

Food, Drug, and

FDC

Cosmetic Division

Control

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Our Vision

Resources for quality systems and leadership development in FDC-regulated industries.

Our Mission

To achieve increased customer satisfaction and continuous improvement by identifying, communicating, and promoting knowledge and the use of management concepts, technologies, and regulations as they relate to quality principles in all functional areas of the food, drug, and cosmetic industries.

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Dr. James B. Kohnen, Editor
<http://www.asq-fdcdivision.org/>



ASQ

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CHAIR'S Message

by Don Singer

Hello All Division Members!

The weather may be warm in the West and the South or still a bit chilled in the North and East, but spring is in the air everywhere. The January Southeast Conference was a big success with more than 100 attendees, and a big thanks goes to Mike Ferrante and his team for making it happen. Now, we are continuing our hot conference schedule for 2004 with plans for educational gigs in April and May. These conferences will be going full throttle soon. Our conferences always offer relevant topics with top-notch speakers from both the regulatory agencies and industry.

The FDC-FDA West Coast Conference is planned for April 2, with the title "Basic Strategies for Safety and Regulatory Compliance." Topics include effective recalls, dietary supplements, counterfeit drugs, and how industry plans to meet the Bioterrorism Act requirements. It will be held at the Disneyland Resort, in the Anaheim, CA, sun. The FDC-FDA Northeast Conference, in neighborly Somerset, NJ, will be held in May and offers its usual mix of hot topics for those who love to keep up with the networking of FDA and industry advisors.

The 58th Annual Quality Congress will be held in Toronto, Ontario, and will offer an international flavor. We have many members and potential new members in Canada, and we welcome the opportunity to share the AQC educational experience with them. Make sure you look closely at the program

to determine what courses to take, what presentations to attend, what certification to seek, who is giving the keynote address each day, and what activities and tours are available for you and your guests. I



Don Singer

used to live in Rochester, NY, and it was wonderful to have Toronto so close because it offered so much in the way of culture, sports, and food.

First, the FDC Division will hold its annual membership meeting on Monday, May 24, at the headquarters hotel, starting at 5:00 p.m. Immediately following the meeting we will head over for what is expected to be a memorable evening of wonderful food, plenty of drinks, a ballgame, and socializing at the famous SkyDome. It is sure to be the most fun going on in Toronto that night! We will be combining our party with the Biomedical Division, and the more people who attend, the more fun it will be. Bring your spouse, significant other, and friends (see RSVP e-mail address in the accompanying announcement on p. 3). Come and join us for a super fun evening!

The educational experience hits its peak on Wednesday, May 26, at 9:30 a.m., with the FDC Division presentation of "New Markets Through Quality Standards, Regulatory Compliance, and Industry Trends." Register early for AQC, choose your education priorities, select your tours, listen as the keynote speakers motivate you, and join us for the networking and fun. See you there!

Quality Systems and CE Marking—The Transition to ISO 13485:2003

by Laura A. Halper, Ph.D.

An effective quality management system is a key element for achieving the CE mark. This article explains the relationship among various quality system standards and their revisions, the current status of transition to ISO 13485:2003, and some future trends. Words in *italics* are defined in a glossary at the end of the article.

Quality Systems and the CE Mark

Manufacturers wishing to sell medical devices in the European Union (EU) must affix the CE mark to their products. The CE mark is the manufacturer's claim that the product meets the *essential requirements* of the

applicable European medical device *directive*: Active Implantable Medical Devices Directive (90/385/EEC), Medical Devices Directive (93/42/EEC), or In-Vitro Diagnostic Medical Devices Directive (98/79/CE).

Each of the three device directives requires that the manufacturer have an established quality system. Although the directives vary in their details, they all require manufacturers of high-risk devices to implement a full quality system to control design, production, and inspection. For low-risk devices, the manufacturer may choose to submit product for testing and thereby employ a more limited quality system. To avoid submitting product for testing, however, the manufacturer of low-risk devices may also choose to implement a full quality system.

