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BioFeedback
BIOMEDICAL DIVISION NEWSLETTER

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Vision

To be the leading authority on quality issues related to the biomedical community.

Mission

To promote the awareness and use of quality principles, concepts, and technologies in the biomedical community.

asq.org/biomed

Chair's Message | Teresa Cherry

World Conference on Quality and Improvement in Seattle, WA, was great!

Thank you to everyone who attended the Saturday meetings, our Sunday division meeting, and those who served their four hours at the booth. It's because of great volunteers like yourselves that we have such a great division!

I think everyone enjoyed the Monday night dinner, and we got a lot of great feedback from our members that we will compile and use for our 2019 strategic planning. Sixty-six people joined us for the dinner cruise event.

It was great seeing all of you who could attend. For those of you who could not attend, please plan on attending in 2019! The conference will be in Fort Worth, TX, next year, with a little later date in May. The Saturday meetings/training will be on May 18, our division meeting will be on May 19, and WCQI will be May 20 – 22. Start planning now.

Teresa Cherry
2018 Chair, Biomedical Division

Above: The Biomedical Division leadership team at WCQI.

Left: Teresa Cherry (-Dream Team), with Jim Shore (-Need Vacation) and others.

My First WCQI | Cinta Burgos, Social Media Co-Chair, NEDG board

At the end of April, this year, I attended the World Conference on Quality and Improvement (WCQI) in Seattle, WA. I have to admit that conferences are not my preferred manner of learning or socializing, but I was asked to participate in the preconference leadership meeting and volunteer at the ASQ biomedical division exhibition booth, so I thought this was a good year to attend my first WCQI. I knew I would learn more about ASQ and spend time with my colleagues, but what I did not expect was how energizing it would be with 3,000 other quality professionals. I do not think I ever thought of 3,000 quality professionals being in the same place at the same time. And I certainly did not expect it to be fun! WCQI is fun, it is energizing, and it is definitely good for your career, and I also believe it is good for our well-being to know there are so many like-minded quality people out there. Anyone who works in a small company or is a quality department of one person will understand what I mean. We all work in a global marketplace, and it was helpful to connect with people from other areas of the country and the world. This was a good, relaxed setting for making these types of connections.

WCQI is a wonderful place to find the professional support and camaraderie you need. At the center of the exhibit hall is the ASQ marketplace, with many books, interactive displays, and a way to check out **myASQ**. If you have not signed into **myASQ** yet, please do so at **my.asq.org/home** to connect with others and your divisions. The 2018 conference theme was the Innovation of You, with topic areas such as Big Data, Data Management, Cybersecurity, Risk, The Culture of Quality, Fundamentals in the Digital Age, and a Masters' Series. The keynotes were from Mel Robbins of the *5 Second Rule*, Luke Williams on disruptive innovation, futurist John McElligott, and Adam Steltzner of NASA/Mars Rover. While the conference had a packed itinerary, there was still time to socialize and visit sites in Seattle such as the Chihuly Garden and Glass Museum, the first Starbucks, and the fish throwing at the Pike Place Market.

I am planning to attend the next World Conference and hope to see you there!

Cinta Burgos points to Jd Marhevko's ribbon vest

Note

The next World Conference on Quality and Improvment will be May 20 – 22, 2019, in Fort Worth, TX.

The ISO 13485:2016 Transition Journey

View results of an ASQ Biomedical Division survey on the move to the new standard.

Jim Shore, Chair-Elect, ASQ Biomedical Division

This year has seen unprecedented change with regard to the medical quality and regulatory aspects of the industry. ISO 13485 has three revisions that are still active (2003, 2012, and 2016). The European Union (EU) has approved its Medical Device Regulation, going from a 40-page Medical Device Directive to the 500-page Regulation. The Medical Device Single Audit Program (MDSAP) has increased in adoption and has increased such demand with ISO Registrars that it has become very difficult for companies to schedule ISO audits before the end of 2018. It's quite clear the ISO 13485:2016 transition journey is an arduous one.

