Biomedical Division
The Global Voice of Quality®
ASQ

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BioFeedback
BIOMEDICAL DIVISION NEWSLETTER

Inside This Issue

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

Welcome to 2018 and another exciting year in the medical device industry!

The main focus of the Biomedical Division is, and has always been, to provide training opportunities through division conferences, regional discussion groups, joint programs with other ASQ divisions and sections, sessions with regulatory agencies, activities with other professional organizations, and presentations at the World Conference on Quality and Improvement. We believe our strongest assets are our body of knowledge and the industry experience we can share. With all of the new requirements and upcoming changes that affect our working lives, we are striving to provide a platform for individuals, such as yourself, to share ideas on how to navigate the ever-changing quality and regulatory world!

Our 2018 plans include sessions and networking activities at the ASQ World Conference on Quality and Improvement in Seattle, WA, in April and a division fall conference in October in San Diego, CA. These opportunities for training are in addition to our monthly regional discussion group activities. We currently have discussion groups in New England (NEDG), Midwest (MWDG), Northern California (NCDG), Southern California (SCDG), and Dallas-Fort Worth, TX (DFWDG). We are also planning on starting a new discussion group … maybe near you!

If you've ever had an interest in becoming more involved with the division, we are always looking for new member volunteers! We have a new Social Media Committee, which runs our LinkedIn group page and will be looking at other platforms for sharing information. In addition, will need volunteers to get involved with the new discussion group! Also, we will be looking for ASQ Certified Biomedical Auditors (current CBA certification holders) to help update the body of knowledge for the next version of the exam.

There's never a dull moment in the medical device world. I hope you know you can count on the ASQ Biomedical Division for information sharing and networking!

Teresa Cherry
2018 Chair,
Biomedical Division

SAVE THE DATE

The same organizations that bring you the Annual FDA Update program each December,

- **ASQ Biomedical Division/ New England Discussion Group**
- **MassMEDIC**
- **RAPS-Boston Chapter**

PRESENT:

Global Regulatory Update 2018

The new MDR and IVDR – The time to prepare is now!

Join your medical device and diagnostics colleagues for a day of in-depth briefings by leading industry experts and regulators on significant and critical changes required to your technical documentation and processes in order to achieve or maintain product approval in the EU.

June 19, 2018
Massachusetts Medical Society, Waltham, MA
8:00 a.m. – 3:00 p.m.
Cost: $175.00

Save the date in your calendars now and watch for more information in future emails on speaker and topic details.

Great Article on the Case for Quality

Stephanie Christopher of Medical Device Innovation Consortium (MDIC) has a guest column in the March 19, 2018, edition of *Med Device Online*, titled "**Proactive Quality Systems: FDA Has Made Them A Priority — Has Your Organization?**" As we know, proactive is preventive action, and this is an important item. Christopher says, "Taking predictive and proactive measures to improve quality can have far-reaching effects—from more efficient resource allocation to decreased probability of a recall. Conversely, manufacturers that fail to implement quality objectives as value drivers could put the future of their companies at risk. A 2017 McKinsey analysis revealed that the direct cost of quality is $26 billion to $36 billion dollars annually, representing 6.8 to 9.4 percent of device industry sales.

Sections of the paper include

- **FDA's Steps To Incentivize Quality**
- **Six Benefits Of Investing In Quality**
- **Investing In Quality: First Steps**

Go to https://www.meddeviceonline.com/doc/proactive-quality-systems-fda-has-made-them-a-priority-has-your-organization-0001 for the full article.

You can get additional information on the **Case for Quality** from FDA at https://www.fda.gov/medicaldevices/deviceregulationandguidance/medicaldevicequalityandcompliance/ucm378185.htm.

Biomedical Roundtables Evolve: NCDG Extends Sessions to Remote Online Attendees

As one of the original discussion groups for Biomedical Division, the Northern California Discussion Group (NCDG) has been holding monthly roundtables for more than 25 years. The NCDG roundtable sessions (generally, 10 to 11 sessions a year) have been held at various sponsor company locations in the San Francisco Bay area on the fourth Wednesday of the month from 7:00 p.m. – 9:00 p.m.

