

Medical Device Concessions:

FREE PASS OR RED FLAG FOR YOUR QUALITY SYSTEM?

BY MARTIN BROWNING
President and Co-Founder, EduQuest, Inc.

FORMER FDA INVESTIGATOR AND SPECIAL ASSISTANT TO THE ASSOCIATE FDA COMMISSIONER OF REGULATORY AFFAIRS

FDA Expectations for Device Concessions

Under regulatory guidance not well understood within the industry, the U.S. FDA allows medical device manufacturers to release “nonconforming products” (we’ll clarify that term below) using what’s known as a concession.

The danger is that some manufacturers tend to rely on concessions as fall-back remedies when they lose control of their processes and produce out-of-spec products. Instead of immediately identifying and correcting quality problems at their source – which is what the FDA expects – these manufacturers are quick to claim a concession and then move on with business-as-usual, hoping the problems are not serious and will eventually correct themselves.

But FDA is clear it doesn’t consider a concession the same as a free pass for side-stepping quality issues. Instead, a concession always should be:

- Limited in time and quantity

TABLE OF CONTENTS

Nonconformance Possible at Several Levels 2

Difference from a Deviation or Variance..... 3

FDA Adopts ISO Concept of a Concession 4

FDA Expects Concessions to be Limited 4

Justifying a Concession..... 5

Reliance on Concessions Can Backfire..... 5

About the Author..... 7



1896 Urbana Pike, Suite 14
Hyattstown, MD 20871 USA
(Near Washington, DC)
Phone: +1 (301) 874-6031
Email: Info@EduQuest.net
www.EduQuest.net

© EduQuest 2010

FOLLOW ME ON 

In FDA's world, the phrase "specified requirement" covers a multitude of expectations...

- Carefully controlled
- Appropriately authorized
- Well documented, and
- Claimed after identifying the nonconformance.

If not, FDA has instructed its investigators to regard concessions as red flags signaling potential quality problems worthy of further scrutiny and possible enforcement action.

Nonconformance Possible at Several Levels

To fully understand the concept of a concession, let's start with the definition of a nonconformance. You also need to understand that a nonconformance, deviation, and variance are not the same thing, although the terms are sometimes used interchangeably in industry.

According to both ISO 13485:2003 and 21 CFR Part 820 (FDA's Quality Systems Regulation), **a nonconformance is the failure to fulfill a specified requirement.**

Sounds simple enough, but in FDA's world, the phrase "specified requirement" covers a multitude of expectations and manufacturing levels, including requirements, specifications, and process parameters that are stated – explicitly and implicitly – by an organization, its customers, or other interested parties.

A nonconformance, according to FDA, can be at the product, process or quality system level. A nonconforming product could include a finished device, in-process device, device component, returned device, or specific manufacturing material.

So a nonconformance might include any or all of the following:

SIDEBAR 1:

ISO 9001:2000

DEFINITIONS

3.6.2 nonconformity: A non-fulfillment of a requirement.

3.6.11 concession: Permission to use or release a product that does not conform to specified requirements.

NOTE: A concession is generally limited to the delivery of a product that has non-conforming characteristics within specified limits for an agreed time or quantity of that product.

3.6.12 deviation permit: Permission to depart from the originally specified requirements of a product prior to realization.

NOTE: A deviation permit is generally given for a limited quantity of product or period of time, and for a specific use.

- Failing to meet a design specification
- Not following a standard procedure
- Failing to control a validated process parameter
- Ignoring a customer's written requirements, or
- Missing test limits – or not testing at all – just to name a few examples.

Difference from a Deviation or Variance

Many people confuse a nonconformance with a deviation or variation, but they differ by an important degree of timing and intent. Deviations are issued **prior to performing the operation** and not in response to a nonconformance or nonconforming activity. ISO 9001:2000 provides a definition for a “deviation permit” that allows release prior to what it calls “product realization” (**see Sidebar 1**). Deviations should be reviewed and approved in advance of the action to be deviated from – such as a purchasing decision, manufacturing change, or other operation under the quality system. An authorized signature, date, and written justification are required for each approved deviation.

