White Paper Series by Noblitt & Rueland

Quick & Informative

FDA Citing Training Deficiencies in Warning Letters

by Brent Noblitt, Senior Partner

Consulting Services:

- Submissions (510(k), CE Mark, PMA, IDE)
- Quality Systems (FDA GMP/QSR, ISO 13485)
- Audits (Quality System, Design Control, Software, etc.)
- Design Control
- Risk Management (inc. EN/ISO 14971, Device & Process)
- Software (V&V, QA, Development)
- Device Safety & EMC (IEC 60601-1, Usability/Alarms/Home)
- Complaint Handling, MDRs, Recalls
- Electronic Recordkeeping (Part 11)

In-house Training Courses:

- Process Validation for Medical Device Manufacturers
- Design Control Compliance for FDA & ISO
- Risk Management, ISO 14971 and FDA Requirements
- Auditing Quality Systems: for FDA & ISO Compliance
- FDA Quality System Regulation (QSR/GMP) & Inspections
- Software Compliance and Verification & Validation for FDA & ISO
- FDA Electronic Recordkeeping & Signatures (Part 11)
- Complaint Handling, MDRs, & CAPA
- 510(k) Submissions: How to Get FDA Clearance Fast
- CE Marking Devices, IVDs, & AIMDs
- IEC 60601-1 3rd Ed. Medical Device Safety Requirements
- ISO 13485 Implement & Maintain

Noblitt & Rueland

FDA & International Consulting & Training Services

Offices: So. Cal - SF Bay - N. Carolina - Texas

Consulting & Auditing Sevices

In-house Training & Workshops

Contact us for consulting or to set up a private in-house training course.

Phone: (1) 949-398-5222
Toll free: (1) 888-892-4664
Fax: (1) 949-398-5223
e-mail: info@fdaconsulting.com
web: www.fdaconsulting.com

www.fdaconsulting.com

Celebrating 25 years of helping clients!

Noblitt & Rueland
U.S. FDA & International Consulting and Training Services

5405 Alton Parkway 5A, #530
Irvine, CA 92604-3718
Telephone: +1 949-398-5222
Facsimile: +1 949-398-5223
E-mail: info@fdaconsulting.com

Web Site: *www.fdaconsulting.com*

White Paper Series- Quick & Informative

FDA Citing Training Deficiencies in Warning Letters

Brent Noblitt, Senior Partner, Noblitt & Rueland

Since 2001, over 251 FDA Warning letters to medical device companies have cited training deficiencies as one of major issues found during an inspection. The general statement found in these Warning Letters, prior to listing the specific inspection finding, is usually something similar to the following actual quotes…

"Failure to ensure that all personnel are trained to adequately perform their assigned responsibilities; and failure to implement your training procedure, as required by 21 CFR §820.25(b). "

"Failure to establish procedures for identifying training needs, ensure that all personnel are trained to adequately perform their assigned responsibilities, and document training, as required by 21 CFR 820.25(b). Specifically…"

The actual training regulation requirements for both FDA 21 CFR Part 820 and ISO 13485 can be found at the following link http://www.fdaconsulting.com/training_regulations.html .

Why do companies receive a Warning letter that cites training?

There are many reasons, some of which include; lack of oversight, lack of funds to properly train, budget cutting, inadequate resources, lack of knowledge of training requirements, or simply being too busy to take the time to train and document.

The reason training is a part of the Quality System Regulation (QSR / 21 CFR Part 820) and ISO13485 is that companies with adequate training manufacture higher quality products with less problems. This makes FDA happy and customers happy. Proper training also lessens the risk of product liability action and payments which may be a bigger financial concern than FDA regulatory risk. Training is just good financial business practice in which regulatory compliance should be a by product.

In a down economy, one of the first things that some vulnerable companies will scrimp on is the training budget. From an overall financial and risk management perspective, decreasing or eliminating training exhibits poor financial judgment. Proper training will reduce the number of product defects, decrease or minimize product liability risks, improve efficiencies, decrease the

Noblitt & Rueland
U.S. FDA & International Consulting and Training Services

5405 Alton Parkway 5A, #530
Irvine, CA 92604-3718
Telephone: +1 949-398-5222
Facsimile: +1 949-398-5223
E-mail: info@fdaconsulting.com

Web Site: *www.fdaconsulting.com*

ancillary costs of defects (i.e. Costs associated with CAPA, Re-design, dealing with FDA in enforcement resolution, etc.), keep customers returning, and improve moral by decreasing interdepartmental bickering and wasted time dealing with problems and compliance headaches.

What steps should all medical device manufacturers do to implement an effective training program and thereby avoid a warning letter that cites training?