Our current location is Stellartech Research Corp., now located in Milpitas, CA, which has been a host location coordinated through Gary Seager and Stellartech management for many years.

NCDG roundtables have been a sustained success, with attendance averaging in the 30s and occasionally ranging to 80-plus for FDA topics or other networking-focused events. Having annual focused themes such as **21CFR820 QSR compliance** this year has been the norm and has proven very successful. The foci on topic delivery are value-added basics, application-focused discussions, and providing takeaways that are actionable or potentially actionable (often with takeaway templates or draft examples).

Remote Access Efforts

Over the last few years, led by ASQ Fellow Barry Craner's effort to adopt new technologies, NCDG has expanded to offering remote access for individuals who could not physically attend due to work travel, increasing Bay area traffic, or other conflicts that arise.

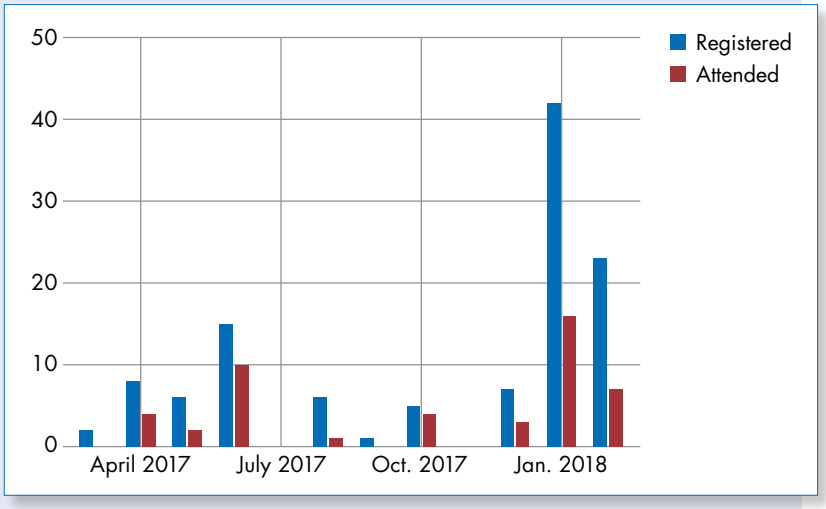
This was a piloted effort for most of 2016 led by Craner and our NCDG board members Dishita Purohit, Anesh Tilwani, and Shreya Chandrasekhar. Their hard work—along with our other board member volunteers—in facilitating our roundtables is what makes it possible.

Author

George Marcel is an ASQ Senior member and has been involved in various groups, sections, and activities over his quality management career in ASQ and in related industry groups. He is currently director, quality assurance, for Focal Therapeutics Inc. in Sunnyvale, CA.

Registration and sign-in data over time

	REGISTERED	ATTENDED
March 2017	2	0
April 2017	8	4
May 2017	6	2
June 2017	15	10
August 2017	6	1
September 2017	1	0
October 2017	5	4
December 2017	7	3
January 2018	42	16
February 2018	23	7



After getting the program content delivery aspects established for GoToWebinar application, NCDG began to advertise this option in all our Eventbrite postings in March 2017, as a no-cost option, but without associated CEUs/RUs.

Implementation has been a learning experience and challenge at a high-quality level. We've had a range of microphone, lighting, connection, and other challenges, but in good continuous improvement measure and spirit, we are implementing improvements. Benchmarking other discussion group efforts, such as Dallas-Fort Worth discussion group (DFWDG), will help NCDG's delivery in the future.

Baby Steps for Content Delivery Success

In 2017, we had a total of 24 individuals join us remotely, with a high mark of 10 for the June 2017 roundtable by Tim Stein on "Software Quality: FDA 21st Century Cure Act and EU's Medical Device Directive."

