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Mission
SQA is a professional membership organization dedicated to promoting and advancing the ethics, 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 was an honor and a privilege!

2018 was an exciting and successful year, and I am honored to provide this introduction to the 2018 SQA Annual Report. Look inside to learn more about our accomplishments and how our members have provided value to our membership and our business communities. I believe you will find our accomplishments inspiring and encouraging. See what we have done and then ask yourself, what can I do to keep the momentum moving forward!

The 2018 Annual Meeting in Anaheim, CA, was a success in so many ways. The Quality College continued to provide excellent educational opportunities to our members, potential members, and colleagues. We had 751 registrations for the SQA Annual Meeting and Quality College. The Fall Quality College and Symposium was also a great success with 110 registrants.

We doubled the number of SQA webinars and almost tripled the number of total attendees to SQA webinars. We conducted 17 webinars in 2018, up from 8 the previous year. Overall attendance of SQA webinars increased from 1500 attendees (2017) to over 4500 in 2018! WOW! What a huge value-added program for our membership. But we didn’t stop there; last year we held our first joint webinar with the National Alliance of Independent Crop Consultants (NAICC), and while attendance was moderate, we are building on this relationship to offer additional joint webinars and encourage other Specialty Sections to look for similar opportunities where our organizations can find mutually beneficial projects.

I am thankful for our Council on Professional Registration (CPR) who oversees the RQAP programs. The CPR and the exam committees (GLP and GCP) work all year long supporting the registration and re-registration process for our QA professionals. The RQAP program has registered 87 new QA professionals in 2018, bringing our totals to 617 RQAP-GLP and 273 RQAP-GCP.

We had a banner year for expanding our programs. The SQA Learning Foundation launched two new interactive online learning programs. The GLP Study Director and Principal Investigator Training (launched September 2018) and the Introduction to 21 CFR Part 11: Electronic Records; Electronic Signatures (launched April 2018) were added to the library, and many other topics are in development. If you have ideas for learning topics to be developed into online learning modules, be sure to let us know by offering up your ideas to sqa@sqa.org. Your ideas are the first note that begins the book that becomes an online learning program.

The strength of our organization resides in our membership and the leaders therein that donate their time and amazing talents putting our programs together and supporting the work of our Committees and Specialty Sections. The SQA membership again and again rises to the occasion and always exceeds everyone’s expectations by designing and executing timely, thoughtful, relevant, and useful programs that not only enhance our membership’s understanding of current events, but go beyond to provide them with resources and real world knowledge that they can take to their businesses and offer real world information and solutions.

As I reflect on 2018 and my year as your President, there are so many people to thank for their contributions, support, kind words of encouragement, and dedication to our Society. Personally, I wish to extend my gratitude to the members of the Board of Directors (BOD). You may not know it, but each one works with their Specialty Sections and Committees continually to facilitate and support their groups. Many of them are also active members of those same Committees and Specialty Sections and not only do their work as BOD members but also take on additional assignments to help bring the groups’ ideas and initiatives to life. I thank them for their hard work and dedication to our Society. On a special note, Steve Rogenthien and Melissa Eitzen, thank you for your guidance and for your support. A special note of thanks to outgoing BOD members Jackie Bushong, Kim Frazier, and Hector Gamboa. Your presence on the BOD will be missed, but we know that your efforts in supporting SQA and our chapters will continue. For that we are grateful.

It was a brilliant year, and I know that SQA will accomplish even more in 2019 under the leadership of the 2019 President, Steve Rogenthien. We are all in very capable hands.
## SQA Membership by the Numbers

**2,086 Members in 2018**

- **Active Members**: 695
- **Affiliate Members**: 1,303
- **Outreach Members**: 80

