Notes From the Chair

It’s hard to believe 2016 is past the halfway mark. Seems like time really does fly. I started my journey with the Biomedical Division more than nine years ago, and I never thought that journey would find me writing a brief article called Notes From the Chair to you today. I am glad I started that journey; because as a member leader of the ASQ Biomedical Division, I have had the opportunity to meet some of the best and brightest people in the quality industry. One of the driving forces keeping me engaged in the Biomedical Division is the dedication these people have to making our industry better for all. If you want to know how to get involved, please reach out to any of our division officers listed in this newsletter.

So, what have we done and where are we going?

• We had four students from Miami University attend the ASQ World Conference on Quality and Improvement and present their senior project, which was partially funded though the Biomedical Division grant and scholarship programs.
• We had our spring conference in Tampa, FL, on changes to ISO 13485:2016, UDI, MDSAP, effective training, human factors, CAPA, and complaints. Our keynote speaker was Kimberly Lewandoski-Walker of the FDA.
• Our discussion groups continue to provide great roundtables and conferences on various quality-related topics like supplier controls, UDI, statistics, and changes to ISO 13485:2016, just to name a few.
• We are sponsoring the ASQ Audit Division’s conference and will have four members present. Mark Moyer is conducting the preconference CBA prep course; Barry Craner is presenting on preparing your risk management file for an audit; David Manalan is presenting on the medical device single audit program (MDSAP and key factors the FDA looks for during an establishment inspection); and Jim Shore is presenting on supplier management.
• We are planning a fall conference October 5 – 6 in Irvine, CA, with similar topics to our spring conference. We have invited back Kimberly Lewandoski-Walker of the FDA as our keynote speaker.
• Scott Blood, education chair, and his committee are working a spring 2017 conference in Costa Rica—stay tuned for more details about this conference.
• Closing comments: Jim Shore and I published a book on Proactive Supplier Management in the Medical Device Industry. The book can be purchased through ASQ Quality Press for $60 (member price). All royalty proceeds for the authors will be donated to a veteran’s organization. Don’t delay, get a copy today!

Best wishes,

John A. Freije
2016 Chair, ASQ Biomedical Division
Hello Biomed Division Members!

by Scott Moeller

We are seeking nominations for the 2017 Biomedical Division leadership team. Our current proposed slate is:

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<th>Proposed slate of officers for 2017</th>
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<tr>
<td>Chair</td>
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<td>Kimberly McCoy</td>
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<td>Chair-Elect</td>
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<tr>
<td>Teresa Cherry</td>
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<td>Vice Chair of Discussion Groups</td>
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<td>Robert Sestrick</td>
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<td>Treasurer</td>
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<td>Jim Shore</td>
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<td>Secretary</td>
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<td>Karen Brozowski</td>
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Position descriptions are at asq.org/member-leader-community/positions/index.html. Any Biomedical Division member in good standing can self-nominate by sending a valid petition, signed by at least 10 members in good standing, to our nominating chair at maryellen.delaney@pfizer.com by September 1.

Please also remember that as a Biomedical Division member, you are part of a strong community of more than 4,300 medical device and diagnostic industry professionals.

The best way to get the highest value from your Biomedical Division membership is to get involved! Be sure to take advantage of all of our many activities and opportunities, including:

- Join our regional discussion groups. Discussion groups are an ideal opportunity to learn, teach, and discuss issues specific to the medical device and diagnostics industries.
- Attend one of our seminars specific to the medical device and diagnostic industries.
- Attend a joint program that we host with other ASQ sections, divisions, and regulatory agencies.
- Visit our website.
- Study to become an ASQ Certified Biomedical Auditor and be recognized for your competence.
- Utilize our available publications.
- Participate in one of our many working groups and committees.
- Network with other medical device and diagnostic industry professionals.
- Attend our annual meeting held before ASQ’s World Conference on Quality and Improvement.

I'd like to hear from you!

Do you have any questions about our division or how the division can bring value to you? Let me know!

scott_moeller@baxter.com

Biomedical Division’s Vision and Mission:

We strive to be recognized as:

- Our member’s best source for achieving professional and organizational excellence
- A provider of information and learning opportunities relating to quality for the worldwide biomedical community
- The leader in operational excellence and delivering value to our members
- A leader worldwide for advancing individual and organizational performance excellence for the biomedical community
Recap of Xavier MedCon

by Bob Turocy

I was truly impressed with the Xavier MedCon conference in Ohio, held May 3 – 6 of this year. The presentations, information provided, and expert representatives from government, industry, consultants, etc., was truly enlightening. In addition, the Xavier facility and staff hospitality was great.