Survey Results of Medical Device Professionals

In March, the ASQ Biomedical Division surveyed more than 150 medical device professionals about the 13485 transition. The ASQ Biomedical Division was uniquely positioned to design the survey and analyze the results because its mission is "to promote the awareness and use of quality principles, concepts, and technologies in the biomedical industry."

A five-question survey was designed to be delivered via the ASQ Division LinkedIn group page and in-person. The questions were as follows:

1. Have you completed the transition to ISO 13485:2016? If no, do you have a date for your audit?
2. What are the challenges you experienced or are experiencing right now obtaining the new standard?
3. For your current quality procedures, do you use flowcharts as part of the documents?
4. Do you conduct management review meetings more than once a year?
5. Do you have an electronic documentation system? If yes, what is the name?

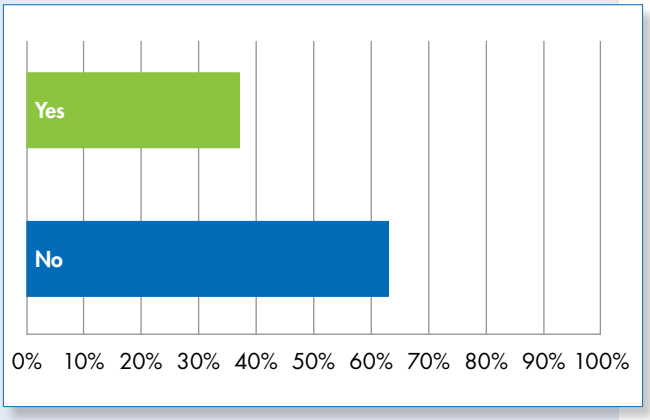
From the beginning of March to the end of April, 133 responses were received from the ASQ Biomedical Division LinkedIn group page, and 23 in-person responses were collected. Statistical significance could not be calculated because the exact number of individuals who viewed the LinkedIn survey could not be determined.

Metrics: Completion in the Transition

At the time of the survey, only 37 percent had completed the certification process.

Responses to Question 1

Have you (your company) completed the transition to ISO 13485:2016?

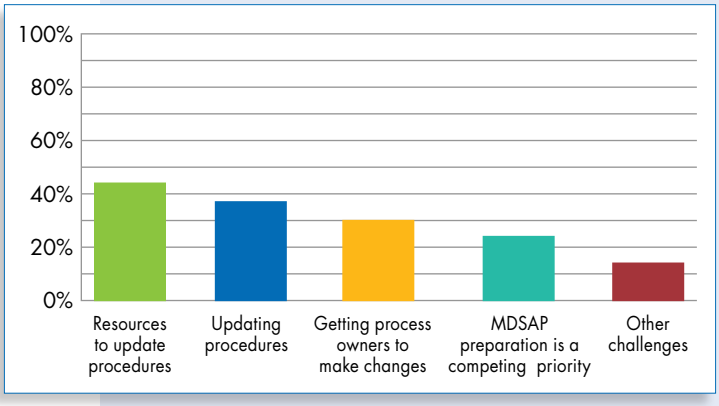


You may be surprised to see the low number of companies that have achieved their certification thus far. When the ASQ Biomedical Division probed this further, it was learned that the major factor to completing it was by starting the plan and activities a year ago, as well as scheduling the audit early in the year. Most ISO Registrars were available in the beginning of the year, but as the year progresses, their capacity has diminished. In fact, the next question provides more insight into the availability of ISO Registrars and scheduling an audit date.

Challenges to Reaching the Goal

Survey participants were permitted to provide multiple answers regarding the challenges they experienced or were experiencing now. It is very interesting to see that 44 percent of respondents were challenged by resources to update the procedures, while 37 percent were challenged by updating the procedures themselves. This demonstrates the changes needed to upgrade their ISO quality procedures took more effort than originally anticipated.

Responses to Question 2
What are the challenges you experienced or are experiencing right now obtaining the new standard?