Essentially there should be a procedure in place that is followed and audited. The procedure should be simple and straightforward including several key activities:

- Assessment (of each employee's training needs, identification of training requirements)
- Plan (how to provide and then track the training that is identified)
- Implementation (provide or hold the actual training and monitor its effectiveness)
- Document (the details of the training each employee receives in a form that can be easily audited and provided to an FDA investigator or ISO auditor during an inspection or audit)
- Track (training progress and reassess each employees training needs periodically or whenever there is a change of position or task)
- Audit (periodically and independently audit the training records and compliance to the training procedure)

To effectively implement training it is important to consider what type of training is to be provided. There are generally two types of training 1) Task Specific training (i.e. manufacturing instructions) and 2) Process related training (i.e. Quality system, design control, risk management, software quality procedures, etc.). Usually task specific training is performed by a supervisor or someone very knowledgeable on the specific manufacturing operation needed during production. Process related training is related to understanding and properly implementing processes or procedures. This type of training is most effective when everyone impacted by the process (i.e. multi-departmental teams) can be trained together so that everyone understands everyone else's roles and responsibilities; thereby reducing confusion and conflict. Process related training can be very effectively done onsite using highly trained and experienced internal resources or by using expert external resources such as consultants or training companies. Individuals needing general process requirements training can typically learn about process requirements during external offered training programs offered by training companies.

In summary, FDA enforcement issues related to training and many other resulting enforcement issues due to poor or non-existent training can be effectively eliminated by investing and implementing a robust training program that will greatly benefit the company financially, with improved customer relationships, and increased employee moral.

For assistance or questions please contact us toll free at 888-892-4664 or bkn@fdaconsulting.com

Noblitt & Rueland
U.S. FDA & International Consulting and Training Services

5405 Alton Parkway 5A, #530
Irvine, CA 92604-3718
Telephone: +1 949-398-5222
Facsimile: +1 949-398-5223
E-mail: info@fdaconsulting.com

Web Site: *www.fdaconsulting.com*

Author:

Brent Noblitt is a Senior Partner and co-founder of Noblitt & Rueland, professional firm providing regulatory and technical training/consulting services to medical device manufacturers around the world for over 25 years. His consultation has been used to market medical devices throughout the world. Mr. Noblitt's associations range from start-up ventures to Fortune 100 corporations. His marketing background and technical training allows him to comprehend and advise on the marketing planning process and opportunities of various technologies. Prior to founding Noblitt & Rueland, Mr. Noblitt held management & executive positions in the medical device industry. Mr. Noblitt's product experience includes various critical care devices, cardiac output computers & pulmonary catheters, extravascular lung water computers, ultrasound devices, phono-angiography, computerized patient databases, patient monitoring systems, disposable & reusable pressure monitoring devices & accessories, ejection fraction computers, continuous mixed venous oxygen saturation systems & catheters, surgical laser systems, implantable defibrillators, pacemakers, continuous blood pressure control systems, as well as, home healthcare delivery systems. His academic training includes a B.S. and M.S. in Electrical Engineering-Biomedical from Purdue University complemented by an M.B.A. degree earned from Pepperdine University and he is a member of ASQC-Biomedical & Healthcare Divisions. He can be contacted by phoning toll-free 888-892-4664 or via e-mail at bkn@fdaconsulting.com.

Noblitt & Rueland

Noblitt & Rueland is the leading medical device consulting firm specializing in technical FDA & international regulatory issues including Quality Systems, Submissions, Design Control, Risk Management, Software, electronic recordkeeping (Part 11), electrical safety (IEC 60601-1) & regulatory consulting for FDA & Internationally regulated medical industries.

Noblitt & Rueland assists manufacturers in both the medical device and pharmaceutical industries. Our areas of expertise include FDA & International regulatory issues, quality systems, design control, risk management, software development, software quality assurance, software compliance assessments, independent verification & validation, software testing, reverse engineering, electrical safety and submissions. Noblitt & Rueland provides GMP-QSR-QSIT-ISO audits, software GMP audits, creation of 510(k), IDE, PMA, & CE Mark submissions including software sections, and numerous other technical regulatory services. Our clients have identified Noblitt & Rueland as a qualified supplier and have added us to their approved vendor lists. See our consulting section for additional consulting information. General and in-house training seminars are presented on FDA/International issues including GMP/QSR (Quality System Regulation), design control, risk or hazard analysis (including FMEA & FTA), software SQA (design and manufacturing), CE Mark/ISO 13485, electrical safety/EMC (IEC 60601-1). Our services integrate seamlessly with your current RA/QA and R&D efforts. We also assist other regulatory affairs consulting firms to provide additional support and expertise per their client requirements.