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Message from the President

Thank you for your interest and involvement in our society and welcome to our first annual e-report. We hope you enjoy this new publication and find it to be a useful resource for your membership and that you will use it to invite your colleagues to join SQA.

Mission
SQA is a professional membership organization dedicated to promoting and advancing the principles and knowledge of Quality Assurance essential to human, animal and environmental health.

Vision
SQA members envision a world with safe foods, drugs, chemicals and medical devices for humans, animals, and the environment.

It has, indeed, been another great year for the Society and its members. We reached out to our colleague organizations moreso than ever in the past, by participating in their meetings:

• American Chemical Society Division of Agrochemicals
• Association of Clinical Research Professionals
• European QA Forum
• GMP by the Sea
• Regulatory Affairs Professionals Society
• National Data Integrity Conference
• Research Quality Association
• Society of Toxicology
• U.S. Science and Engineering Festival

With this broad outreach, we are becoming well known around the world and our programs and activities are supporting QA professionals and others working in the field.

The 32nd Annual Meeting of SQA was held in Grapevine Texas, 3 – 8 April 2016, and the SQA Quality College was held in Seattle Washington, 27 – 29 September 2016, followed by a special symposium on the Changing Future for QA Professionals. Also as part of that meeting, a special forum addressed the Notice of Proposed Rule-Making to amend the FDA GLP regulations.

The Board has been working hard to develop more online training programs through the SQA Learning Foundation. A course on Writing Effective SOPs for GLPs was launched in August and the Basic GLP course was launched in December. These two modules join the Basic GCP course and lay the foundation for many more modules in the coming years.

The Learning Foundation has launched several other programs, such as the two online, searchable databases for SQA members. One database includes 483s issued by FDA since 1 October 2012, and the other includes inspections conducted by EPA and FDA since 30 October 1989.

Probably the most exciting program in the Learning Foundation is our commitment to the STEM program – Science, Technology, Engineering and Math. The Learning Foundation’s STEM Task Force is creating simple experiments for children in all grades to learn the basic fundamentals of credible and reproducible research, and the role of QA in the process. The experiments and tool boxes will be posted to the website as they are created. We hope our members will take advantage of the resources and share with their children’s classrooms on career day and through other civic events.

I hope you have taken advantage of all the educational, outreach and membership opportunities SQA and the SQA Learning Foundation has provided this year. The Society remains dedicated to ensuring that our members continue to develop as the very best QA professionals, while fostering a community of friends and colleagues.
SQA Membership by the Numbers

1,948 Members in 2016

1,158 Affiliate Members
697 Active Members
85 Outreach Members

Emeritus members: 3
Student members: 5

SQA continues to welcome members from World Bank defined low-and middle-income countries, by providing a membership category at no cost that provides these professionals with access to the resources on the website that will help them do their jobs.

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<th>Specialty Sections</th>
<th>2016 members</th>
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<td>Animal Health</td>
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<tr>
<td>Beyond Compliance</td>
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<tr>
<td>BioAnalytical</td>
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<td>GLP</td>
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<td>Scientific Archiving</td>
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<td>University</td>
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<th>Volunteer Committees</th>
<th>2016 members</th>
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SQA Members Around the Globe

47 U.S. states were represented in 2016!

38 countries were represented by 317 members outside of the United States in 2016!

SQA Members’ Regulatory Responsibilities

- **ANIMAL WELFARE**
- **GCP-HUMAN**
- **GCP-VETERINARY**
- **GLP-ENVIRONMENTAL CHEMICAL**
- **GLP-PHARMA/MEDICAL DEVICE**
- **GMP-API**
- **GMP-BULK CHEMICAL**
- **GMP-CLINICAL**
- **GMP-FINISHED PHARMACEUTICALS**
- **GMP-FOOD**
- **GMP-MEDICAL DEVICE**
- **GMP-PACKAGING**
- **GMP-VETERINARY BIOLOGICS**
- **OTHER**
2016 Professional Development

The 32nd SQA Annual Meeting & Quality College was held 3-8 April 2016 at the Gaylord Texan Resort & Convention Center in Grapevine, Texas.