In January 2018, we added marketing through the ASQ Biomedical Division LinkedIn group, and featured the no-cost remote option in addition to the normal Eventbrite emails and other local advertisement links. It seems this may be a source of new interest. In January and February 2018, we had 65 online registrants, with 23 actually signing in.

Moving Forward

NCDG will continue to refine the process and benchmark to improve, perhaps creating a good practice guide with the other discussion groups looking at remote delivery and expanding membership reach.

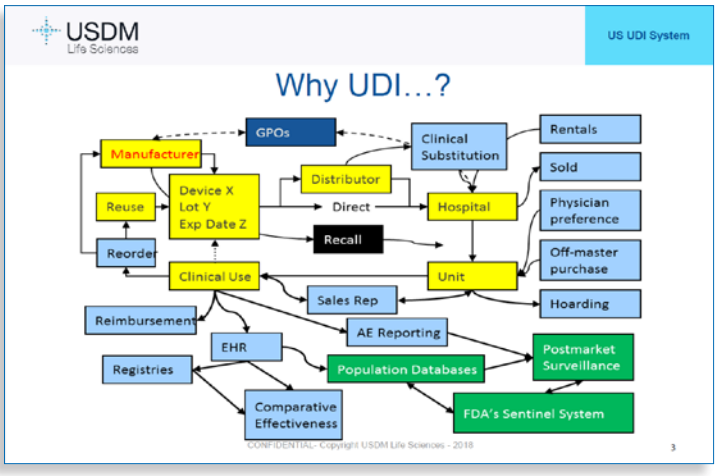
Follow-up surveys are being done online with those who have signed in to learn about good and bad experiences. We plan to track and update on how to gain repeat attendance. We will update our 2018 performance at the end of the year.

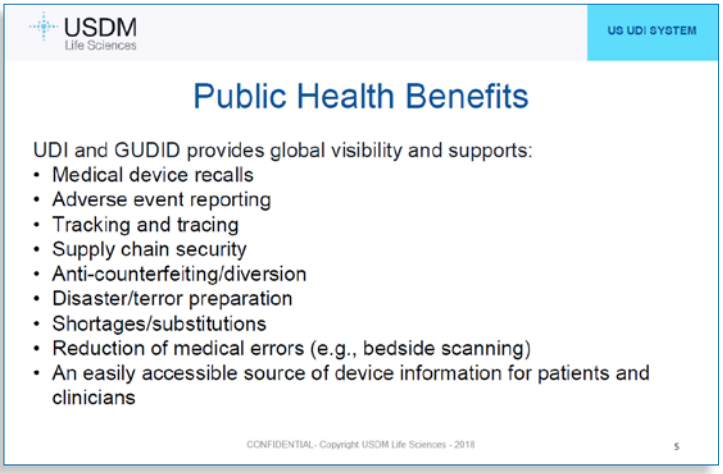
Key to our continued success is continued volunteer efforts to share good practices via material and provide a forum for discussions that add value to those attending from biomedical companies. Remote access is just another way to share discussion group efforts across the regions and beyond.

In addition to the roundtables, the NCDG has had an ongoing joint effort with the local RAPS chapter as well, usually in the spring or summer months, with attendance between 120–200. The NCDG has also held joint programs with San Jose State University (SJSU) biomedical program, Society of Manufacturing Engineers, the ASQ Silicon Valley Section, and others.

Learn More About GUDI

At BOSCON 2018, an annual conference hosted by the ASQ Boston Section, Jay Crowley of USDM Life Sciences presented a very informative talk on "The U.S., EU, and Global UDI Requirements: The Product Visibility and Control Imperative." Many of us remember Crowley as a lead author at FDA during the drafting of unique device identifier (UDI) regulations and guidance.





Crowley pointed out the purpose of the UDI was similar to the drug NDC, a unique identifier that accessed a dataset with all the components and companies involved in manufacture and distribution. The UDI thus makes post-market surveillance and similar activities work better for identifying problems and enabling action.