Contrary to what many people believe, the directives do not require that the quality system comply with any particular standard. Indeed, a company may use a unique quality system of its own design, provided that the system is appropriately documented and can be shown to ensure that the resulting devices meet the requirements of the directive. Most device companies in the past have chosen to implement a system that complies with the *harmonized standards* of either ISO 13485/13488 or the ISO 9000/EN 46000 series¹ despite the availability of other options. Compliance with a harmonized standard affords a presumption of conformity with the applicable essential requirements. All *notified bodies* are familiar with the harmonized standards, and will rather easily understand a quality system that is based on those standards. By contrast, you may have to do a lot of explaining to convince your notified body that you meet the requirements for CE marking if you implement a different type of quality system.

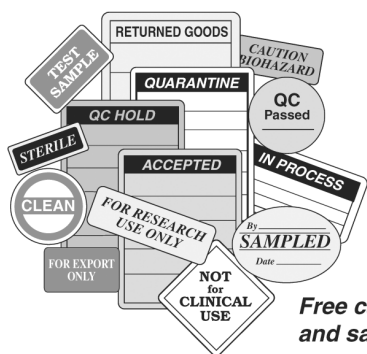
Standards, Standards, Standards

The ISO 9000 series provides for a basic quality system. The provisions are rather general so that they can be applied across a wide range of industries. The *European Commission* believed that the medical device industry needed more prescriptive requirements than those in the ISO 9000 series. The European standard-setting bodies then developed a set of three harmonized standards (the EN 46000 series) that referenced the ISO 9000 series, but added quality system requirements specific to the medical device industry. The latest EN 46000 revisions are:

¹ The terms "ISO 9000 series" and "EN 46000 series" are used in this article to mean ISO 9001/9002/9003 and EN 46001/46002/46003, respectively.

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EN 46001: 1996 (used with ISO 9001:1994), EN 46002: 1996 (used with ISO 9002:1994), and EN 46003:1999 (used with ISO 9003:1994). Similarly, the International Organization for Standardization (ISO) also recognized the need to modify the ISO 9000 series for application to the medical device industry. They developed two more standards: ISO 13485:1996 for use in conjunction with ISO 9001:1994, and ISO 13488:1996 for use in conjunction with ISO 9002:1994. The EU later harmonized these standards as EN ISO 13485:2000 and EN ISO 13488:2000. Device companies could then comply with either the EN 46000 series or EN ISO 13485/13488 in order to apply the CE mark.

The ISO 9000 standards have been adopted by many countries as national standards. Because these standards are so widely recognized, many medical device companies in the past chose to certify their quality system to ISO 9000/EN 46000 for the purpose of CE marking. However, this is no longer an option since the latest revision of the ISO 9000 series.

Impact of the ISO 9000 Series Revision

The December 2000 revision of the ISO 9000 series incorporated several changes. The format was changed to consolidate what had been three separate standards (ISO 9001:1994, ISO 9002:1994, and ISO 9003:1994) into one standard—ISO 9001:2000. Companies are permitted to exclude requirements related to product realization if they are not applicable to their business.

Another significant change was replacing the earlier 20-element approach to quality assurance with a more integrated, process-based approach to quality management. Associated with this change was a reduction in the number of required written procedures. Other

major changes included a new focus on enhancing customer satisfaction and an emphasis on continual improvement. With the latest revision, ISO 9001 changed from a relatively prescriptive standard slanted toward manufacturing operations, to a more general, “total quality management” standard that was easier to apply to service-related business, the educational sector, and other non-manufacturing concerns.

Many of these changes troubled the regulatory bodies in the *Global Harmonization Task Force (GHTF)*, who were trying to move toward harmonizing worldwide GMP regulations with ISO 9001 requirements. Both regulators and the device industry were concerned that the new requirements in ISO 9001 went beyond what was needed to control the safety and effectiveness of devices. For example, while continual improvement may be an admirable business model, it does not fit the “either you meet it or you don’t” nature of regulations and could allow regulators to continually raise the bar for compliance. The new focus on customer satisfaction was another concern. Not only was it difficult to define in a precise manner, it also had the potential for imparting legal significance to nonsafety/nonefficacy issues such as pricing or on-time delivery. And of course, the regulatory agencies were opposed to the elimination of the many previously required written procedures.