725 Annual Meeting attendees

136 abstracts submitted

91 concurrent presentations

141 speakers

62 posters

11 awards given

0 successful bull rides

42 exhibitors
### April 2016 Quality College Courses

1. Basic Training: Good Laboratory Practice  
2. Good Clinical Practices: Understanding the Basics  
3. Basic Concepts in Computer Validation  
4. CAPA Day One: Problem Definition – Beyond Human Error  
5. GLP Beyond the Basics  
6. CAPA Day Two: Creation and Effectiveness – Beyond Training  
7. Next Generation QA  
8. Basic GCP for Veterinary Studies  
9. Archiving 101  
10. Data Quality/Data Integrity  
11. SQA Leadership Development  
12. Archiving 201  
13. GCP Data Stewardship  
14. QA Consulting  
15. Fraud and Misconduct in PV and GMP  
16. History of FDA GLPs  
17. E2E Electronic Laboratory  
18. GCP Beyond the Basics  
19. No Such Thing as GxP Compliance  
20. Auditing Software and Data Providers  
21. Study Director Training

### September 2016 Quality College Courses

1. History Behind the FDA GLPs  
2. Good Clinical Practices: Understanding the Basics  
3. Business Continuity and Disaster Recovery  
4. Basic Training: Good Laboratory Practice  
5. Auditing Software and Data Providers with a Focus on Cloud Services  
6. CAPA Day One: Problem Definition - Beyond Human Error  
7. Pharmacovigilance for QA  
8. GCP Beyond the Basics: Quality Management in the Clinical Study Environment  
9. Data Quality/Data Integrity: Can You Trust the State of Your Data?  
10. CAPA Day Two: Creation and Effectiveness - Beyond Training (Across GxPs)  
11. Special Symposium: A Changing Future for QA Professionals
SQA STEM Task Force launched in 2016!

The task force exhibited at the 5th U.S.A. Science and Engineering Festival, 15-17 April 2016 at the DC Convention Center. SQA Learning Foundation was one of more than 1,000 exhibitors that informed more than 350,000 attendees!

Going forward, the SQA Learning Foundation will work to develop toolkits for introducing quality assurance to students, for use in large exhibit halls or in your child’s classroom on career day. Join us in this exciting outreach to the next generation of QA professionals!
The SQA Learning Foundation is a new initiative that will fund educational offerings in conjunction with SQA, including online training courses in the Online Learning Center.

The SQA Online Learning Center now features these online learning opportunities!

**Basic Training: Good Laboratory Practice**

**Good Clinical Practice: Understanding the Basics**

**Writing Effective Compliant GLP SOPs**

The SQA Learning Foundation also launched and maintains two searchable databases: one includes 483s issued by FDA since 1 October 2012 and the other is all inspections conducted by EPA and FDA since 30 October 1989.

Love the training opportunities available to you through the SQA Learning Foundation?

The SQA Learning Foundation (SQA-LF) uses charitable gifts to develop, promote, and sustain the highest quality in educational opportunities for life science and environmental researchers, and quality assurance professionals.

[www.sqa-lf.org](http://www.sqa-lf.org)
SQA Structure and Leadership

SQA is organized into: the Board of Directors (and an Executive Committee comprised of the officers); 14 standing Committees; 12 Specialty Sections; a professional credentialing body; and 11 independent Regional Chapters. Encompassing this organizational structure is the membership body of the Society, including 5 member types.

SQA Operations

The Board of Directors has oversight of all operations conducted by the Society. The Committees perform ongoing specific tasks by function and as assigned by the Board.

The Specialty Sections provide members with a forum for discussion and information sharing in their specific areas of the research Quality Assurance field and also contribute to Society education and publications in their specialty areas. Drawing membership from the Specialty Sections and selected Committees is the Regulatory Forum, overseen by the Regulatory Forum Council, that provides a forum for discussion and analysis of regulatory issues, legislation and trends across QA disciplines.

The professional credentialing body, the Council on Professional Registration (CPR), provides QA professionals with the opportunity to earn a credential in research quality assurance by passing an intensive examination in their field and to maintain that credential through ongoing professional activities.