Another observation made from the results of this question is that only 24 percent of the respondents identified MDSAP preparation as a competing priority. Although an inquiry was not posed to better understand why MDSAP was not a competing priority, it's quite possible these companies were not working toward this certification or didn't have other resources in place to assist. Those who have gone through the MDSAP journey, however, know the amount of work required to prepare for these intense audits.

Three additional challenges in obtaining the new standard were identified from the survey results:

- Scheduling a date from ISO Registrar/Availability of ISO Registrar
- Resources needed to comply with the requirements
- Competing priorities

It has been observed at other companies that the amount of time and resources needed has been underestimated. In addition, the need to make several changes within the procedures was not realized regarding the amount of time it would take to implement them. For example, the changes to the supplier controls and having quality agreements as applicable was not a simple task to implement. This required cooperation from the purchasing and legal departments, as well as review time by the suppliers.

Making Procedures Easier With Flowcharts

It has always been the direction of quality professionals to make the procedures easy to read and follow. If reading a procedure is as challenging as reading a college thesis, one can predict that people will have a challenging time following it. Therefore, one approach shown to be effective is the use of flowcharts, either to replace the paragraphs or supplement the procedure.

Link to the full article:
https://www.mpo-mag.com/issues/2018-06-01/view_features/the-iso-134852016-transition-journey

MEDICAL DEVICES – RISK MANAGEMENT

Application of Risk Management to Medical Devices, ISO 14971 and ISO TR 24971 Guidance

2019 Proposed Update

In 2015, ISO and IEC polled their respective national committees on their position on revising or reaffirming ISO 14971 medical device risk management standard. The reason both were polling is a product of a joint effort to develop and maintain a risk management standard for all medical devices, whether electrical or not. The results of the effort were mixed, and insufficient votes to revise the standard were received; however, sufficient requests were received to provide more information on implementing the standard. This was the reason the standard was previously revised, creating the 2007 edition. Later, a supporting guidance document, ISO TR 24971, was created and released in 2013 to provide additional information (the medical device industry is largely unaware of this very important and useful document).

It seems the industry still feels they have insufficient information to implement the standard, a document that has now been around 18 years. However, there have been a number of device manufacturers that have created risk management files that support the safety of their medical devices in spite of the perceived lack of information.

ISO TC 210's Joint Working Group 1, the group responsible for creating and maintaining the document, kicked off the effort in June 2016 to provide the requested information in response to the requests of their parent organizations, IEC and ISO. There were

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Edwin L. Bills is an ASQ Fellow, Certified Quality Engineer (CQE), Quality Auditor (CQA), Manager of Quality/Organizational Excellence (CMQ/OE), and RAPS-RAC. Bills has held a number of quality and regulatory affairs positions including corporate director of risk management. He has over 36 years' experience in the field of quality and regulatory affairs. Currently, he consults and provides training in the area of medical device quality, regulatory, and risk management. With Stan Mastrangelo, he co-authored Lifecycle Risk Management for Healthcare Products: From Research Through Disposal. *Bills currently participates in the revision of ISO 14971 risk management standard as an international member of the technical committee. He also serves on the US national committee for the medical devices quality system standard, ISO 13485, and the AAMI technical committee developing a combination products risk management guidance. Email: elb@edwinbillsconsultant.com.*

several specific requests embedded in the charge to the committee. First, and most important to the industry, was the charge to NOT change the ISO 14971 risk management process. The comments received in the 2015 votes again supported the risk management process defined in the ISO 14971 standard.

So, if the process did not change, what had the committee done? In late July 2018, after two years of meetings and task team work, JWG1 released a Draft International Standard, ISO DIS 14971:20XX, and a Draft Technical Report, ISO DTR 24971:20XX, were sent to ISO and IEC. It was then circulated to the respective national committees for comment and vote of the acceptance of these two documents. It is up to the national committees to solicit comments and form a position on these two documents, which is required to be submitted in early October 2018.

