master Validation Plan.
- How software validation relates and integrates with your overall Validation Plan.
- Understand how & when to implement pFMEA (Process Failure Mode Effects Analysis) into Process Validation and Equipment Qualification Processes.
- Using an organized approach unlocks the confusion when changes are proposed.

**Course Instructors:** Ray Pizinger, Jim Kozick, Dennis Rubenacker

*or*

**FRIDAY, JULY 14**

## 510(k) Submissions: How to get to Market

510(k) experts will provide an understanding of how to get a device requiring a 510(k) submission to market quickly with minimal delay. Knowing how to create and properly submit a 510(k) for a device or change to a device has become more difficult and complex. Getting through FDA review quickly and successfully is critical financially and competitively. The instructors will describe the submission process and the submission package required by the FDA for successful submissions. You will learn about trends and new policies, including FDA's new E-copy Policies and Refuse to Accept (RTA) in which ***~40% are refused on 1st submission.*** The instructors will illustrate and discuss a real life **510(k) submission example** and provide an understanding of the common pitfalls, delays, and successful techniques. We will be discussing submissions and techniques that apply to a wide variety of devices including disposable, reusable, sterile, non-sterile, IVD, and electrical, including software controlled devices.

### What you will learn:

- **When & how to submit a 510(k) for a new product or modified product.**
- Understanding of the submission process.
- Importance of Intended use and Substantial Equivalence (SE).
- Types of 510(k) submissions and when to use each.
- What is a predicate and why do I care. How do I select.
- **What is contained in a 510(k) submission package and how it is assembled.**
- What to do if you make a change to your device, including **new draft guidance**.
- What is required for software and how device software impacts a submission.
- **How to interact with the FDA reviewer and how to respond to questions.**
- Knowing when clinical data may be required.
- New Policies including Refuse-to-Accept (RTA) ***(~40% are refused)*** & **e-Copy**.
- How to avoid delays.

**Course Instructors:** Corrine Bonfiglio, Marc Goodman

## Critical Considerations for Attending

- Learn to avoid FDA enforcement from 30 yr FDA veteran
- Documented training is required by FDA GMP/QSR & ISO
- *Latest FDA & ISO Guidance, Standards & Practice discussed*
- Prevent delays in device Submissions & 510k clearance
- Large Civil Penalties have been given for FDA violations
- Executive Management cited in enforcement actions
- Effective Auditing can prevent FDA non-compliance
- Warning Letters repeatedly cite Design Control violations
- Risk Management & ISO 14971 implementation is critical
- Class 1 Recalls (highest risk) have increased dramatically
- Improper handling of Complaints & MDRs are FDA red flags

## REGISTRATION INFORMATION

*New Guardians of the Galaxy and experience the Summer of Super Heros! Book On-line!*

**Locations & Dates.** The Paradise Pier Hotel is a beautiful, magical hotel located within the 60 tropical acre storybook Disneyland Resort. Just a 5 minute walk to **Downtown Disney** heading to **Disneyland** and **California Adventure Theme parks** for fun experiences such as the classic **Main Street Electric Light Parade** before it fades away later this summer. The resort's Monorail Pool features 2 towering waterslides — themed after the Disneyland Park classic attraction — that splash down into an immersive water play area. Refresh in the pool or relax in the spa. Enjoy the marina, stroll through the boardwalk shops, enjoy a drink at the wharf, or **Trader Sam's – Enchanted Tiki Bar** offering live music and cocktails. The fun does not stop in the evening, after training, experience the excitement, sounds, food, shopping, and action found at the **Downtown Disney Entertainment Center**. Never before have Disney visitors had so many options for fun! While strolling Downtown Disney marvel at the most innovative fireworks display in Disneyland history, test your skills at the **ESPN Zone**, or feast your palate at one of numerous mouthwatering restaurants. During your stay keep your energy up at the hotel exercise center. Stay the weekend and enjoy the pleasures that will make even Grumpy grin! *Be sure to inquire about early admittance to the Park for hotel guests.* ***Visit our web site for an extensive listing of links and information to Disneyland and a variety of Southern California fun during your stay! (http://www.fdaconsulting.com).***

**Disney Paradise Pier Hotel, Anaheim CA** Go on-line to book your Hotel room, buy Discounted Park Tickets and get Disneyland Resort information: Book on-line at **http://www.fdaconsulting.com/reginfo.shtml** or call (714) 520-5005 for hotel reservations (ask for "Noblitt & Rueland" discount).