The following is a brief summary of most of the presentations. Some paragraph summaries include a few presentations, i.e., the FDA paragraph contains several presentations, as called out in bold text.

FDA

The CDRH is embarking on protecting the public health by equating and balancing safety, effectiveness, quality, and speedy access to new medical devices by the general public. A case for quality vs. compliance was a driver. The ecosystem was also brought to the forefront. The MDSAP was referenced as well as its timeline. Other issues of importance include: training, streamlining, specialization, importation requirements, lab optimization, etc. FDA and International Update on Cybersecurity Progress recommendations were provided as well as FDA’s position and preventive actions. Collaboration is the key to success in the environment. Regulatory Strategy for Innovation took on a benefit vs. risk from the patient perspective. Least burdensome, interactive, and customer service orientation data concerning 510Ks, PMA, DE Novo, etc., were highlighted. Critical Thinking: The Secret to Responding to FDA was one of the best presentations that will benefit a medical device manufacturer. There are examples of 483 Form Observations and Warning Letters with appropriate replies to the FDA. Internet and Social Media Concerns are monitored by both the FDA and the FTC. Therefore, medical devices are subject to scrutiny by both government entities. FTC has a dual mission of protecting the consumers and promoting competition. Be aware of what your organization is doing and stating on the Internet. Update From the Office of Device Evaluation was an impressive presentation that intended to show the transparency of the FDA. Statistics were provided to show performance and accomplishments of the ODE. Future MDUFAs will enhance the FDA’s output with bringing new devices quicker to patients. When to File a 510(k) for Modifications to Your Cleared Device: What You Don’t Know Can Hurt You had an emphasis on claims. If a company does not file a 510(k), then it is important to describe with good documentation justifying one’s position when not to file. The FDA explained that the Guidance Document K97-1 is in the process of being revised to be clearer with the intent of the guidance. The revised flowchart will be published and sent out for comment in the near future. Continue to use the original guidance until the new is published. What to Expect With FDA’s Program Alignment? showed that the FDA plans a realignment of its programs by year-end 2017. Why is the FDA doing this? Most likely due to the complexity of globalization innovation and legislative changes. The agency is becoming more focused on products or customer needs and how to best implement and attain its objectives. The FDA will train new and existing employees to audit a device manufacturer. Pay attention, this new program will affect you. Investigator Insights (Breaking News): The intent was to provide information from past years’ experience of the FDA. Presenters shared the data and trends from the FDA’s inspections. It is worthwhile to see what is being cited as far as inspections, citations, and WLs are concerned.

Japan

Navigating Japan’s Regulatory Environment: JPAL transmission to PMDL was provided as well as the impact to manufacturers. Medical device labeling requirements and MASH expectations and responsibilities were provided.

Europe

European Medical Device Regulation Progress: The EU is proposing changes to the medical device directives and CE marking during the next two years. It appears that the EU
is aligning itself with other country regulations. This means that it may take a little longer to
gain entry into the EU market with a medical device. Brooks provided an excellent presen-
tation. Potential changes to the medical device directive and CE marking is shown in red on
the slides.

**Canada**

**Canada’s Changing Quality System Requirements: 13485/MDSAP/CMDCAS**: Canada
has mandated ISO 13485 as the base for medical device accreditation in its country. It
is possible that MDSAP will replace CMDCAS. This activity may be completed in 2016.
Brazil, Canada, Japan, Australia, and the United States are partners in the MDSAP.
Countries from the EU have not yet signed agreements with this program. Therefore, if
your organization markets a medical device in one of these areas, then it will benefit your
organization to get involved in the MDSAP. Contact Canada and get the schedule for the
MDSAP if your Notified Body is authorized to perform an audit. You owe it to your organi-
zation in saving resources (time, money, and manpower). Get involved!

**MDIC/Xavier University**

**MDIC/Xavier University Medical Device Metrics Initiative**: Metrics are the heart and
soul of a corporation’s decision and action plan to process that which benefits an operation.

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Members of the Biomedical Division are encouraged to review the presentations that
either affect their operation or are of interest. The presentations can be attained at the ASQ
Biomedical Division Share Point website in the near future.

Finally, I found this conference to provide current information and data from regulators,
industry, and consultants. It was truly beneficial to a medical device manufacturer.

