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Message from the President

I am extremely excited to provide this introduction for the 2017 SQA Annual Report. Inside you will discover some impressive numbers and learn about major accomplishments achieved as a result of the diligent efforts from our members.

Whether you volunteered to check name badges at the 33rd SQA Annual Meeting and Quality College in National Harbor, MD, participated as a member in one of our Specialty Sections or Committees, served on one (or more) of seven Rapid Response teams, contributed to an article in Quality Matters, or served in a leadership position, all of these activities strengthen our profession and satisfy our mission statement to “promote and advance the principles and knowledge of quality assurance essential to human, animal and environmental health.”

This year our total number of members exceed 2,000, for a total of 2,062 members. To better support membership, the Education Committee accepted the responsibility to organize and host educational webinars and as a result, we doubled the number of offered webinars in 2017. These webinars are free to SQA members. Additionally, the Program Committee and the Board of Directors agreed to hold the 33rd SQA Annual Meeting and Quality College in a location that was in closer proximity to the agencies and as such, participation from the regulatory community increased. We also launched a graduate student webpage to better support our student members thanks to suggestions provided by a subgroup of the University Specialty Section.

To serve our international members and to participate in the broader regulatory community, SQA participated in the 5th World Conference on Research Integrity on 28-31 May 2017 in Amsterdam, The Netherlands and the 5th Global QA Conference hosted by RQA (and co-sponsored by JSQA and SQA) on 1-3 November 2017 in the beautiful city of Edinburgh, Scotland. We also renewed our Memorandum of Understandings with multiple national societies and initiated conversations for future collaborations.

SQA promoted QA as a profession by jointly presenting (with Purdue University’s Center for Biotechnology Innovation and Regulatory Science) the 1st Annual Summit of Academic Excellence in Quality Assurance and Regulatory Science on the campus of Purdue University in West Lafayette, IN on 18-19 May 2017. Several SQA members attended, and RQAP credits were awarded for attendance. Additionally, the STEM Committee from the SQA Learning Foundation participated in the GETT (Girls Exploring Tomorrow’s Technology) in March 2017 and the Virginia Tech Science Fair in November 2017 while also developing materials for SQA members to use at their local schools and science fairs and launching a new page on the SQA website!

In addition to the accomplishments described above, here are a few more major activities completed in 2017:

- SQA website refresh
- Launched RQAP-GLP and RQAP-GCP practice exams
- Established a Distinguished Speaker List
- Initiated audio interviews with SQA’s founding members
- Expanded our online course curriculum by developing Part 11 Electronic Signatures and Study Director training
- Contracted for 2020-2023 Annual meetings

The year 2017 was also a year for leadership transition as we waved good-bye to Elliott Graham who started her well-deserved retirement, and we welcomed the talents of Alison Cockrell as the new SQA Executive Director (she previously served as Deputy Director of SQA) and Jennifer Alluisi as SQA Deputy Director.

Thanks to each and every one of you for contributing to the success of this organization. There are many activities already underway for 2018. Let’s see if we can increase our membership to (at least) 2,100! After all, our tagline does state that we are “the home to the world’s best QA professionals!”
SQA Membership by the Numbers

2,062 Members in 2017

<table>
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<th>Committees</th>
<th>2017 members</th>
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<td>Annual Meeting Program</td>
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<td>Articles of Incorporation and Bylaws</td>
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<td>Council on Professional Registration</td>
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<td>RQAP-GCP Exam Committee</td>
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<td>RQAP-GLP Exam Committee</td>
<td>17</td>
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<td>Education</td>
<td>19</td>
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<td>Ethics &amp; Membership Credentials</td>
<td>7</td>
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<td>Finance</td>
<td>3</td>
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<tr>
<td>Historical</td>
<td>13</td>
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<td>International Relations</td>
<td>43</td>
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<td>Membership Retention &amp; Development</td>
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<td>Mentoring Program</td>
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<td>Nominating</td>
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<td>Regional Chapter Presidents</td>
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<td>Regulatory Forum Council</td>
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<td>SQA-LF STEM</td>
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<th>Specialty Sections</th>
<th>2017 members</th>
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<tr>
<td>Animal Health</td>
<td>146</td>
</tr>
<tr>
<td>EDC Subcommittee</td>
<td>26</td>
</tr>
<tr>
<td>Beyond Compliance</td>
<td>124</td>
</tr>
<tr>
<td>BioAnalytical</td>
<td>257</td>
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<tr>
<td>Clinical</td>
<td>245</td>
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<tr>
<td>Computer Validation Initiative</td>
<td>58</td>
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<tr>
<td>GLP EPA Subcommittee</td>
<td>478</td>
</tr>
<tr>
<td>GMP EPA Subcommittee</td>
<td>120</td>
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<tr>
<td>GMP</td>
<td>103</td>
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<tr>
<td>Medical Devices</td>
<td>99</td>
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<tr>
<td>Pharmacovigilance</td>
<td>73</td>
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<tr>
<td>QA Consulting Support</td>
<td>100</td>
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<tr>
<td>Scientific Archiving</td>
<td>126</td>
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<tr>
<td>University</td>
<td>75</td>
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</tbody>
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Emeritus Members: 6
Student Members: 6
Increase over 2016: 114