A limited room block is being reserved until June 17 at fantastic discounted rates of $179/night at the Paradise Pier Hotel! ***Be sure to ask for the "Noblitt & Rueland" discount rate.*** Hotel accommodations are not included in the seminar fee. Course registration is 7:30 to 8:00 am. Courses begin at 8:00 am and end about 5:00 pm. Complimentary lunch & refreshments will be provided each day.

***Registrations and hotel rooms will sell out. Be sure to make your room reservations early!***

**Fees & Discounts.** Register for one or more courses. Note that discounts are available for advance registration, registration for any five (5) courses, or if two (2) or more participants register at the same time for the same course. Please use copies of the attached registration form. *Individuals registering for any five (5) courses will also receive up to $250 off their total fees.* Fees may be paid by check, purchase order, or credit card.

| Fees & Discounts | Individual Registration Fee | | Multiple Registrants Fee | |
|---|---|---|---|---|
| | *By June 10* | *After June 10* | *By June 10* | *After June 10* |
| Per Course Fee | $635 | $675 | $575 | $635 |
| Any Five Course Discount | $250 off* | $200 off* | $250 off* | $200 off* |

*Applies to total registration fee for each individual.

**CEU Awarded.** Noblitt & Rueland awards nationally recognized Continuing Education Units for satisfactory completion of our programs. A CEU certificate will be awarded at the completion of each course and can be used to document employee training & competency per FDA GMP and ISO.

**Speakers.** Noblitt & Rueland trainers are experts in their respective fields. In the unlikely event of an emergency or speaker unavailability, Noblitt & Rueland reserves the right to reassign presentation material or substitute speakers.

**Refund/Cancellation Policy.** Full refund will be made if cancelled two weeks prior to the seminar. Cancellation less then two weeks prior receive credit toward future programs. Cancellations less than 72 hours prior receive credit less a $150 cancellation fee.

**Airports.** The closest airport is Orange County's John Wayne Airport (SNA). Other airports in the Orange County/Los Angeles area are Long Beach (LGB), Los Angeles International Airport (LAX), Ontario (ONT), and Burbank (BUR). Our website has information about local transportation, buses & shuttles.

**Car Rental Discounts.**

Hertz *CV#02ZV0029. Call 800-654-2240 or on-line*
AVIS *#D086933 (AWD), Call 800-331-1600*

**Registration.** Preferred registration method is to register on-line, or fax your registration and mail your payment. Or you may mail your registration and your payment :

**On-line:** http://www.fdaconsulting.com/rf.shtml

**Fax: 949-398-5223**

For further information or to register by phone please call our seminar registration line:

**Phone: 888-892-4664**

For consulting or in-house training information please call 949-398-5222

---

**Copy & Fax or Mail this Form for more Information or to Register**

FAX# 949-398-5223, you may also register at www.fdatraining.com

**To register:** Please indicate which seminars you are registering for below. Use the fee table shown above for determining your total fee. Make checks payable to Noblitt & Rueland, 5405 Alton Parkway 5A #530, Irvine, CA 92604-3718. Purchase orders are accepted, please add a $25.00 processing fee per purchase order requiring an invoice. Please call if you have questions. Please Fax and/or Mail your completed form and payment.

- ❑ Please send me a Free Pocket Reference of the FDA's GMP/QSR.
- ❑ Please register me in the courses indicated below.
- ❑ Please send information on the following In-house training programs: _____
- ❑ Please send information on the following consulting services: _____
- ❑ Unfortunately I am unable to attend, but please keep me on your mailing list.

| | | | | |
|---|---|---|---|---|
| #1 QSR ❑ July 10 | or | #3 Auditing ❑ July 11 | or | #5 ISO 13485 ❑ July 12 |
| #2 Des. Ctrl ❑ July 10 | or | #4 Risk Mgmt ❑ July 11 | or | #6 Ver & Val ❑ July 12 |
| #7 Complaint... ❑ July 13 | or | #9 Process Valid. ❑ July 14 | | |
| #8 CE Mark ❑ July 13 | or | #10 510(k) ❑ July 14 | | |

| | | |
|---|---|---|
| $ | Seminar # 1 | |
| | or Seminar # 2 | |
| | Seminar # 3 | |
| | or Seminar # 4 | |
| | Seminar # 5 | |
| | or Seminar # 6 | |
| | Seminar # 7 | |
| | or Seminar # 8 | |
| | Seminar # 9 | |
| | or Seminar #10 | |
| $ | **Total Fee** | |

❑Bill my Credit Card. Please circle card type: **VISA MasterCard Discover AmericanExpress**

Card Number: _____ Expires: _____

Name: _____ Phone: _____

Title: _____ Fax: _____

Company: _____ E-Mail: _____

Address: _____

City: _____ State: _____ Zip: _____

## Instructor Biographies

(See www.fdatraining.com for entire speaker list and detailed biographies.)

