



# ***ASQ Biomedical***

## ***Discussion Groups***

Presented by:  
Mark Moyer

# Our Vision

To be the leading authority on quality issues related to the Biomedical Community



# Our Mission

To promote the awareness and the use of quality principals, concepts, and technologies in the Biomedical Community  
(Biomedical = Device + IVD)

# ASQ Membership/Models

- Senior
- Full
- Associate
- Student
- Form/Division



Forum/Division



Section



Community

# ASQ Divisions

- **Audit**
- **Automotive**
- **Aviation/Space & Defense**
- **Biomedical**
- **Chemical and Process Industries**
- **Customer-Supplier**
- **Design and Construction**
- **Education**
- **Electronics and Communications**
- **Energy and Environmental**
- **Food, Drug, and Cosmetic**
- **Government**
- **Healthcare**
- **Human Development and Leadership**
- **Inspection**
- **Lean Enterprise**
- **Measurement Quality**
- **Product Safety & Liability Prevention**
- **Quality Management**
- **Reliability**
- **Service Quality: Six Sigma:**
- **Software**
- **Statistics**
- **Team and Workplace Excellence**

# ASQ Calendar



## **16-Hour ISO 9001:2008 Lead Auditor Training**

Monday, Dec 15 - Tuesday, Dec 16 - 2008

Fort Lauderdale, FL

United States Of America



## **ASQ Section 0922 Christmas Party**

Monday, Dec 15 05:30 - Monday, Dec 15 08:00 - 2008

Hopkinsville, KY

United States Of America



## **NEDG Biomedical Sampling Plans, round table**

Thursday, Dec 11 - Thursday, Dec 11 - 2008

Waltham, MA

United States Of America



Headquarters



Forum/Division



Section



Community

# E-Mail Preferences

## My Account

My Membership   My Contact Information   Change Password   My Community   **E-Mail Preferences**   My Profile

### E-mail Preferences

Please uncheck the box in front of any e-mail type you don't want to receive.

- Section updates** — sent periodically from ASQ Sections about upcoming events and local quality-related news. (Section Members only)
- ASQ Product and Services** — sent periodically about new quality products, services, and upcoming events.
- ASQ Weekly** — News that members can use, e-mailed every week.

ASQ does not sell e-mail addresses.

- Updated your contact information
- Consider enabling email contact

# My ASQ Events Calendar

## Upcoming Events

- Dec/11 - [NEDG Biomedical Sampling Plans, round table](#)
  - Dec/11 - [Preparation for FDA Inspections and What to Do During and After the Inspection](#)
  - Dec/13 - [ASQ Greater Fort Worth Saturday Seminar - Certification Math Tutorial \(Technician-level\) - NO COST](#)
  - Dec/15 - [16-Hour ISO 9001:2008 Lead Auditor Training](#)
  - Dec/15 - [ASQ Section 0922 Christmas Party](#)
  - Dec/15 - [Auditor/Lead Auditor Training for ISO 13485](#)
- ▶ [view more events](#)

# [ What we do ... ]



## ■ Conferences

## ■ Speakers

Exceptional Biomedical Experts!  
Timely and Relevant Topics  
*... Industry, FDA, ISO, and Consultants*



# [ What we do ... ]



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# What we do ...