The Regional Chapters provide chapter members with the opportunity for professional development and networking in a geographical region that is close to them. Chapter membership is separate from SQA, but many QA professionals maintain membership in both. SQA Headquarters manages the membership of the eight US-based Regional Chapters.
2016 Board of Directors

The SQA Board meets monthly. Eight times per year are by teleconference and four times per year are face to face.
**SQA MEMBERS**

Member types: Active Affiliate Student Emeritus Outreach
(Active members may vote and stand for election)

### Board of Directors

Officers make up Executive Committee.

#### Committees

**Elected**
- Articles of Incorporation & Bylaws
- Education
- Ethics & Membership Credentials

**Appointed**
- Board of Publications
- Finance
- Legislative Oversight Task Force
- Nominating
- Regional Chapter Presidents

**Volunteer**
- Historical
- International Relations
- Membership Retention & Development
- Mentoring Program
- Program
- Regulatory Forum Council

#### Specialty Sections

- Animal Health
- Beyond Compliance
- Bioanalytical (with Biotechnology subcommittee)
- Clinical
- Computer Validation
- GLP (with EPA subcommittee)
- GMP
- Medical Device
- Pharmacovigilance
- Scientific Archiving
- University
- QA Consultants

#### Council on Professional Registration

- Chair
- Chair-Elect
- Past Chair
- Secretary
- GCP Member at Large
- GLP Member at Large
(Elected by Registered QA Professionals [RQAPs] who may or may not be SQA members.)

#### Committees

- GCP Exam
- GCP Exam Prep
- GLP Exam
- GLP Exam Prep
- PR
- Re-Registration

### Headquarters

Executive Director and Deputy Executive Director liaise with Board of Directors.
Staff members liaise with Committees, Specialty Sections, CPR and Regional Chapters.

### Regional Chapters

- Canadian
- Indian
- Nigerian
- USA
- Mid-Atlantic
- Midwest
- National Capital Area
- New England
- North Carolina
- Pacific
- Rocky Mountain
- Southern
SQA is managed by Custom Management Group (CMG), an accredited Association Management Company in Charlottesville, VA. Throughout the year, all CMG employees serve the needs of SQA, but those responsible for the programs and activities are identified below:

SQA Headquarters

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www.sqa.org

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SQA is managed by Custom Management Group (CMG), an accredited Association Management Company in Charlottesville, VA. Throughout the year, all CMG employees serve the needs of SQA, but those responsible for the programs and activities are identified below:
SQA Financial Overview

2016 Income
$1,289,787

Net Assets
$1,497,191

- Annual Meeting
- Training
- Dues
- Contributions
- Symposium
- Interest & Investments
- Professional Registration
- Advertising
- Unrealized Investment Income

2016 Expenses

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<th>Category</th>
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<td>Programs</td>
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<td>Management</td>
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<tr>
<td>Fundraising</td>
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SQA Learning Foundation
Financial Overview

2016 Income
$26,273

- 16% Contributions
- 40% SQA Support
- 44% Sale of Educational Materials

2016 Expenses
$28,240

- 13% Fundraising
- 51% Program
- 36% Management

Net Assets
$6,534
Regional Chapters

**Mid-Atlantic (MARSQA)**
www.marsqa.org

**Mid-West (MWSQA)**
www.mwsqa.org

**National Capital Area (NCARSQA)**
www.ncarsqa.org

**New England (NERCSQA)**
www.nercsqa.org

**North Carolina (NCCSQA)**
www.nccsqa.org

**Pacific (PRCSQA)**
www.prcsqa.org

**Rocky Mountain (RMRCQA)**
www.rmrcsqa.org

**Southern (SRCSQA)**
www.southernsqa.org

International Chapters

**Canada**
Canadian / Canadienne (CCSQA/FCSQA)
www.ccsqa.org

**Indian**
ICSQA
www.icsqa.org

**Nigerian**
NRCSQA
www.nrcsqa.org
2016 Corporate Supporters

Platinum Supporters

- BIOVIA
- charles river
- EtQ
- Genentech
- A Member of the Roche Group
- Veeva

Silver Supporters

- BSI
- CSRC
- Formpipe
- SNBL USA
- the Experts in Primate Research

Bronze Supporters

- CIMCON Software, Inc.
- complya consulting
- EPL ARCHIVES
- SEVENTHWAVE
- PRAHEALTHSCIENCES