The national committees have their own processes to solicit comments. In the United States, the national committee will meet in late September through AAMI to formulate a position on the documents and develop a vote with any suggested comments. Brazil has also established a meeting for their committees to solicit votes and comments. Other countries will follow their own processes.

The total page count for ISO 14971:2007 (83 pages) and ISO TR 24917:2013 (15 pages) is 98 pages. The total page count for ISO DIS 14971 (34 pages) and ISO DTR 24971 (98 pages) for a total of 132 reflect the added information but do not account for the textual changes mainly in the information contained in the two new drafts for vote. Also, ISO DTR 24971:20XX has numbered clauses from 1-10 to provide direct guidance on Clauses 1-10 in ISO 14971. The alpha clauses in ISO DTR 24971 are guidance on cross-cutting topics. ISO DTR 24971 is entirely guidance and is not required to implement the ISO DIS 14971 risk management process. However, the numbered clauses in ISO DIS 14971 are requirements and must be covered in the risk management system of the medical device manufacturer. The alpha clauses in ISO DIS 14971 are not requirements to implement the standard, but are also guidance on the implementation. It important that manufacturers use both the ISO 14971 standard and the ISO TR 24971 guidance to develop and implement an effective risk management process.

Also important is that those responsible for implementation of a medical device risk management process have read and understood the discussions in ISO DIS 14971 in Clause A-Rationale for requirements section. This is the thinking of JWG1 on each of the requirements in the standard, and are essential for effective implementation.

Here is what was released compared to ISO 14971:2007:

ISO 14971:2007	ISO 14971:20XX
Clauses and Titles	
1. Scope	1. Scope
2. Terms and definitions	2. Normative references
3. General requirements for risk management	3. Terms and definitions
4. Risk analysis	4. General requirements for risk management
5. Risk evaluation	5. Risk analysis
6. Risk control	6. Risk evaluation
7. Evaluation of overall residual risk acceptability	7. Risk control
8. Risk management report	8. Evaluation of overall residual risk acceptability
9. Production and post-production information	9. Risk management review
No Clause 10	10. Production and post-production activities
A. Rationale for requirements	A. Rationale for requirements
B. Overview of risk management process for medical devices	B. Risk management process for medical devices
C. Questions that can be used to identify medical device characteristics that could impact on safety	Moved to ISO DTR 24971-Annex A-Identification of hazards and characteristics of safety
D. Risk concepts applied to medical devices	Annex C-Fundamental risk concepts
E. Examples of hazards, foreseeable sequences of events and hazardous situations	Moved to ISO DTR 24971-Included in Clause 5.4-Identification of hazards and hazardous situations and Clause 5.5-Risk Estimation
F. Risk management plan	Moved to ISO DTR 24971-Clause 4.3
G. Information on risk management techniques	Moved to ISO DTR 24971-Annex B-Risk analysis techniques
H. Guidance on risk management for *in vitro* diagnostic medical devices	Moved to ISO DTR 24971-Annex H-Guidance for in vitro diagnostic medical devices
I. Guidance on risk analysis process for biological hazards	Moved to ISO 10993-1
J. Information for safety and information about residual risk	Moved to ISO DTR 24971-Annex D-Information for safety and information on residual risk and also Clause 5-Differention of information for safety and disclosure of residual risk

BIOMEDICAL DIVISION AND SAN DIEGO SECTION JOINT CONFERENCE

Illumina | 5200 Illumina Way | San Diego, CA 92122

SAVE THE DATE

EU MDR PLUS COMPLIANCE, QUALITY, AND CULTURE

October 19 – 20, 2018 | San Diego, CA

ASQ Biomedical Division and the ASQ San Diego Section 703 are partnering to provide a truly international conference with high-caliber speakers on a wide range of topics. A full-day EU Medical Device Regulation (MDR) program, multiple Saturday topic tracks, and a medical device company tour.

Friday begins with Oliver Christ, a well-known, popular, and respected speaker speaking on the EU MDR.

