

Biomedical Division Activities

The Biomedical Division provides 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.

Join the Biomedical Division!

Go to www.asq.org or call 1-800-248-1946.

What Do We Do?

Grants & Scholarships

(More than \$500,000 in grants and scholarships has been awarded since 1995.)

Networking

Publications and Training Aids

Provide Biomedical Presentations and Speakers for ASQ Divisions and Sections, and Industry Associations

Example U.S. and International Collaboration

- FDA
- AdvaMed, Washington, DC
- ASQ Food, Drug, and Cosmetic Division
- ASQ Software Division
- CQI Certified Quality Institute, London
- RAPS, San Francisco, Denver
- IMDA, Irish Medical Devices Association, Ireland
- IQA, Institute of Quality Assurance, London
- Management Forum, London

Biomedical Division History

In 1968, the ASQ Board of Directors established a Biomedical Technical Committee, seeing the need for improved attention to quality principles in medical devices, medicine, healthcare, and related fields. As the scope of activities increased and as substantial interest in the committee's activities was evident within the biomedical professions and related fields, full division status was granted in 1972. Today, the division has nearly 5,000 members worldwide.

Biomedical Division Strategic Objectives

To be recognized as ...

- The best source for achieving professional and organizational excellence and the leader in delivering value to our members.
- A provider of information and learning opportunities relating to quality for the worldwide biomedical community.
- A worldwide leader for advancing individual and organizational performance excellence for the biomedical community.

Who Are We?

Our members include:

- Medical device manufacturers and users
- Hospital and healthcare professionals
- Regulatory personnel
- Instrumentation producers and users
- Government agency personnel and contractors, consultants, and suppliers to these groups

The Biomedical Division is managed by volunteers like you:

- **Elected Officers**
- **Standing Committee Chairs**
- **Regional Discussion Group Committee Chairs**

VISION

To be the learning 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.

CONTACT US!

Visit our Web site at www.asq.org/biomed for contact information.



Biomedical Division



Scholarship Program

The ASQ Biomedical Division established the William J. Feingold Scholarship Program to:

- Promote the awareness and the use of quality principles, concepts, and technologies in the biomedical community.
- Provide learning opportunities relating to quality for the worldwide biomedical community.
- Encourage consideration of the quality profession in the biomedical community as a career choice.



Certification

The Biomedical Auditor Certification add-on to the Certified Quality Auditor was realized in 2000, and became a stand-alone certification in 2005. Obtaining this certification establishes the competence of an auditor in the biomedical industry.

Additional training will be available in 2009.

For more information, go to www.asq.org/biomed/certification/.

Available Publications

- *The Biomedical Quality Auditor Handbook*
- Quality System Regulation for Medical Devices - 21 CFR Part 820 - Final Rule (print)
- Quality Management Systems 101: Back to the Basics (CD)
- FDA Guide to Inspection of Quality Systems

For a current listing of all documents, additional information, and ordering information, go to www.asq.org/biomed/pub/.

Annual Program Examples

Division Conferences:

- Risk Management: ISO14971 for Safer Medical Devices
- Off the Shelf Software-Practical Validation

Discussion Group's Full-Day Seminars:

- Risk Management Seminar
- Failure Investigation-Root Cause Analysis
- How to Handle an FDA Inspection
- Quality Tools: Optimizing Product Development
- Transitioning to ISO 14971:2007
- Process Validation

Discussion Group's Roundtables:

- How to Make FDA Inspections Work for You
- Electrical Safety: Keep the Sparks From Flying
- Information Management: Looking Past Part 11 Compliance
- Standards and Guidance Documents for the Medical Device Industry
- Configuration Management: Logistics and Software
- Data Analysis Errors

Regional Discussion Groups

Where Are Our Regional Discussion Groups?

- New England – NEDG (Boston)
- Northern California – NCDG (SF Area)
- Dallas Fort Worth – DFWDG (Texas)
- MidWest – MWDG (Indianapolis)
- Southern California – SCDG (LA, Orange County, San Diego County)
- In your region?



What Is a Regional Discussion Group?

- Managed by a volunteer committee. Member demographics is a key driver to establish and maintain a DG.
- Models vary in type of event and frequency, such as roundtable meetings and one-day seminars.
- The division has an active program for creation and development of regional discussion groups. These discussion groups provide a local venue for division members and other interested parties for conferences and roundtable discussions.

The discussion groups partner with local FDA for support. Discussion groups are flexible. They can work independently, jointly with a parent division or with local ASQ sections, or with related professional organizations...whatever it takes to provide better product and services, and enhance member value.

Member Benefits

- Provide learning opportunities and tools to help you achieve professional and organizational excellence
- National and regional seminars
- New issue awareness
- *BioFEEDBACK*, division newsletter
- Network with peers
- Biomedical Auditor Certification

Volunteer Activities to Maximize Your Member Benefits

- Actively participate on division committees: Programs, Publications, Standards, Membership, Newsletter, Certification, and more...
- Work with, or start, a discussion group
- Earn recertification units (RU) from your volunteer commitment
- Support your profession and industry
- Get recognition for your contributions
- It's fun to volunteer!

