Important Medical Industry Training Programs:
-attend one or more, select one course per day, mix & match courses, create your own track-

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<td>FDA Quality System Regulation (QSR/GMP) &amp; FDA Inspections, Design Control Compliance for FDA &amp; ISO</td>
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<td>Tuesday</td>
<td>Auditing Quality Systems for FDA &amp; ISO Compliance, Risk Management, ISO 14971 &amp; FDA Requirements</td>
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<td>Wednesday</td>
<td>ISO 13485:2016 Towards a Global Quality System, Software Verification &amp; Validation Compliance Strategies</td>
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<td>Thursday</td>
<td>Complaint Handling, MDRs, &amp; CAPA for Devices, 510(k) Submissions: How to get FDA Clearance for Devices</td>
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<td>Friday</td>
<td>Process Validation for Medical Device Compliance, CE Marking: Medical Devices, IVDs &amp; AIMDs (new EU MDRegs)</td>
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July 8-12, 2019
Disneyland Resort, Anaheim, California

These courses provide:
- How to comply with FDA QSR, ISO 13485:2016 & Canadian Quality Regulations.
- Preparation for your FDA inspection, or ISO/EN 13485, or 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.
...and much more! See website for complete course information.

FDA and International Regulations Will Impact You!
Be Prepared for additional enforcement and coming changes.
Join us this summer in Southern California!
• Discuss confidential or sensitive issues openly
• Train multiple employees and across disciplines
• Save travel expenses and time away from job
• All courses offered for training at your site

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 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 & IEC 62366-1 Consulting. How to comply with FDA & ISO (including 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:
• 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, Ray Pizinger

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
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 14985. 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.
• Hands on experience with auditing techniques for FDA & ISO 14985 audits.
• 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, Rich Basler

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 14985:2016 requires Risk Management throughout the quality system. Impacting your ability to CE Mark, ISO 14985 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 14985, 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 requirements for hazard analysis for submissions.
• FDA & ISO 14985 Requirements (including ISO 14985:2016) 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

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 documentation. 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, OC/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

Discounts Available
• Early & Multiple Registration Discounts
• Multiple Day Discounts
• Airline & Hotel Discounts Available
• Continuing Education Units Awarded
• Training Certificates for FDA & ISO
### Complaint Handling, MDRs & CAPA

**According to FDA’s recent published data, ~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 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. Jim Kozick, previous Director of Domestic Investigations, FDA Los Angeles District Office will be an instructor along with Maureen Johnson, 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, investigate, and manage product complaints.
- 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 and reportable events (MDRs).
- 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, Maureen Johnson

### 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 indicated process validation (21 CFR Part 820.75) deficiencies since 2005. There were 164 FDA-483 Observations in 2017 alone. A “lack of or inadequate process validation” was the 3rd highest Warning Letter observation 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 validation & qualification 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

### 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 E-Copy Policies and Refuse to Accept (RTA) in which ~30% 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 and new FDA Pathway Guidance.
- 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 final 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.
- Policies including Refuse-to-Accept (RTA) (~30% are refused) & e-Copy.
- How to avoid delays.

**Course Instructors:** Rebecca Pine, 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

### CE Marking: Medical Devices, IVDs & AIMDs

All medical devices, including IVDs, must have a CE Mark in order to be sold in the European Union. The rules for CE marking are changing. This course will delve into the details of CE Marking medical devices, active implantables, and IVDs. Topics such as product classification (IVD classification changes significantly in the new regulation), Technical File construction, authorized representatives, Notified Body selection/audits, directives & the EU MDR (new regulations vs directives), and timing of regulations impacts will be reviewed. Special focus on planning for moving from the directives to the new 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 new rules. It will be of interest to companies that are looking to CE Mark new products and those wishing to maintain their CE Mark. The course will be of interest to staff involved in CE Mark approvals, 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 & new Regulations, how to achieve compliance (CE Mark) with both.
- 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 General Safety and Performance Requirements (formerly Essential Requirements).
- Standards, Guidance, & Common Technical Standards used to show compliance.
- Electronic IFU Rules – can you avoid printing? What Languages are required?

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

Experience the The New Star Wars Land: Galaxy’s Edge, the Incredicoaster, and much more!

Locations & Dates. The Paradise Pier and Disneyland Hotels are both beautiful hotels 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 many new experiences such as the new Star Wars Land: Galaxy’s Edge, the Incredicoaster, and Pixar Pier. 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, A Pixar Nighttime Spectacular, grab a burger while bowling at Splitsville, sip a brew at Ballast Point Brewery, or feast your palate at one of numerous mouthwatering restaurants. 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 or Disneyland Hotel Go on-line to book your Hotel room, buy Discounted Park Tickets and get 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 15 at fantastic discounted rates of $209/night at both hotels! 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.

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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 than 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.

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<td>Avis</td>
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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/registration.html
Fax: 949-229-6294

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
Instructor Biographies
(See www.fdaconsulting.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 QSTI 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.

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 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.

Deborah Madsen 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.

Christine Ruther has extensive experience in Post-Market reporting and domestic and international regulatory compliance for both domestic and international regulatory agencies. Christine has worked on medical devices and biologics, from start-ups through Fortune 200 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).

Maureen has 20 years of regulatory experience covering all classes of medical devices. Maureen 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. Maureen has written various supporting documents including: literature reviews, protocols, adverse event summaries, clinical study reports, directions for use, patient brochures, operator’s manuals, benefit / risk analyses, device descriptions, publications, promotional materials, informed consents, and case report forms.

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 has held several roles at Underwriters Laboratories (UL) including product safety engineer (IEC 61010 and IEC 60601), lead auditor, instructor/mentor, auditor qualifier, and technical file assessor. She conducted audits in accordance with ISO 9001, ISO 13485, implementation of CMDR requirements under the CMDCA 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 worldwide. Deborah holds a degree in Electrical Engineering, and is a Registered Professional Engineer in the state of California.

Brent Noblitt is co-founder and Senior Partner of the consulting firm Noblitt & Rueland. Mr. Noblitt specializes in international and U.S. medical device strategic planning, development, and marketing. His consultation has been used to market medical devices globally. Mr. Noblitt’s associations range from start-up ventures to Fortune 100 corporations. His marketing background and biomedical technical training allows him to advise on the marketing planning process and opportunities of various technologies. His academic training includes a B.S. and M.S. in Biomedical Electrical Engineering from Purdue University complemented by an M.B.A. degree earned from Pepperdine University and he is a member of ASQ and OCRA.

Register early. Seating will be limited. Rooms will sellout! © Copyright 2019 Noblitt & Rueland

These courses provide:
-How to comply with FDA QSR, ISO 13485:2016 & 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
-Limited liability risk of Product Safety issues & FDA Enforcement.
...and much more! See www.fdaconsulting.com for more information.