The International Medical Device Regulators Forum (IMDRF) UDI WG7Final:2013 describes a vision for Global UDI that has largely been realized in the United States. Integration and harmonization with other countries will be a major future project.

Many informative slides later, Crowley summarized what is needed to succeed:

- Deep understanding of the regulation specifics and how they affect you
- Reassessment of your current UDI strategy vs. new requirements and gaps
- Single source of truth to house and easily share your key data
- Meet requirements while maximizing business operations and reducing costs

Your destination is UDI capability, not a series of UDI projects.

Jay Crowley can be reached at jcrowley@usdm.com. He is willing to send you the whole set of slides on request.

2018 Biomedical Division Business Plan | James (Jim) Shore

What is the division's focus, what are the tasks and priorities, who is responsible, and how will it be measured? The division has used the ASQ template to plan for 2018 as follows:

ASQ Strategy: Membership Transformation

Serve the needs of individuals around the world to ensure their professional success through membership, products, and services.

Objective	Action Description and Priority (L-M-H)	Action Plans	Owners (or Roles)	Measure
Increase Member Growth	Develop and execute recruitment plan HIGH priority	1. Send at least one member leader to visit each DG at least once during 2018 (six locations)	Leadership team: Teresa, Jim, Karen, Lisa, Kimberly, Tiffany	Number of Member Leader visits to DG sites
	Partner with other professional/ regional organizations HIGH priority	1. Partner with three other professional organizations (i.e., MassMedic, RAPS, BioNorth Texas) for opportunities for joint events	All DG leaders	Successful event (revenue is >/= expenses)
	Each DG will partner with at least one local ASQ section and other divisions and hold or co-host one event MEDIUM priority	1. Each DG will identify a section or division to partner with 2. Determine time and location 3. Hold the event or co-host the event	All DG leaders	Successful event (revenue is >/= expenses)
Improve Member Retention	Make members feel appreciated MEDIUM priority	1. Send CBA congratulatory letters to division members following passing the CBA certification	Sally Thorsen	% of letters sent
	Reach out to new members MEDIUM priority	1. Update welcome letter to new BD members 2. Send letter to new members introducing them to the BD	Sally Thorsen Teresa Cherry	% of letters sent (via email)
	Contact new members (less than one year) and engage them LOW priority	1. Create a script for calls 2. Contact members 3. Provide reporting on monthly division calls	Sally Thorsen	% of new members contacted each month
	Voice of the customer survey (either call or qualtric software) HIGH priority	1. Conduct survey based on 2017 questions 2. Compare the results with previous year 3. Send out survey at the end of 2018	Scott Laman	Receipt of completed surveys (% of members)

ASQ Strategy: Growing Organizations

Serve the needs of organizations around the world providing quality solutions to increase impact through membership, products, and services.

Improve Organizational Products and Service	Provide division SME for other conferences MEDIUM priority	1. Sign up through ASQ HQ for speaker list. At a minimum, the leadership team plus five other people 2. Have at least three division members speak at other conference	Leadership team: Teresa, Jim, Karen, Lisa, Kimberly, Tiffany	Number of division members speaking at other conferences
	Offer at least one division conference MEDIUM priority	1. Education Committee to create plan and budget for a one-day conference	Pam Goldstein, Beth Kelly	Successful event (revenue is >/= expenses)
Increase DG Membership	Look for one regional area to start new DG HIGH priority	1. Review the membership list to identify areas with lots of division members that do not already have a DG 2. Send out survey to determine if there is interest 3. Support development by organizing the first meeting/ roundtable 4. DG to have two more meetings with their own leadership team	Scott Laman, Sally Thorsen, Tiffany Abrams	New DG having its own meeting (independent of Division leadership team)
	Provide support for NEDG, NCDG, DFWDG so they each have a monthly meeting HIGH priority	1. Have quarterly call with DG leaders; provide support as necessary	Tiffany Abrams	DGs having monthly meetings (based on % : #DG*#meetings/#DG * 12)
	Work with the SCDG and MWDG to improve membership and at least one event per quarter HIGH priority	1. Offer assistance with scheduling meetings, finding speakers	Tiffany Abrams	DGs having quarterly meetings (based on % : #DG*#meetings/#DG * 4)

Division and Discussion Groups

In 2017, 26 educational events were provided to members by the division and its discussion groups, plus four joint events with other professional organizations.