Get answers to questions such as:

- Why do we need new regulations on medical devices?
- What are the main benefits for patients and consumers?
- Which products are affected by the new regulations?
- Will the new rules be able to keep up with the future progress?
- Will the transition to the new rules create any disruptions to the availability of medical devices? What are the arrangements?
- How will the market surveillance be improved?
- What are the rules on reprocessing single-use medical devices?
- Does the regulation address the issue of risks of use of nanomaterials used for medical devices?

Oliver P. Christ
CEO at
PROSYSTEM

There will be a Friday night networking event at the Karl Straus Brewery.

https://www.karlstrauss.com/visit/sorrento-mesa/

There will be three Saturday conference session tracks—speakers and topics to be announced.

https://www.eventbrite.com/e/eu-mdr-plus-compliance-quality-and-culture-tickets-45841937469

Questions?

Larry Miller, San Diego conference chair, Lmiller@Illumina.com

Beth Kelly, Biomedical Division conference chair, Beth@KellyQC.com

Hope to see you in beautiful and exciting San Diego, CA!

UPDATES ON THE FDA'S CASE FOR QUALITY

Device Makers Are Boosting Quality by Appraising the Capability of Manufacturing Sites

Shawn M. Schmitt, Medtech Insight

Part 1:

The pursuit of quality can be a daunting task for device makers. One wrong step can cause costly product recalls affecting patient health—among other troubles tied to poor-quality products and processes. To help firms move toward a goal of best-in-industry quality, U.S. FDA, through its Case for Quality initiative, has convened a pilot program to measure a manufacturer's capability and maturity to help put it on a path to continuous improvement. The pilot uses an industry-tailored version of the Capability Maturity Model Integration (CMMI) model and method, developed jointly by FDA, industry, and CMMI Institute. Visit https://bit.ly/2jGPlL1 to read the full story.

Part 2:

Baxter Healthcare's Elizabeth Zybczynski was excited when she first heard that her company would join a U.S. FDA pilot program to measure the capability and maturity of medical device manufacturing sites. Having worked in the aerospace and defense industries before moving to the healthcare arena, Zybczynski knew that the tried-and-true Capability Maturity Model Integration (CMMI) approach could elevate quality in the device industry. CMMI Institute's Kimberly Kaplan and CMMI appraisers Becky Fitzgerald and George Zack explain the maturity model process that Baxter—and several other manufacturers—have gone through, from initial intake phone calls to the unveiling of final appraisal results. Visit https://bit.ly/2K6TWRV to read the full story.

Part 3:

Quality, compliance, and regulatory officials at device giants Boston Scientific, Edwards Lifesciences, and Baxter Healthcare—along with their peers at Steris and CVRx—open up about appraisals conducted at their facilities under a voluntary U.S. FDA pilot program that uses Capability Maturity Model Integration (CMMI) to measure the capability and maturity of their manufacturing sites. Along with providing a step-by-step walk-through of the assessments, the officials explain how a CMMI appraisal is nothing like a typical regulatory audit. They also talk about the types of benefits they're seeing (hint: cost savings, and better manufacturing capability and quality), and how they network via monthly conference calls linked to the pilot. Also: Baxter explains why it made its own maturity model, and how it plans to eventually replace the homemade tool with CMMI at all its facilities. Visit https://bit.ly/2K69U34 to read the full story.

Editor's Note

Additional information at FDA's web page, https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/default.htm

Pocket Stats: Sample Size for Pass-Fail Tests

Andy Sleeper, Senior Verification and Validation Engineer at Hach, Past Speaker at ASQ BOSCON

The meeting was tense. After a splashy release, users have complained about the uPod music player. Vibration from jogging or dancing tends to lock up the uPod, requiring the user to remove and replace the battery. Bloggers have been ruthless, and this product is fast becoming a stinker for Durian Computer Company.