Instead of the term deviation, FDA uses a similar concept and calls it an “approved variance”. As described in 21 CFR 820.1(e)(2), FDA can grant a variance from any device quality system requirement when the Agency determines the variance is in the best interest of public health. A manufacturer can seek a variance by petitioning FDA **in advance of the activity**, or the Agency itself can initiate a variance in response to a specific public health need.

SIDEBAR 2:

FROM THE PREAMBLE TO 21 CFR PART 820, COMMENT 156:

156. FDA has rewritten § 820.90(b)(1), “Nonconformity review and disposition,” to make clear that the section requires procedures that define the responsibility for review and authority for disposition of nonconforming product and that set forth the review and disposition process. FDA believes that proper disposition of nonconforming product is essential for ensuring the safety and effectiveness of devices. Manufacturers have made determinations that nonconforming product may be used which have resulted in defective devices being distributed. Thus, although it may be appropriate at times to use nonconforming products, the disposition process must be adequately controlled.

The revision requires that disposition and justification for concessions be documented. FDA believes that the justification should be based on scientific evidence, which a manufacturer should be prepared to provide upon request. *Concessions should be closely monitored and not become accepted practice. [Editor’s emphasis added]* This section is consistent with ISO 9001:1994, section 4.13.2.

Several comments on the Working Draft stated that the term “concession” should be deleted because it is confusing. FDA has rewritten the sentence to ensure the meaning of this requirement is clear. The sentence now reads, “Documentation shall include the justification for the use of nonconforming product and the signature of the individual(s) authorizing the use.”

FDA Adopts ISO Concept of a Concession

Now we can move on to concessions. FDA has no official definition of a concession, but in the preamble to 21 CFR Part 820 the Agency says it doesn’t define terms it thinks are adequately covered by ISO standards or generally known within the industry.

The ISO standards define a concession as a means of releasing product for further manufacturing or commercial use, even when the product doesn’t conform to a pre-established requirement or specification (or the process by which it was manufactured doesn’t conform).

Like an ISO deviation or an FDA approved variance, the concession process is limited by time and condition. Note also that a concession is issued **after** the finding of a nonconformance. And similar to a deviation or variance, a concession must be reviewed and approved prior to release of the product. Again, authorized signatures and dates are required – as is the justification for each concession (**see Sidebar 2**).

FDA Expects Concessions to be Limited

In the *FDA Guide to Inspections of Medical Device Manufacturers* (**see Sidebar 3**), the Agency says it expects concessions to be the exception, not the rule. If a manufacturer evaluates and releases one product lot, batch or shipment “on concession”, FDA expects the company will **not** treat the next product lot, batch or shipment similarly. Instead, FDA expects the manufacturer to make some kind of change to correct the nonconformity from re-occurring.

The expected change could be to the product design, the manufacturing process or the acceptance criteria, to cite just a few examples. Furthermore, the change should be

SIDEBAR 3:

FROM THE FDA GUIDE TO INSPECTIONS OF MEDICAL DEVICE MANUFACTURERS

Nonconformity Review and Disposition - 21 CFR 820.90(b)(1)

Review all records for the proper disposition of nonconforming products for assurance that use of nonconforming product has not resulted in the distribution of defective devices. The distribution and justification for concessions (allowance to use otherwise nonconforming product, often done through a Material Review Board) must be documented and based on scientific evidence. ***Concessions should be closely monitored and not become normal practice. [Editor's emphasis added]***

Deficiencies would include a lack of scientific evidence for justification of the concession. If a concession resulted in a change of product specifications (form, fit or function), the change should be evaluated for possible 510(k) submission. At a minimum, a risk analysis should always be considered for any changes.

documented, scientifically justified and verified, and validated as appropriate.