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.
43 countries were represented by 348 members outside of the United States in 2017!

New Countries Represented: Botswana, Indonesia, Rwanda, St. Kitts and Nevis, and Zambia

**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
2017 Professional Development

The 33rd SQA Annual Meeting & Quality College was held 26-31 March 2017 at the Gaylord National Resort & Convention Center in National Harbor, Maryland.

- 836 Annual Meeting attendees
- 173 speakers
- 59 posters
- 9 awards given
- 3 bobblehead presidents visited our exhibit hall!
- 145 abstracts submitted
- 63 concurrent presentations
- 45 exhibitors
March 2017 Quality College Courses
1. Basic Training: Good Laboratory Practice
2. Good Clinical Practices: The Basics
3. Basic Concepts in Computer Validation
4. Implementing a GLP Quality System in a University Setting
5. CAPA Day One: Problem Definition – Beyond Human Error
6. Basic Training: History and Introduction of US FDA GMPs
7. GCP Audits in Biostatistics: Enhancing Data Integrity
8. CAPA Day Two: CAPA Creation and Effectiveness - Beyond Training (Across GxPs)
9. An Auditor’s Primer on the Science, Practice, and Auditing of Chromatography and Mass Spectrometry
10. Making Social Media Work for You
11. SQA Leadership Development
12. QA Consulting 101
13. History Behind the FDA GLPs and Their Application
14. FDA Inspections: Tales from the Trails
15. Implementing 21 CFR Part 11 Compliant e-Signatures
16. GLP Metrics and You: Perfect Together
17. No Such Thing as GxP Compliance - A Quality System Management Approach to Navigate a Complex Regulatory Environment
19. GCP: Beyond the Basics
20. Next Generation QA
21. Data Quality/Data Integrity: Can You Trust the State of Your Data?
22. Archiving 101: What You Need to Know About a GLP-Compliant Archive
23. Archiving 201: Beyond a GLP-Compliant Archive

September 2017 Quality College Courses
1. Basic Training: Good Laboratory Practice
2. Good Clinical Practices: The Basics
3. Good Clinical Practices: Beyond the Basics
4. Auditing Software and Data Providers with a Focus on Cloud Services
5. History Behind the FDA GLPs and Their Application
6. Business Continuity & Disaster Recovery

1 Special Symposium: Quality Metrics for the QA Professional
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
SQA Learning Foundation

The SQA Learning Foundation funds educational offerings in conjunction with SQA, including online training courses in SQA’s Online Learning Center and K-12 educational resources and outreach regarding quality, integrity, and safety in science.

The SQA Learning Foundation also 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.

SQA-LF STEM Committee

The mission of the STEM Committee is to engage students and foster the next generation in the field of Quality, Integrity, and Safety in Science (QISS) while promoting their interest in STEM careers.

In 2017, the committee participated in the Girls Exploring Tomorrow’s Technology Expo (Phoenixville, Pennsylvania) and the Virginia Tech Science Festival (Blacksburg, Virginia).

New in 2017!

SQA Distinguished Speakers

The SQA Learning Foundation established a Distinguished Speaker program that identifies and recognizes the top-rated SQA speakers each year. Individuals who are invited to join the Distinguished Speaker Inventory are experts on a wide variety of Quality Assurance (QA) topics, and they have demonstrated their skill in presenting to audiences in a meaningful and engaging way. A current list of Distinguished Speakers is listed at sqa.org/speakers.
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 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.
The SQA Board meets monthly. Eight meetings per year are by teleconference and four meetings 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.