**Feingold Scholarship Awarded to Five Miami University Students**

*by Steven Walfish*

The Biomedical Division Awards and Grants Committee, under the leadership of David
Manalan, awarded a grant to five senior engineering students at Miami University as part
of their senior design project. Under the advisement of Dr. Michael Bailey-Van Kuren, the
project focused on the need for an engaging, versatile activity that benefits pediatric phys-
ical therapy, specifically at ABC Pediatric Therapy Network. ABC Therapy uses exercise
for its physical therapy to improve coordination, overall mobility, and muscle strength.
Through play-based techniques, movement becomes natural and fun. However, at ABC
Therapy the development in age-appropriate equipment for older children and preteens is
limited. Additionally, there is no present means for the pediatric therapists to record prog-
ress, since the activities played often involve standard toys.

Therefore, the team’s goal was to create an age-appropriate game using a piano mat to
assist the pediatric therapists, deliver useful feedback, and provide motivation and enter-
tainment to the child. One of the activities was a Simon Says-type game where notes from
a song play and the child must repeat them back in the correct order using the piano mat.
While the notes are played, an LED light will light up the note to make apparent which key
the child needs to press when repeating back. The other game is a “free” mode where the
child can play whatever notes desired without having to repeat them back. In response to
both forms of games, an output to record progress will be available to the therapist. The
pressure sensors located under the piano keys will record not only the measure of force but
also the duration under said force. Therefore, the therapist can track progress and strength
of the child throughout his or her use of the mat. His or her piano mat will be different from
existing piano mats on the market because it will be customized to the therapist. The thera-
pist requested the mat to be smaller and slower, allowing the child to be able to repeat the

*cont. on p. 5*
notes at his or her individual pace. The mat also has the added feature of feedback to the therapist unlike the existing mats. Finally, the mat can be used on the floor, table, and also hung on the wall for flexibility in therapy options.

What Is My Failure Rate?

by GM Samaras

Introduction

The quality of a product not only includes fitness for intended use, but also the reliability of that product attribute. In the August 2015 issue, we discussed medical device life-cycle risk management with emphasis on the similarities of pre- and post-market risk management and discriminating system use vs. human user errors. In both pre- and post-market risk management we have the opportunity to acquire failure event data (so-called “numerator” data). These are values of observed events that may or may not be statistically valid or scientifically useful depending upon how, when, where, and from whom we acquired the data. In the pre-market setting, limited testing results in limited cost, but also limited data; in the post-market setting, uncontrolled “natural experiments” yield real-world results, but in a manner that makes the data difficult to analyze and generalize (i.e., to justify external validity). This is often used to minimize the utility and value of the FDA-required complaint-handling process, because of the perceived quality of the data. This is both technically incorrect and wasteful of corporate resources. Post-market data have enormous value for sentinel event (safety signal) recognition and health hazard evaluation, but only if they are properly analyzed and the failure rate is properly computed. Ignoring or mishandling these data undermines competitiveness, profitability, and perceived corporate excellence; it also violates federal regulations in the United States and exposes the firm to product liability.

Failure Rate Computation

Whether you are tasked with investigating reliability or survivability, what you are fundamentally concerned with is (repairable or nonrepairable) failure rate. The rate can be based on time, product units in use, product uses, or some other denominator. Very often, those unskilled in reliability engineering will choose the largest possible denominator, so as to make the failures look good with a small rate value. From an engineering perspective, this is both nonsensical and counter-productive, as it masks the triggers necessary to justify making changes to design, manufacturing, or distribution of the product. The central objective of reliability engineering is to identify product defects, so that they can be corrected; obfuscating those defects protects nothing, except possibly sales commissions. Obfuscating defects will cost the enterprise far more in the long-term. To help identify product defects, you need to choose the correct denominator.

In the pre-market phase, most medical device manufacturers seem to rely on subjective estimates of probability of occurrence, rather than quantitative failure rate data, for their construction of a design (or device) failure mode and effects analysis (DFMEA). Furthermore, they typically do the analysis with a single unit in mind, rather than the aggregate of units that are expected to be sold. As you transition to the post-market phase, expected frequency of occurrence of an event is typically derived from your failure mode and effects analysis (FMEA) and incorporated into your health hazard analysis (HHA). But,

2. 21 Code of Federal Regulations 820.198: Complaint Files.
3. If you estimate your individual product will fail only once every million uses (10⁻⁶; “improbable” per ISO 14971), but you plan on selling at least 1,000 units, then your probability estimate has to be somewhere close to once every thousand uses (10⁻³; “frequent” per ISO 14971, assuming independence, same epochs, etc.).
post-market medical device risk management requires you to update your pre-market predictions with post-market data, which then changes the results of your DFMEA and your residual risk analysis. To do this correctly, you need a robust complaint management system that actively seeks product failure information and correctly determines the root cause.