**Jim Kozick** has over 30 years of experience working extensively with FDA regulations and enforcement. Prior to consulting, he has 29 years of investigative and enforcement experience with the U. S. Food and Drug Administration (FDA) including 8 years as the Director of Domestic Investigations for the Los Angeles District Office. In this capacity, he directed the investigative and enforcement activities of seven Supervisory Investigators and seventy-five FDA Field Investigators comprising the largest field investigative operation within the FDA and served as the pilot District for the current QSIT device inspectional strategies. In addition, Mr. Kozick has 19 years of hands on experience as a Field Investigator performing compliance assessment inspections and related activities.

**David M. MacKenzie** has over 25 years of experience in the design and program management of medical, industrial, and aerospace products. He specializes in Design Control, Hazard Analysis, risk management & software safety. He has lectured in conjunction with the FDA on the design of safe microprocessor systems, hazard analysis, and the design & validation of international medical products. He is a U.S. delegate to ISO/IEC JTC1/SC7/WG9 on Software Integrity and is an ISO Lead Assessor. Mr. MacKenzie has worked with numerous medical device manufacturers solving problems such as those related to Design Control and Risk Management. Mr. MacKenzie graduated from the California Institute of Technology with a B.S. in Electrical Engineering specializing in Solid State Physics, and has completed graduate work in Integrated Circuit Design at the University of California at Irvine. He is a member of IEEE and ASQ.

**Corrine Bonfiglio** has over 20 years of accomplished quality assurance, regulatory and clinical affairs experience. She offers in-depth expertise with FDA & ISO requirements, including FDA 21 CFR Part 820 & ISO 13485 quality systems, submissions (510(k), PMA & CE Marking), and clinical trials. She assists medical device manufacturers with compliant quality system implementation, auditing and training. Corrine has extensive experience with strategies for IDE & 510(k) submissions and with Master Files as well as import/export approvals for devices and biologics. Corrine has assisted numerous manufacturers to become compliant with quality systems requirements, including correcting deficiencies found during FDA, State of California or Notified Body inspections. She holds a BS in Biology (University of California, San Diego) and attended Georg-August University (Göttingen, Germany). Corrine is Regulatory Affairs Certified (RAC) by RAPS and is a member of Orange County Regulatory Affairs (OCRA).

**Raymond M. Pizinger** has over 25 years experience specializing in international and US regulations which define quality systems, process validation, design controls, CE Mark, software quality assurance, medical device reporting, and vigilance. Mr. Pizinger worked with the FDA to implement the first electronic MDR reporting system and assisted the first medical device manufacturer to report MDRs electronically. Mr. Pizinger has audited and implemented numerous Quality Systems that meet the requirements of FDA's QSR/GMP, ISO 13485, and ISO 9001. He has worked with companies and Notified Bodies to obtain CE Marks approvals, 510(k)s, IDEs, and has assisted companies responding to enforcement issues.

**Rebecca Pine** has over 20 years experience in the medical device industry assisting both industry-leading corporations as well as small business start-ups. Ms. Pine is an expert in submission compilation and management including 510(k)'s, PMA's, and CE Mark Technical Files & Design Dossiers. Her background includes all classes of devices and IVD's. She has helped facilitate her clients' successes by directing and implementing regulatory strategies and executing aggressive project plans. She specializes in gaining U.S. and international regulatory approvals and implementing Quality Systems to assure both domestic and international regulatory compliance. She has significant experience in all aspects of domestic and international Medical Device Regulatory management, including Quality Assurance and Quality Systems for FDA 21 CFR Part 820 & ISO 13485 compliance.

**Marc Goodman** is a specialist on issues and strategies related to FDA and international software compliance with emphasis in software verification and validation, software quality assurance, and project planning/management including preparation for regulatory submissions including FDA 510(k) submissions. Mr. Goodman has developed software for medical devices, manufacturing/test software, information systems for clinical labs, data communications, and real-time data base access for over a 20 year period. Mr. Goodman has consulted on products and processes for all Classes of Medical Devices and Levels of Concern and is a member of the IEEE Computer Society and OCRA.