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<tr>
<th>Committees</th>
<th>Specialty Sections</th>
<th>Council on Professional Registration</th>
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<tr>
<td><strong>Elected</strong></td>
<td>Animal Health</td>
<td>Chair</td>
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<td></td>
<td>Beyond Compliance</td>
<td>Chair-Elect</td>
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<td></td>
<td>Bioanalytical</td>
<td>Past Chair</td>
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<td></td>
<td>(with EDC subcommittee)</td>
<td>Secretary</td>
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<td></td>
<td>Clinical</td>
<td>GCP Member at Large</td>
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<td>Computer Validation</td>
<td>GLP Member at Large</td>
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<td></td>
<td>GLP (with EPA subcommittee)</td>
<td>(Elected by Registered QA Professionals</td>
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<td></td>
<td></td>
<td>[RQAPs] who may or may not be SQA members.)</td>
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<td>GMP</td>
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<td>Medical Device</td>
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<td>QA Consulting Support</td>
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<td><strong>Appointed</strong></td>
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<td>Board of Publications</td>
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<td>Finance</td>
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<td>Regional Chapter Presidents</td>
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<td><strong>Volunteer</strong></td>
<td>Historical</td>
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<td>Program</td>
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<td></td>
<td>Regulatory Forum Council</td>
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### Regional Chapters
- Canadian
- Indian
- Nigerian
- **USA**
  - Mid-Atlantic
  - Midwest
  - National Capital Area
  - New England
  - North Carolina
  - Pacific
  - Rocky Mountain
  - Southern

### 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.
SQA Headquarters

Custom Management Group

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 Staff

Time of Transition
SQA’s Executive Director, Elliott Graham, RQAP-GLP (Em.), retired 1 September 2017. Alison Cockrell became Executive Director of both SQA and its Learning Foundation, and Jen Alluisi now assists her as Deputy Executive Director of both organizations.

Alison Travis
Program Director and Database Administrator
allison.travis@sqa.org

Paige Hulsizer
Program Director
paige.hulsizer@sqa.org

Lynne Valentic
Conference Director
lynne.valentic@sqa.org

Erin Irtenkauf
Director of Publications and Website Services
erin.irtenkauf@sqa.org

Katelyn Wagner
Member Services
katelyn.wagner@sqa.org

Alison Cockrell
Executive Director
alison.cockrell@sqa.org

Jennifer Alluisi, MA Ed, CAE
Deputy Executive Director and Director of Educational Programs
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Marilla Owens
Director of Publications and Website Services
marilla.owens@sqa.org

Sarah Ray
Chapter Liaison
sarah.ray@sqa.org

Elisabeth Jacobs
RQAP Manager
elisabeth.jacobs@sqa.org

Nicole Edgecomb
Accountant
nicole.edgecomb@sqa.org

www.sqa.org

Society of Quality Assurance
154 Hansen Road, Suite 201
Charlottesville, VA 22911 USA
Telephone: +1 434.297.4772
Facsimile: +1 434.977.1856
E-mail: sqa@sqa.org
SQA Financial Overview

2017 Income
$1,516,460

2017 Expenses
$1,392,193

- Programs $1,249,099
- Management $143,042
- Fundraising $52

Change in Net Assets
$124,267

Year End Net Assets*
$1,619,800

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

* includes unrealized investment income
SQA Learning Foundation
Financial Overview

2017 Income
$49,593

- 40% SQA Support
- 57% Sale of Online Training
- 3% Contributions

2017 Expenses
$44,739

- 75% Program
- 21% Management
- 4% Fundraising

Change in Net Assets
$4,854

Year End Net Assets
$11,389
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 (RMRCSQA)
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
2017 Corporate Supporters

Platinum Supporter

Veeva

Silver Supporters

BSI

Instem

Formpipe

RD Jones & Associates Consulting Services

zoetis

Bronze Supporters

compya consulting

FDA Quality + Regulatory Consultants, LLC

MasterControl Compliance Accelerated

Prelude Dynamics

QA Compliant

Quality Associates Incorporated
Society of Quality Assurance
HOME TO THE WORLD’S BEST QA PROFESSIONALS
www.sqa.org