No matter what the change, FDA insists that before the product can be released into the marketplace, it still must:

- Meet all essential outputs, and
- Be safe and effective for its labeled and known intended uses.

Justifying a Concession

Documentation and justification are essential to support a concession claim. If you have data from any design control effort that establishes the safety and efficacy of the product despite the specified nonconformance, show it. For validated processes, the nonconformance may be acceptable if it falls within the validated range, even if outside the operating or optimized range. However, always be prepared to demonstrate that a process-related nonconformance doesn't adversely impact the safety and efficacy of the product.

Even with a concession, you still must meet all 510(k) and PMA requirements. If a product or its manufacturing process fails to comply with those activities approved in a 510(k) or PMA, you may need to seek a new, cleared 510(k) or an approved PMA supplement prior to release of the product. For some 510(k)s, you may need only to change the product's intended uses. For a class II or III 510(k), your change must specify any special controls you're adding or alterations you're making to the manufacturing process.

Reliance on Concessions Can Backfire

Although the concept of a medical device concession may seem like a loophole in the quality regulations, in reality a

FDA equates frequent concessions with poor product design, transfer, manufacturing, and monitoring.

company with a large volume of concessions is waving a red flag to regulators and its customers. You may as well signal “we don’t have adequate control over our products or processes”.

FDA equates frequent concessions with poor product design, poor design transfer, poor manufacturing processes, poor monitoring – or a toxic combination of all the above.

Overuse of concessions also may indicate the likelihood you have a poor vendor/supplier management process, which has become one of the FDA’s top enforcement targets.

FDA has given explicit instructions to its inspectors to look for abuses to the concession process. To meet the Quality Systems Regulation as well as ISO standards, you need to keep your concessions on a short leash, limiting them to very narrow nonconformance conditions and supporting them with thorough scientific justifications and proper authorizations.

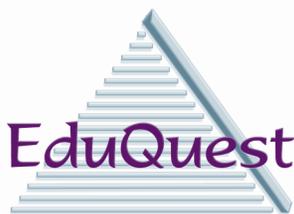
Otherwise, your presumed free pass may just earn you a 483, Warning Letter, product recall, or worse.

For Additional Information:

EduQuest offers an eight-hour training class on **QSR Compliance Fundamentals: Complying with FDA’s Medical Device 21 CFR 820 Quality Systems Regulation**. The course is available on-demand at your site and presented nationally as an open enrollment class several times each year. The class also can be accompanied by a 16-hour class on **Medical Device Design Control**, a frequent source of concessions when not handled properly. Contact Martin Heavner at MartinHeavner@EduQuest.net or visit www.EduQuest.net for course outlines and pricing.



MARTIN BROWNING
President and Co-Founder
EduQuest, Inc.



1896 Urbana Pike, Suite 14
Hyattstown, MD 20871 USA
(Near Washington, DC)

Phone: +1 (301) 874-6031

Fax: +1 (301) 874-6033

Email: Info@EduQuest.net

www.EduQuest.net

© EduQuest 2010

FOLLOW ME ON 

About the Author:

Martin Browning is the President and Co-Founder of EduQuest, Inc., a global team of FDA compliance experts based near Washington, D.C.

He has more than 30 years of regulatory experience at the FDA and as a highly sought-after advisor to industry. Martin's 22-year career at FDA included work in the field offices as an investigator and as a senior manager in the Office of Regulatory Affairs at FDA headquarters. He capped his FDA career by serving as a special assistant to the Associate Commissioner for Regulatory Affairs. He also served as vice chair of FDA's electronic record and signature working group, where he helped draft the original 21 CFR Part 11 regulations. In addition, Martin served as the chair of the U.S. government's ISO 9000 committee and was a member of the FDA committee that developed the medical device Quality Systems Regulation (QSR).

At EduQuest, which has been serving medical device, pharmaceutical, biologics companies since 1995, Martin helps clients solve problems related to FDA regulation, quality assurance, software and systems engineering, and compliance auditing, including assessing vendors and outsourced operations.