FDA Citing Training Deficiencies in Warning Letters
by Brent Noblitt, Senior Partner

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FDA Citing Training Deficiencies in Warning Letters

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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](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
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
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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.

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