## ■ US Collaborations

Provide Biomedical Tracks for

- ASQ Divisions
- ASQ Sections
- Industry Associations

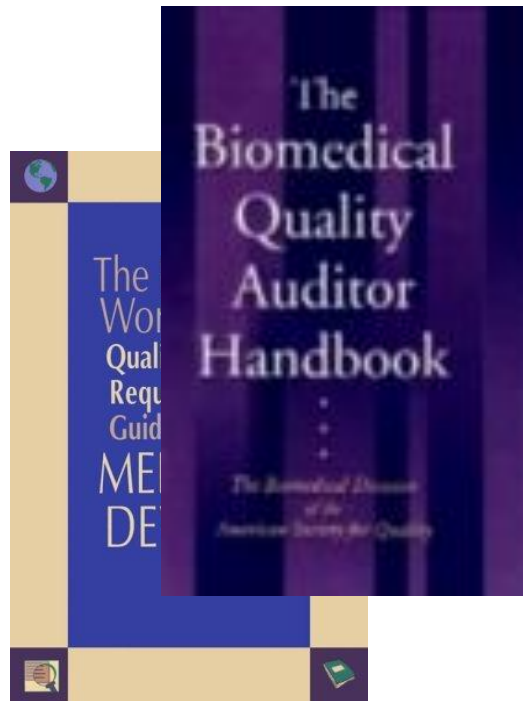


## ■ International Collaborations

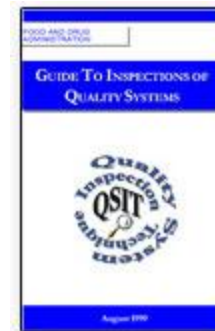


# What we do ...

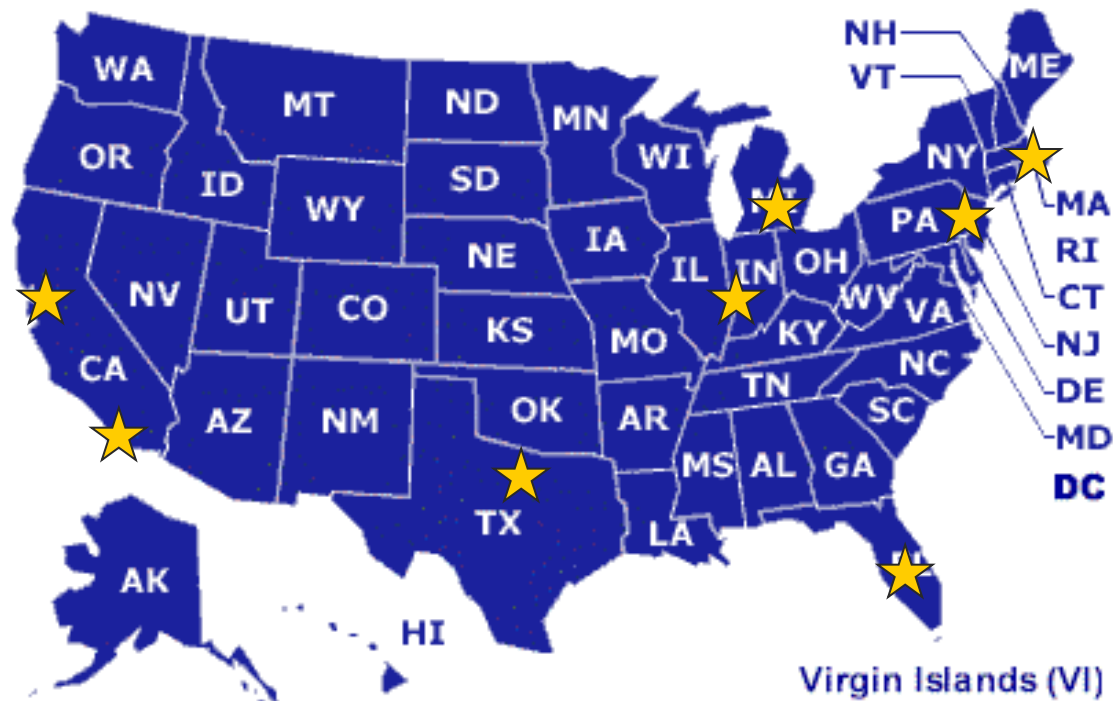
- Publications



- Grants & Scholarships  
Over \$500,000 since 1995



# What we do Regionally ... Biomedical Discussion Groups



# DG Mission Statement



To provide a forum for professionals involved in the development, quality, manufacture, testing, and regulation of medical devices and diagnostics, to learn, teach, and discuss issues specific to the medical device and diagnostics industry.

# Forum Member Benefits



- Provide learning opportunities and tools to help you achieve professional and organizational excellence
- National and Regional Seminars
- New Issues Awareness
- BIOFEEDBACK, Division Newsletter
- Network with peers
- Biomedical Auditor Certification



# Volunteer Opportunities



- Actively Participate on Division Committees
  - **Programs**
  - **Publications**
  - **Standards**
  - **Membership**
  - **Newsletter**
  - **Certification**
  - ... *and more*
- Work with the Discussion Group
- Earn Recertification Unites (RU) for your volunteer commitment
- Support your profession and Industry
- It's fun the volunteer!

# Biomedical Division

- Membership is up 3-4% over last year
- Division memberships is sustained and growing
- Biomed Members in Florida: 250+
- Biomed Members in Sec 1508: 25+
- CBA Certified FL/1508: 15+/5+