For these reasons, regulatory authorities in the European Union and elsewhere felt they could not adopt ISO 9001:2000. Meanwhile, the ISO organization was planning to revise 13485/13488, because the original edition specifically referenced the 1994 version of ISO 9001/2. The GHTF urged the ISO organization to revise 13485/13488 with a view toward achieving a standard that could be used by regulatory authorities throughout the world.

cont. on p. 4

The Food, Drug, and Cosmetic Division Invites You to the 2004 AQC Skydome Bash!

Date: Monday, May 24, 2004
Time: 6:30 p.m.
Location: Windows Restaurant at the Toronto SkyDome

Join us for dinner, a ballgame, socializing, and networking. Bring your spouse/guest and friends. Sign up ahead of time by e-mail. RSVP by May 1 to: donald.c.singer@gsk.com

The revised standard ISO 13485:2003 was published July 15, 2003. The revision consolidated 13488 into 13485. Companies are permitted to exclude requirements for product realization if these are not applicable to the nature of their devices. The revised standard mandates more documentation than ISO 9001:2000 and contains requirements specific for medical devices. ISO 13485:2003 excludes those troublesome provisions of ISO 9001:2000 that are not appropriate as regulatory requirements. For example, ISO 13485:2003 focuses on meeting customer requirements instead of enhancing customer satisfaction, and replaces the requirement for continual improvement with the requirement for maintaining the effectiveness of the quality management system. ISO 13485:2003 incorporates much of the wording of ISO 9001:2000 verbatim rather than referencing that standard. With ISO 13485:2003, medical device companies now have a stand-alone standard for demonstrating compliance of their quality management systems to regulatory requirements.

ISO 13485:2003 incorporates a process-approach for quality management. This is reflected by a change in the title of the standard. The 1996 versions were called “Quality Systems—Medical devices—Particular requirements for the application of ISO 9001 [or ISO 9002].” The 2003 version was renamed “Medical devices—Quality management systems—Requirements for regulatory purposes.” ISO 13485:2003 had not yet been harmonized at the time that this article went to press. It is expected to be harmonized in the near future.

Although certification to ISO 9001:2000 will not suffice for CE marking, some device companies may want to obtain certification to that standard as well, as a way to incorporate customer satisfaction and continual improvement into their company practices.

Schedule for Transition

The transition period from the ISO 9000:1994 series to ISO 9001:2000 ended December 15, 2003. ISO 9001/2/3:1994 are no longer in effect. The EN 46000 series will be fully withdrawn March 1, 2004. Companies that were certified to the EN 46000 series can either: 1) obtain certification to the similar standard EN ISO 13485/88:2000, and then transition to ISO 13485:2003; or 2) obtain certification directly to ISO 13485:2003.

The transition period from ISO 13485/88:1996 to ISO 13485:2003 ends July 15, 2006², after which the

1996 versions will be withdrawn. Companies that are currently certified to EN ISO 13485/88:2000 should start working now to obtain certification to ISO 13485:2003 during the transition period. Companies that plan to start applying the CE mark in the future should obtain certification directly to ISO 13485:2003.

The first step toward compliance is to conduct a gap analysis of your existing quality system against the requirements of ISO 13485:2003. The standard has two annexes that can help. Annex A is a chart showing the correspondence between ISO 13485:2003 and ISO 13485:1996. Annex B is a chart explaining the differences between ISO 13485:2003 and ISO 19001:2000. Guidance for implementing ISO 13485:2003 should be available soon in ISO Technical Report 14969, which is currently being updated for the new standard.

Future Trends

Risk management is an area that is receiving increasing emphasis. The 1996 version of ISO 13485 simply required the organization to evaluate the need for risk analysis throughout the design process. The 2003 version requires the organization to establish documented requirements for risk management, not just risk analysis. Furthermore, requirements for risk management must now be established not just during the design process, but throughout product realization.

ISO 13485:2003 refers to ISO 14971, “Medical devices—Application of Risk Management to Medical Devices,” for guidance related to risk management. This standard, which has been harmonized as EN ISO 14971:2000, will replace the earlier standard EN 1441:1997 as of April 1, 2004. EN 1441 addressed the more narrow topic of risk assessment. ISO 14971 has a wider focus that includes managing risk throughout the life cycle of the product. In addition to risk assessment, ISO 14971 also requires risk evaluation and control, and collection of post-production information.