**Emeritus Members**: 2

**Student Members**: 6

**Increase over 2017**: 24

### Specialty Sections

<table>
<thead>
<tr>
<th>Specialty Sections</th>
<th>2018 members</th>
</tr>
</thead>
<tbody>
<tr>
<td>Animal Health</td>
<td>159</td>
</tr>
<tr>
<td>EDC Subcommittee</td>
<td>25</td>
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<tr>
<td>Beyond Compliance</td>
<td>154</td>
</tr>
<tr>
<td>Bioanalytical</td>
<td>290</td>
</tr>
<tr>
<td>Clinical</td>
<td>285</td>
</tr>
<tr>
<td>Computer Validation &amp; IT Compliance</td>
<td>157</td>
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<tr>
<td>Audits &amp; Vendor Assessments Subcommittee</td>
<td>30</td>
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<tr>
<td>Data Integrity &amp; Governance Subcommittee</td>
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<tr>
<td>Steering Subcommittee</td>
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<tr>
<td>Training Subcommittee</td>
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<td>GLP</td>
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<td>EPA Subcommittee</td>
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<td>GMP</td>
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<td>Medical Devices</td>
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<td>Pharmacovigilance</td>
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<td>QA Consulting Support</td>
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<tr>
<td>Scientific Archiving</td>
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<tr>
<td>University</td>
<td>76</td>
</tr>
</tbody>
</table>

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Numbers include liaisons, including Board and other group liaisons.

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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.
46 U.S. states were represented in 2018!

39 countries were represented by 349 members outside of the United States in 2018!

New Countries Represented: Macedonia, Slovakia, and Uganda

SQA Members’ Regulatory Responsibilities

- ANIMAL WELFARE: 156
- GCP-HUMAN: 391
- GCP-VETERINARY: 104
- GLP-ENVIRONMENTAL CHEMICAL: 235
- GLP-PHARMA/MEDICAL DEVICE: 601
- GMP-API: 99
- GMP-BULK CHEMICAL: 54
- GMP-Clinical: 133
- GMP-FINISHED PHARMACEUTICALS: 126
- GMP-FOOD: 19
- GMP-MEDICAL DEVICE: 81
- GMP-PACKAGING: 63
- GMP-VETERINARY BIOLOGICS: 0
- OTHER: 4
I’m in my first year of QA in a GLP environment after several years in the lab. I learned a TON! Especially regarding our role in the industry, how to come from an education point of view instead of training, making our concerns relevant, etc. Overall, I enjoyed being surrounded by professionals in the field and having conversations about my career and ways to grow. Everyone was so happy to discuss, educate, and share experiences - it was awesome!
- 2018 Annual Meeting Attendee

The 34rd SQA Annual Meeting & Quality College was held 8-13 April 2018 at the Anaheim Marriott in Anaheim, California.

751 Annual Meeting attendees

135 abstracts submitted

54 posters

44 exhibitors

173 speakers

15 awards & scholarships presented

(at least) 2 Board members in mouse ears

76 concurrent presentations
2018 Professional Development

April 2018 Quality College Courses
1. GLP 101: Basic Training
2. GCP 101: Understanding the Basics
3. CAPA 101: Problem Definition - Beyond Human Error
4. CSV 101: Basic Concepts in Computer Validation
5. GMP 101: Basic Training: History and Intro of US FDA GMPs
6. GCP 301: Audits in Biostatistics
7. CAPA 201: Creation and Effectiveness (Across GxPs)
8. GLP 103: Basic GLP Archiving
9. GCP 202: Hot Topics & Industry Trends
10. GLP 301: Metrics and You: Perfect Together
11. GLP 203: Intermediate GLP Archiving
12. General 102: SQA Leadership Development
13. GLP 202: Regulatory Surveillance Inspections
14. General 103: The Biologics Super Highway
15. General 101: QA Consulting
16. General 104: Three Cs of SOPs: Clear, Concise, and Compliant in a Regulatory Setting
17. GCP 201: Advanced Training
18. CSV 203: Auditing in the GxP eData Space
20. General 106: Auditor’s Primer: Chromatography & Mass Spectrometry
21. GLP 102: History Behind the FDA GLPs
22. CSV 204: SEND-Implementation, Validation, and Outsourcing

September 2018 Quality College Courses
1. GLP 101: Basic Training
2. GCP 203: Overcoming the Challenges of Clinical Quality Management in Small Companies and Startups
3. General 104: Three Cs of SOPs: Clear, Concise, and Compliant in a Regulatory Setting
4. GCP 201: Advanced Training
5. CSV 201: Auditing Software and Data Providers with a Focus on Cloud Services
6. GLP 104: Auditing Techniques
7. General 203: Business Continuity and Disaster Recovery
8. GCP 202: Hot Topics & Industry Trends
9. GLP 102: Lies, Deceit, and Drift: The Creation of the FDA GLPs and Why They Are Still Relevant Today