We can think in terms of two types of medical device product failures: (a) those that interfere with user workflow, requiring the product to be serviced or replaced, and (b) those that result in reportable adverse events. The former are typically noncritical, but potentially costly defects related to design, manufacturing, or distribution; the latter may be quite costly and have protracted effects on competitiveness and profitability. How you discriminate these and apportion resources for corrective or prevention action, in part, depends on your calculation of the failure rate. Your choice of denominator is an indicator of your expectation (or implicit assumption) regarding the underlying root cause. It also drives the occurrence value in your updated DFMEA and your HHA. In both we are focused on likelihood of harm given exposure to the hazardous situation—not on likelihood of product failure.

Consider the following scenario. You have a medical device with an accessory and a disposable; the device has no utility without the accessory and the accessory cannot function safely without the disposable. This configuration can be found throughout many medical device classifications and in multiple products outside the medical device domain, driven in part by contemporary marketing strategies. Now consider multiple complaints of reportable adverse events that were potentially caused by, or contributed to, reported product “failures.” And, of course, your job is to figure out whether the most recent complaint is a sentinel event (safety signal) or “just” human error; your enlightened members of management are relying on you to tell them what is actually occurring, so they can take appropriate action and allocate appropriate resources. The complaints group gives you its information (information about the person injured, the injury, and some information about your product that was being used at the time).

### Table 1 – Denominator Examples and Putative Root Causes

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<th>Example Denominator</th>
<th>Implicit Assumption of Root Cause</th>
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<tr>
<td>Number of units</td>
<td>Design, design transfer, or manufacturing</td>
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<tr>
<td>Number of users</td>
<td>Instructions for use, or training and credentialing</td>
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<tr>
<td>Number of uses</td>
<td>Wear, cleaning, or maintenance degradation</td>
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Table 1 offers some example denominators and implicit assumptions of the root cause of the failure. You could choose the number of uses (no. uses) as the denominator, get a really low failure rate, and get on with more important things, since it is obviously human error; but, what if someone asks you to prove that wear, cleaning, or maintenance degradation is not the root cause and the problem is simply a design defect resulting from your choice of materials or the manufacturing process? You could choose the number of users (no. users), which is a smaller denominator than number of uses (no. uses). Sure, you get a larger failure rate, but you still can blame it on human error; but, what if someone asks you why the root cause is not a defective IFU or inadequate training protocol and, oh by the way, can we see your labeling comprehension and usability validation study final?

5. 21 CFR 803.3: Death or serious injury (life-threatening OR results in irreversible harm to body structure/function OR reversible harm to body structure/function that requires surgical/medical intervention to prevent it becoming irreversible).
6. Instructions for Use, part of FDA required medical device labeling and subject to human factors validations since at least as early as 1997.
7. It could be that the user is violating the labeling (resulting in failures indicative of deficient training) or the user is following the IFU and still resulting in failures (indicative of deficient labeling).
report for the IFU and/or the training? You could conclude that the denominator should be the number of units (no. units), because you suspect a—as yet to be uncovered—defect in design, production, or maybe even distribution. But, then you realize that is going to be a serious headache; R&D, manufacturing, and marketing are all going to be very skeptical. Furthermore, are we talking about the disposable, the accessory, or the base device? Or, is it the interface between the disposable and the accessory or is it the interface between the accessory and the base device?

You obviously need more information … much more information, but the complaints group gave you everything they have and claim that is everything it could get.

**Conclusion**

Incorrect failure rate estimation in the pre-market phase is the result of defective risk management and a failure of design control. However, in the post-market phase, incorrect failure rate estimation typically arises from deficient complaint handling and/or choice of an inappropriate denominator. This is, in effect, censoring and can severely limit data validity. Notwithstanding the famous work of Kaplan-Meier 8, ignoring or mishandling complaints of product failures is an effective censoring mechanism that denies corporate management the information necessary to make correct business decisions. Defective failure rate estimation undermines competitiveness, profitability, and perceived corporate excellence; it also unnecessarily exposes firms to failed inspections, unwelcomed audits, and product liability. One approach to ameliorating this is allocating more resources to the complaint-handling process and insisting on greater rigor in the complaint investigation and data collection. You cannot manage what you cannot control, and you cannot exert effective control without necessary and sufficient information.

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