The GHTF has issued a proposed draft guidance, “Risk Management as an Integral Part of the Quality Management System.” The guideline discusses integrating risk management into management responsibilities, each step of design control, traceability, purchasing and acceptance activities, production and process controls, servicing, corrective and preventive

² Some non-European countries that require certification to ISO 13485/88 have a different deadline for transition to ISO 13485:2003.

Calendar of Events

May

- 20 Northeast FDC-FDA Conference
- 22 Workshop on “Significance and Approach to Objectionable Organisms in a GMP Environment,” American Society for Microbiology, New Orleans
- 23 Workshop on “Methods Used to Assess the Efficacy of Topical Antimicrobial Products,” American Society for Microbiology, New Orleans
- 24-26 ASQ 58th Annual Quality Congress, Toronto, Ontario
- 24 FDC Annual Membership Meeting and Social Event, AQC, Toronto
- 26 FDC Educational Track, “New Markets Through Quality Standards, Regulatory Compliance, and Industry Trends,” AQC, Toronto

action, and statistical techniques. The GHTF guidance is meant to complement ISO 14971, and is not intended to be used for assessing compliance with regulatory requirements.

The FDA does not plan to revise the Quality System Regulation to match the format of ISO 13485:2003. However, the agency sees no conflicting requirements between the two documents. U.S. companies can integrate the requirements of both into one quality system. The FDA also is increasing its focus on risk management, and has recognized ISO 14971 as a consensus standard. This means that a declaration of conformity to ISO 14971 may be used to satisfy the risk management needs for a Special 510(k).

Glossary

Competent Authority: the body appointed by each national government within the EU to enforce compliance with the directives in that country.

Directives: European Union legislation published in the *Official Journal of the European Communities*.

Essential Requirements: those requirements in each directive that must be addressed and documented before the CE mark can be applied to a medical device.

European Commission: the administrative branch of the European Union (EU). The Commission proposes

and implements policies approved by the member states of the EU.

Global Harmonization Task Force (GHTF): a voluntary group of representatives from national medical device regulatory authorities and industry. The GHTF encourages convergence in regulatory practices for medical devices. The founding members are Australia, Canada, the European Union, Japan, and the United States.

Harmonized Standards: standards that 1) have been mandated by the European Commission; 2) have been developed by the European standard-setting bodies, 3) address essential requirements of the directives, and 4) have been published in the *Official Journal of the European Communities*. Harmonized standards carry the prefix “EN”.

Notified Body: an entity approved by the competent authority to assess manufacturers’ compliance with the directives.

Laura Halper is the owner and principal consultant of The Halper Group, providing regulatory and quality system consulting, auditing, and training services to the medical device industry.

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Application of Failure Mode and Effect Analysis (FMEA) to Biotechnology Manufacturing Processes

by Robert J. Seely

Failure mode and effects analysis is a very powerful risk-assessment tool widely used in a variety of manufacturing industries and business practices. Like many risk analysis procedures, FMEA provides a rigorous methodology for identifying, evaluating, and documenting potential modes of product or process failure.^{1,2,3} By contrast, FMEA results in a numerical ranking of each potential failure, aiding the prioritization of follow-up investigations and implementation of corrections or controls to mitigate the failure. FMEA is a useful tool in guiding and documenting the thinking process when operating parameters are evaluated for criticality or when a process is transferred to a different manufacturing site. It is a systematic, rigorous method for ranking parameters into (potentially) high risk categories and for defining which variables need further process characterization to minimize the risk of process failure.⁴

The risk assessment is based on assigning a ranking of 1 to 10 (low to high) to three critical criteria: 1) the severity of a failure, 2) the expected frequency of occurrence, and 3) the likelihood of detecting the failure. The product of the three scores (S*O*D) results in a risk priority number (RPN), which can vary between 1 and 1000. It is important to evaluate the potential failure with all three criteria because the effects may either multiply or offset one another.

That is, a failure may be very severe but if the occurrence is low and the detectability is high (therefore scored low) the resulting RPN will be low.

The primary benefits of this tool are that it provides a rational approach to evaluating a process, and it generates a ranked order of parameters requiring characterization, hence a shortening of the total list of operating variables to be studied. In addition, it provides a sound documenting mechanism to record the group decision-making process.