410 Quality College participants
27 mentoring matches
17 member webinars

1 Special Symposium

The QA Risk Symposium
27-28 September 2018
Grand Rapids, MI
An FDA Special Symposium
2018 Online Learning

2018 Courses in the Online Learning Center

Basic Training:
Good Laboratory Practice

Introduction to Writing Effective
Compliant GLP SOPs

Good Clinical Practice:
Understanding the Basics

Introduction to 21 CFR Part 11:
Electronic Records; Electronic Signatures*

GLP Study Director and
Principal Investigator Training*

Visit SQA.org/learn to see all the available courses.

Supported by

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

Please consider a giving to the SQA Learning Foundation at www.sqa-lf.org/give.
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 2018, the Committee participated in the Girls Exploring Tomorrow's Technology Expo (Phoenixville, Pennsylvania), USA Science and Engineering Festival (Washington, DC), and the STEM in the Park Expo (Research Triangle Park, North Carolina).

STEM Committee outreach to future QA professionals in 2018

Distinguished Speaker 2018
53 Speakers in 2018

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 comprised of the Board of Directors (and an Executive Committee comprised of the officers); 12 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 is the Specialty Section Council, which 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 virtual and four meetings per year are face to face.
Organization Chart

SQA MEMBERS

Member types:  Active  Affiliate  Outreach  Student  Emeritus
(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
Finance
Nominating
Regional Chapter Presidents
Specialty Section Council

Volunteer
Board of Publications
Membership Retention & Development
Mentoring Program Program
STEM Committee (SQA Learning Foundation)

Specialty Sections

Animal Health with EDC subcommittee
Beyond Compliance
Bioanalytical Clinical
Computer Validation with subcommittees:
Audits & Vendor Assessments
Data Integrity & Governance Steering Training
GLP with EPA subcommittee
GMP
Medical Device Pharmacovigilance QA Consulting Support Scientific Archiving University

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
Re-Registration

Regional Chapters

Canadian
Indian
Nigerian
USA
Mid-Atlantic
Midwest
National Capital Area
New England
North Carolina Pacific
Rocky Mountain
Southern

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

Headquarters staff manage the daily operations of the Society and provide services in strategic planning, membership, education, event planning, website and publication design, accounting, marketing, and communications. 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

Alison Cockrell
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Erin Irtenkauf
Director of Publications and Website Services
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Katelyn Wagner
Member Services
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Jennifer Alluisi, MA Ed, CAE
Deputy Executive Director and Director of Educational Programs
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Paige Hulsizer
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Lynne Valentic
Conference Director
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Sarah Ray
Chapter Liaison
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Bronwyn Johnson
Program Manager, Educational Programs
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Nicole Edgecomb
Accountant
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SQA Financial Overview

2018 Income
$1,264,949

2018 Expenses
$1,289,517

- Programs: $1,152,012
- Management: $137,459
- Fundraising: $46

Change in Net Assets
<$24,568>

Year End Net Assets*
$1,595,232

* includes unrealized investment income

- Annual Meeting
- Dues
- Training
- Professional Registration
- Symposium
- Advertising
- Interest & Investments*
- Contributions
- Miscellaneous
SQA-LF Financial Overview

2018 Income $79,004

97% Sale of Online Training

3% Contributions

2018 Expenses $47,209

79% Program

19% Management

2% Fundraising

Change in Net Assets $31,794

Year End Net Assets $43,838
Regional Chapters

Mid-Atlantic (MARSQA)
www.marsqa.org

Midwest (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 (SRC-SQA)
www.southernsqa.org

International Chapters

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

Indian
ICSA
www.icsqa.org

Nigerian
NRC
www.nrcsqa.org
2018 Corporate Supporters

Platinum Supporter

charles river

Veeva Vault Quality Suite

Gold Supporter

ZigZag

straightforward QA

Silver Supporters

BSI

CSRC

QA International

zoetis

Bronze Supporters

CSols Inc.

EPL Archives

PharmaLex

Qualtrax

RiverArk

Seventh Wave
Society of Quality Assurance
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