**Rich Basler** has specialized since 1976 in the Quality function of medical device manufacturing including extensive experience in Quality Assurance, Regulatory Compliance, and Regulatory Submissions for a number of medical device companies. Rich has assisted numerous companies from start-ups to Fortune 100 corporations in developing quality systems compliant with US FDA and International standards, including achievement of ISO 9001/ISO 13485 registration and CE Mark approval in addition to FDA Quality System Regulation compliance. On the regulatory side, Rich has extensive experience in Pre-Market submissions for new products and for clinical evaluations. Rich is a Certified Biomedical Auditor & Certified Quality Auditor with ASQ.

**Christine Ruther** has extensive experience assisting manufacturers in safety critical areas of compliance and regulatory engineering for electronic and wireless medical devices. Christine was manager for Medical Device Testing at TUV Product Services including ISO/CE marking auditing responsibilities. Ms. Ruther has worked in industry as Senior Compliance Engineer & Manager and as Director of Product Development & Regulatory Affairs including responsibilities for product failure analysis. Christine works with medical devices manufacturers, from start-ups through Fortune 500 companies; as well as, government agencies such as NIST and ANSI. Her knowledge of global regulations/standards includes MDD, R&TTE, IEC, ISO, AAMI, FDA, & FCC coupled with extensive experience in risk management & design control. Christine received a BS in Physics (Xavier University) and MS in Biomedical Engineering (The Ohio State University). She volunteers for IEEE and the Orange County Regulatory Affairs (OCRA).

**Dennis L. Rubenacker** is co-founder and Senior Partner of the consulting firm of Noblitt & Rueland specializing in medical device software development, software quality management, electronic recordkeeping, design control, and risk management for FDA regulated industries. Mr. Rubenacker has held software engineering, software quality assurance, electronics engineering, and management consulting positions in the research and development of medical devices, aerospace systems, and consumer electronics. He has been involved with the FDA, Los Angeles district, grass roots partnering subcommittee on electronic recordkeeping and is a member of IEEE, RAPS, OCRA, and ASQ.

**Christine Posin** has over 30 years experience in the medical device industry assisting both large and small device manufacturers with regulatory issues especially as related to adverse event reporting, complaint handling, MDRs and vigilance reporting. Chris is active in the Orange County Regulatory Affairs Discussion Group (OCRA). Chris organized a professional network group that focused on medical device reporting (MDR) and international reporting & vigilance, and facilitated this group for over 12 years. The MDR Network Group received the National Performance Review Hammer Award in 1999 as part of the program for innovations in government. In addition, Chris has also served as a Quality Education Instructor while with Johnson & Johnson. Chris has a Bachelor of Science degree from Bowling Green University.

**Deborah Madsen** has over 30 years of experience in the design, manufacture, quality assurance and regulatory compliance of medical and in vitro diagnostic medical devices. Over a period of 21 years, Deborah held several roles at Underwriters Laboratories (UL) including product safety engineer (IEC 61010 and IEC 60601), lead auditor, instructor/trainer, auditor qualifier, and technical file assessor. She conducted audits in accordance with ISO 9001, ISO 13485, implementation of CMDR requirements under the CMDCAS program, Medical Device Directive (93/42/EC), In Vitro Diagnostic Directive (98/79/EC), ISO 14971, and IEC 62304. At Beckman Coulter, she managed product safety, EMC, reliability, product performance laboratory and conducted internal audits at sites world-wide. Deborah holds a degree in Electrical Engineering, and is a Registered Professional Engineer in the state of California.

**Register early. Seating will be limited. Rooms will sellout!**



NOBLITT & RUELAND

***These courses provide:***

-How to comply with FDA QSR, **new ISO 13485** & Canadian Quality Regulations
-Learn firsthand how FDA handles inspections and enforcement from 30 year veteran of FDA and a previous District Director of Investigations.
-Latest information (**risk, software, design control, APPS / AGILE / Cybersecurity, Part 11, 510ks, CE marking, quality systems, auditing, MDR, CAPA, Proc Valid, etc.**).
-Current FDA Policies, enforcement activities & methods of prevention.
-Strategic information for planning, esp. QSR, ISO 13485, IEC, Part 11 & 510(k)s
-Reduced liability risk of Product Safety issues & FDA Enforcement.
...and much more! ***See www.fdaconsulting.com for more information.***

Disneyland © Disney

*Downtown Disney©*

*California Adventure Park©*

California Adventure Park with Paradise Pier Hotel in Background