We have developed a streamlined application of FMEA to two main aspects of bioprocessing—process characterization and process transfer. Process characterization is the portion of process development that examines the ranges to be specified in the manufacturing procedures, robustness of the process, and for a limited number of critical parameters, the edge of failure. In a recombinant protein process there may be several hundred operational parameters and it is not practical, or necessary, to test the high and low value of every range. The FMEA method can be an effective tool to evaluate every variable, first as a paper exercise, then by follow-up study of the variables ranked as high risk if failure were to occur.

The transfer of a process from one site to another has been found to be another area where FMEA can provide a structured thinking process to help ensure success. Process transfers invariably involve some changes—in equipment, processing, raw material sources, water quality, personnel, and environmental conditions. Here the FMEA target is to identify any differences in the two processes, however slight. Many of the operational parameters will remain exactly the same as in the established process and there may be a good deal of historical data to support their associated ranges. The variables that are identified by the group as being different or potentially different are the ones that should be subjected to the FMEA analysis, and the resulting high RPN parameters further evaluated as with additional lab studies by process development.

These applications provide a usable, value-added method to identify potential problems before they occur. The method is readily adaptable to a variety of applications in the biotechnology industry and is simplified such that the readers can readily apply the techniques to their particular processes. In addition, FMEA is an effective mechanism for promoting teamwork and facilitating discussions throughout the development cycle and between departments. The benefits of such applications very much offset the workhours required to execute the analysis.

The most efficient way to capture an FMEA exercise is the use of a simple spreadsheet, as in the example in Table 1. The first column is to prospectively identify and list each and every parameter that is to be evaluated. For a recombinant protein production process this list might be all the input variables for performing a manufacturing process. Here we list every control parameter specified in a Manufacturing Procedure (batch record), such as the setting of flow rate, temper-

Table 1. Example of an FMEA Worksheet

Failure Mode and Effects Analysis				Page ____ of ____					
Process									
Unit Op:									
Leader:									
Date:									
Operational Parameter	Failure Mode(s)	Causes(s)	Effect(s)	Follow-up By	S	O	D	RPN	Recommended Follow-up

ature, mixing speed and time, pH, etc. These are the operating set points that are staged by an operator or by a computer controller to perform a specific unit operation, such as fermentation, centrifugation, and chromatography.

Once this list is completed, and it may be several dozen variables for a given operation, the evaluation team begins to discuss and identify potential mode of failure and their respective causes and effects. Based on the causes and effects the team can then decide on a numerical scoring of the severity of the (potential) failure, the possible frequency of occurrence, and the current ability to detect the failure (S, O, and D, respectively). These numerical assignments are somewhat subjective, but are also based on historical experience with the process or related processes, available data, scientific judgment, and an understanding of equipment capability.

The values for S, O, and D are arrived at by interactive discussions by an interdisciplinary team. It is critical to have the system experts present, as well as plant manufacturing personnel, development scientists, and scale-up engineers. In addition, representatives from quality control and quality assurance may be called in for portions of the assessment that pertain to their roles. From the scores assigned the RPN is calculated and the results can be ranked and graphed in order of magnitude.

The purpose of the FMEA is to collectively evaluate potential failures, prioritize them on a consensus basis, and document the evaluation process. From there, the

process team must decide which of the variables to dedicate future efforts to. As the top ranking risk variables are investigated and corrected or controlled to reduce their risk of failure, individual follow-up reports will be written to document the actions take.

A complete description of the applications cannot be given here. The references below provide guidance on the basics of FMEA; how to define the S, O, and D for particular uses; and how to initiate, perform, and moderate an FMEA. Reference 4 discusses process characterization in general and provides an example of FMEA applied to that exercise.

References

¹R. E. McDermott, R. J. Mikulak, and M.R. Beaugard. The Basics of FMEA. Portland, OR: Productivity, 1996.

²A. Shani. Using failure mode and effect analysis to improve manufacturing processes. Medical Device & Diagnostic Ind. July: 47-51, 1993.

³D.H. Stamatis. Failure Mode and Effect Analysis; FMEA from Theory to Execution. 2nd ed. Milwaukee; ASQ Quality Press (2003).

⁴J.E. Seely and R.J. Seely, "A Rational, Step-Wise Approach to Process Characterization," BioPharm International, 16, 24-34 (2003).

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