The engineering team has duplicated the problem on a vibration table, and now they propose a software patch to fix the problem. Before releasing the patch to the world, the company must verify the problem is solved. How many uPods need to be tested on the vibration table to provide high confidence that the problem is fixed? All eyes turn to you. Fresh from Six Sigma Black Belt training, the team expects you to have the answer to this question

"First, I have a question for you," you say. "We can't prove that the problem is completely solved without testing every unit we sell, but we can come close. What percentage of uPods would be an acceptably small number to still have this vibration problem?" After some discussion, 1 percent seems reasonable, and this would represent a huge improvement over the estimated 10 percent that now have the problem.

Without touching your calculator, you announce: "If we test 300 on the vibration table, and all pass, this will give us 95 percent confidence that the failure rate is less than 1 percent."

Little do they know that you gained this remarkable ability not from your expensive Black Belt training, but from an article you read on the internet!

First, I'll give you the exact formula, and then the Pocket Stats version you can memorize.

Here is the formula to calculate the required sample size for pass-fail tests, assuming zero failures:

Exact Formula

C is the confidence, expressed as a number between 0 and 1

p is the probability of defective units that you want high confidence of detecting

$$n = \left\lceil \frac{\ln(1-C)}{\ln(1-p)} \right\rceil$$

n If this many units pass a pass/fail test with zero failures, you have **C**x100% confidence that the true failure rate is < **p**

The sample size **n** is the minimum number of units that must be tested with zero failures. Since **n** is usually not an integer, round up the results of the calculation. Using the example where **p** = 0.01 and **C**x100% = 95 percent, **n** = 298.07, which rounds up to 299.

A common sense solution would be to test 100 units to look for a 1 percent defective rate. Since 1 percent = 0.01, and 1/.01 = 100, it makes some sense that testing 100 might be enough. But according to the formula, this common sense solution provides only 63.2 percent confidence. If you test 100 units and have zero failures, you still have a 36.8 percent probability that the failure rate could be larger than 1 percent.

Here is the Pocket Stats version of this formula that you can memorize:

Pocket Stats Approximation

p is the probability of defective units

Confidence	Sample Size
95.0%	3/p
99.0%	5/p
99.9%	7/p

Sample Size (n) If this many units pass a pass/fail test with zero failures, you have the specified confidence that the true failure rate is < **p**

First calculate 1/**p** in your head. For round numbers, this is often easy.

- If you test 1/p units with zero failures, you have 63 percent confidence.
- If you test 2 * (1/p) units with zero failures, you have 86 percent confidence.
- If you test 3 * (1/p) units with zero failures, you have 95 percent confidence.
- If you test 5 * (1/p) units with zero failures, you have 99 percent confidence.

Pocket Stats will often require one more unit than the formula. In the example, Pocket Stats indicates 300, when the exact answer is 299. This is a conservative or safe approximation.

This formula also applies to incoming inspection. In this field, acceptable quality limit (AQL) refers to the highest probability of defective units considered to be acceptable. This is **p** in the above formula. If AQL is 2 percent, 1/AQL = 50. Testing a sample of **n** = 2 * 50 = 100 units with zero failures provides approximately 86 percent confidence that the AQL is satisfied, with a 14 percent risk that the defective rate is greater than 2 percent.

In some circles, **1-p** has been called "reliability." Using the initial example, testing 299 with zero failures provides 95 percent confidence of 99 percent reliability. I find this terminology confusing, because "reliability" means different things in different situations. But I admit that "reliability" is simpler than "one minus the probability of defective units."

Sample size problems are often very difficult. But in this case, with pass/fail tests, a relatively simple formula is available, and the Pocket Stats version is easy enough to memorize. In my career, few formulas have been as useful as this one.

Now go be the hero in your next meeting!

Call for Articles

Share your experience and knowledge with your peers in the Biomedical Division while obtaining valuable publishing credits to add to your professional credentials. The ASQ Biomedical Division newsletter is looking for authors. You can submit your piece to be featured in Biofeedback. *The article should revolve around the themes of practical application of industry knowledge, tools, and techniques and should range between 750 – 1,000 words in length. For more information or to submit an article, contact dmanalan@gmail.com.*

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