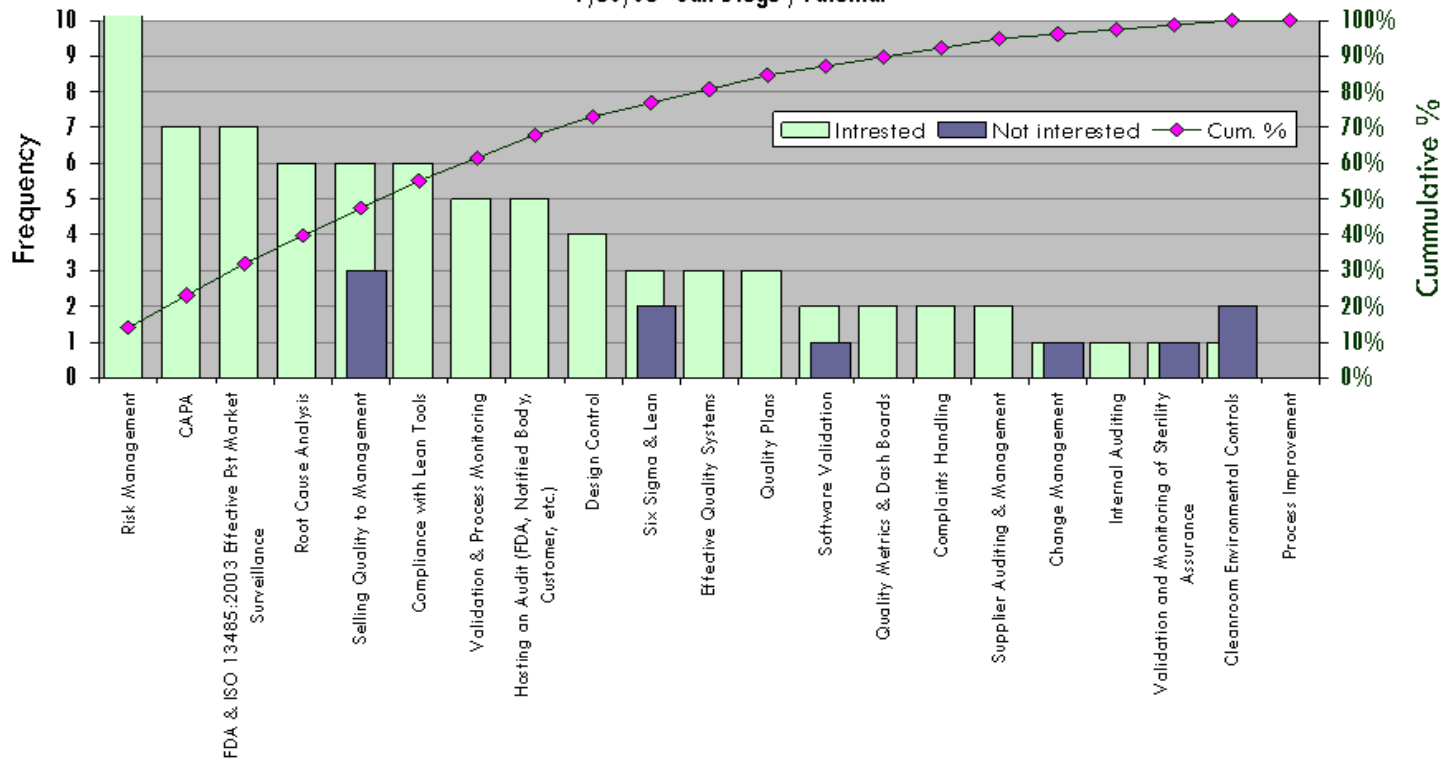
# Recent DG Topic Surveys

Six Sigma & Lean	10
Quality Plans	6
Compliance with Lean Tools	4
Effective Quality System	4
FDA & ISO 13485:2003 Eff. Post Market Surv. Syst.	4
Process Improvement	4
CAPA	2
Complaints Handling	2
Internal Auditing	2
Risk Management	2
Root Cause Analysis	2
Selling Quality to Management	2
Supplier Auditing and Management	2
Validation & Monitoring of Sterility Assurance	2
Hosting an Audit (FDA, NB, Customer)	1
Quality Metrics & Dashboards	1
Validation and Process Monitoring	1

# Recent DG Topic Surveys

## Biomed Division SCDG VOC Survey Results

7/30/08 - San Diego / Palomar



Topics of Interest for Future SCDG Events

# Contact Us!

## Biomedical Division Officers 2008-2009

- Chair *Heather Crawford*
- Chair Elect *Dan Whalen*
- Treasure *Scott Blood*
- Secretary *Bill McLain*
- Vice Chair DG's *Mark Moyer*
- Past Chair *Barry Craner*

# Internet Resources



- Biomedical Division [www.asq.org/biomed](http://www.asq.org/biomed)
  - Upcoming Programs
  - Officer and Committee contact information
  - Discussion Group Events
  - Link to Division Newsletter – Biofeedback
  - Training Materials at membership prices
- ASQ [www.asq.org](http://www.asq.org)



Thank You

*...from the ASQ Biomedical Division*