Total attendance numbers were 933.

Activities

ASQ Biomedical Division current events are at http://asqbiomed.eventbrite.com/.

Northern California Discussion Group (NCDG) current events at https://www.eventbrite.com/o/asq-biomedical-division-ncdg-northern-california-discussion-group-11049705265.

New England Discussion Group (NEDG) current events are at https://www.eventbrite.com/o/nedg-part-of-asq-biomedical-division-700623271.

Dallas-Ft. Worth Discussion Group (DFWDG) current events are at https://www.eventbrite.com/o/dfw-bio-dg-4669357293.

Midwest Discussion Group (MWDG) current events are at https://www.eventbrite.com/o/asq-midwest-biomedical-discussion-group-5333510045.

Southern California Discussion Group (SCDG) current events are at https://www.eventbrite.com/o/scdg-asq-biomedical-5343451149.

Division and Discussion Groups Topics

- BD NCDG: Modern Approaches to Assessment of Bio-compatibility (Updated), Roundtable, December 6, 2017
- Process Validation and Integrating Risk Management
- BD DFWDG: Student-Professional Networking Event, 2017
- BD NEDG: Networking Event, October 26, 2017
- BD NCDG: Complaints "The Bane of Devices! Why are complaints always on the high end of the Gotcha regulatory enforcement lists?" Roundtable, October 25, 2017
- BD DFWDG: Benchmarking Risk and Leadership: One evening, two topics
- BD NCDG: Contamination Prevention and Control in Medical Devices, Roundtable, September 27, 2017
- Data Outliers: Assessment and Their Impact on Normality
- BD DFWDG: Supplier Auditing: Control Your Risk!
- BD NCDG: Data Integrity: Beyond Good Documentation Practices, Roundtable, August 23, 2017
- BD NCDG: Update on Software Regulations: FDA 21st Century Cures Act and EU MDR, Roundtable, June 2017
- Process Validation and Integrating Risk Management
- BD NCDG: Valid Statistical Rationales for Sample Sizes, Roundtable, May 2017
- BD NEDG: Regulatory Inspections, Roundtable, May 11, 2017
- Incoming Inspections: Necessary Evil?
- Biomedical Division Fun and Dinner (WCQI)
- BD NCDG: Risk-Based Approach to Clinical Trial Quality Assurance, Roundtable, April 2017
- BD DFWDG: Risk Management and Pending Changes to ISO 13485
- BD NEDG: Clinical Evaluation Reports Compliance With MEDDEV 2.7.1, Rev 4, April 6, 2017
- BD NCDG: EO Sterilization: Validating and Managing the Process, Roundtable, March 22, 2017
- BD DFWDG: Influence Without Authority: Project Management
- BD NEDG: ISO 13485:2016 Step-by-Step Implementation, March 7, 2017
- BD NCDG: Controlled Environment Rooms (CER), Roundtable, February 22, 2017
- BD DFWDG: Biomedical Division DG Handbook Review
- BD NCDG: E-Beam Radiation Sterilization and Validation, Roundtable, January 2017
- BD DFWDG: Career Management in Today's Hot Job Market

Biomedical Division Officers 2018

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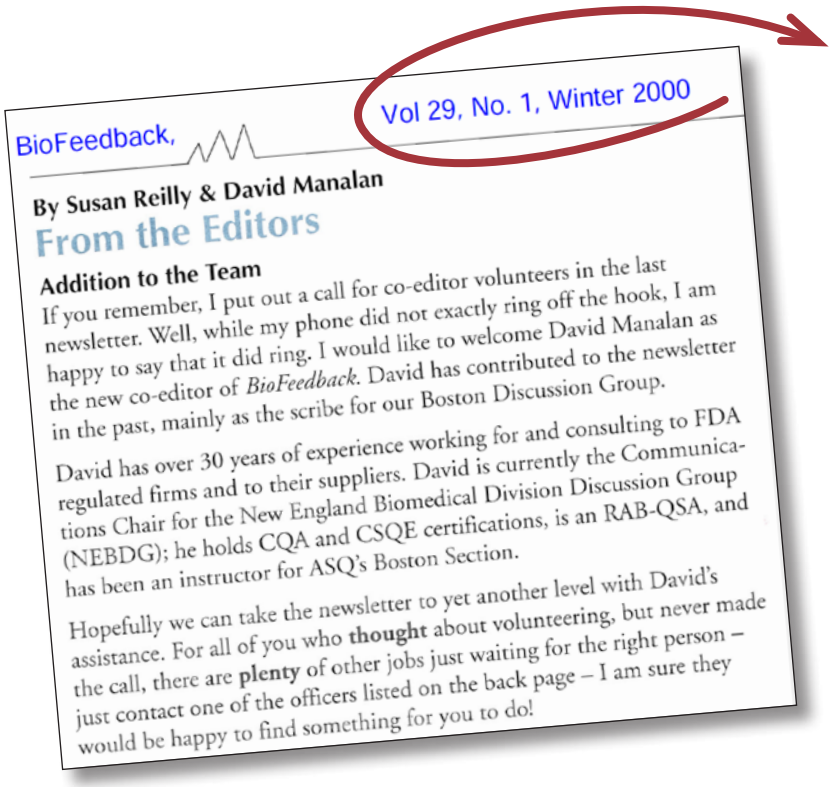
Call for Articles

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.*



BioFeedback, Vol 29, No. 1, Winter 2000

By Susan Reilly & David Manalan

From the Editors

Addition to the Team

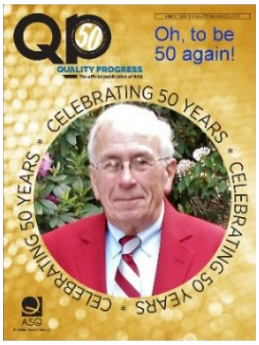
If you remember, I put out a call for co-editor volunteers in the last newsletter. Well, while my phone did not exactly ring off the hook, I am happy to say that it did ring. I would like to welcome David Manalan as the new co-editor of *BioFeedback*. David has contributed to the newsletter in the past, mainly as the scribe for our Boston Discussion Group.

David has over 30 years of experience working for and consulting to FDA regulated firms and to their suppliers. David is currently the Communications Chair for the New England Biomedical Division Discussion Group (NEBDG); he holds CQA and CSQE certifications, is an RAB-QSA, and has been an instructor for ASQ's Boston Section.

Hopefully we can take the newsletter to yet another level with David's assistance. For all of you who **thought** about volunteering, but never made the call, there are **plenty** of other jobs just waiting for the right person – just contact one of the officers listed on the back page – I am sure they would be happy to find something for you to do!

Former Editor Returns, 18 Years Later

David Manalan, editor



I'm your 2018 editor for *BioFeedback*. I've been a member of ASQ since 1976 when it was ASQC. I volunteered as the newsletter editor in 2000. Today, I'm returning to my roots. Many things have changed in the division, and we're still looking for articles, suggestions, and volunteers at *BioFeedback*, YOUR newsletter, not mine. I've tried to put some interesting items in this issue, but I'd love feedback—reminds you of the newsletter's name.

- Would you like summaries of division and discussion group events?
- How about helpful statistical hints?
- Maybe something on MDSAP, or the Case for Quality, or other quality issues driven by regulation. MDR articles?

I welcome the challenge and hope you enjoy the newsletter.

dmanalan@gmail.com