25 YEARS OF SQA

Presented by
Patricia O’Brien Pomerleau
SQA Past President
SQA 25th Anniversary Meeting
San Diego, CA
April 21, 2009
25 YEARS OF SQA

- Changes
- Future
- SQA Past Presidents
25 YEARS OF SQA
CHANGE
25 YEARS OF SQA

CHANGE
25 YEARS OF SQA

- In The Beginning….
- 1980 *First QA Roundtable*
  - share experiences with other QA professionals
  - open lines of communication and networking possibilities
QUALITY

ASSURANCE

ROUNDTABLE

MARIOTT'S HUNT VALLEY INN
HUNT VALLEY, MD

NOVEMBER 10-11, 1980
QA Roundtable 1980 Program

- Opening Remarks, Richard M. Siconolfi
- Organization of the QAU
- Agency Inspection
- “Psychology” of Inspections
QA Roundtable 1981 Program

- Computer Validation
- Training Quality Assurance Professionals
- Avoiding Sponsor/Contractor Conflicts
- Business Meeting
  
  *Should we form a Professional Society, publish Newsletter, etc.?*
QA Roundtable 1982 Program

- Role of QA/QC
- Scope of QA and Image
- Legal Aspects of Regulatory Agency Inspection
- Business Meeting
  - Committee Report on Society Affiliation, Professional Status
QA Roundtable 1983 Program

- Psychology and Stress of QA
- Training Films
- Computer Validation
- Redefining Scope of GLPs and CGPs
- Legal Aspects of FDA Inspection
- **Business Meeting**

*Discussions on Society Affiliation, Professional Status*
QA Roundtable 1984 Program

- IBT – Black and White or Shades of Grey
- International GLP Problems
- Poster Session, Training Films, Discussion Groups
- GLPs
- Validation of Computerized Systems
- Toxicology Studies
- Business Meeting

Vote and Elect Officers of SQA!
QA Roundtable 1985 Program

• Welcome Remarks
  
  *Frederick G. Snyder, President SQA*

• Regulatory Visions
  
  *FDA and EPA*

• Computer Validation Panel and QA Auditing

• Beyond the Inspection
  
  *Technical and Scientific Report Review*

• QA Innovation

• Closing Remarks
  
  *William R. King, President-Elect SQA*
25 YEARS OF SQA

- Professional Organization Founded to Promote Research Quality Assurance Profession
- Volunteers
- Headquarters
25 YEARS OF SQA - SQA Members

- Dedicated to Promoting throughout World
  - highest quality and integrity in regulated research, e.g.
    - Good Clinical Practices (GCP)
    - Good Laboratory Practices (GLP)
    - Good Manufacturing Practices (GMP)

- Abide by SQA Code of Ethics
25 YEARS OF SQA

- Excellent Resource
  - Scientific Community
  - Quality Assurance Professional

- Board of Directors and SQA Headquarters
- Annual Meetings
- Regional Chapters and Meetings
- Specialty Sections
- Committees
- Training
25 YEARS OF SQA

- Regulatory Agency Interactions
- Regulatory Liaisons
- Regulatory Information
- Task Forces
PROFESSIONAL

• Expert
• Specialist
• Qualified
• Proficient
• Skilled
• Trained
• Authority
SQA VISION

• Premier

Quality Assurance

Professional Organization
SQA VISION

- Known as Innovative Leader in:
  - professional development, education and training
  - collaborative relationships with:
    - governmental authorities
    - professional organizations
    - academia
    - industry
SQA VISION

- Participating in Regulatory Processes Related to:
  - human
  - animal
  - environmental health
SQA MISSION

• Professional Membership Organization

• Dedicated to Promoting and Advancing
  - principles and knowledge of QA, essential to:
    human
    animal
    and environmental health
SOA Mission and Vision

In 2004, the SOA Board updated the SOA Mission and Vision statements at a two-day Strategic Planning meeting.

**Mission Statement:** SOA 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 Statement:**
SOA will be the premier Quality Assurance professional organization, known as the innovative leader in the following:

- providing professional development, education and training;
- creating collaborative relationships with governmental authorities, professional organizations, academia and industry; and
- participating in the regulatory processes related to human, animal and environmental health.
25 YEARS OF SQA

• How Did We Get Here?

• Where Have We Gone…..?

• Where Might We Go in the Future…..?
25 YEARS OF SQA

• About 55 Attendees
• Volunteers
  - SQA Headquarters
• Newsletter

• Over 2,400 Members
• Professional Management Firm, CMG
  - SQA Headquarters
• Newsletter and On-Line Availability
• Official QA Journal and On-Line Availability
25 YEARS OF SQA

- GLP
- Membership Directory
- Classified Adds

- GLP, GCP, ICH
- GLP, GCP, ICH, GMP, OECD, ISO…..
- On-Line and Search Capabilities; Members Update Personal Information
- E-mail Updates and Job Postings on Website
25 YEARS OF SQA

- Mailings, Publications, Faxes
- Regulatory Q & A
- Membership USA and Canada

- SQA Website (www.sqa.org)
  - postings
  - URL links
  - members only site
  - shared documents
- Regulatory Q & A
  - on-line
  - web-based list serve
- International Members
25 YEARS OF SQA

- SQA Membership Dues
  - SQA Headquarters

- SQA Membership

- SQA Membership
  - Active and Affiliate

- SQA and Regional Chapters Membership Dues
  - SQA Headquarters

- SQA Regional Chapters and Membership

- SQA Membership
  - Active and Affiliate
  - Emeritus (7 in 2009)
25 YEARS OF SQA

- SQA Regional Chapters
- CCSQA/FCSQA (Canadian Chapter / Filiale Canadienne)
- ICSQA (Indian Chapter)
- MARSQA (Mid-Atlantic Regional Chapter - 1991)
- MWSQA (Midwest Chapter)
- NCARSQA (National Capital Area Regional Chapter)
- NRCSQ (Nigerian Chapter)
- NCCSQA (North Carolina Chapter)
- NERCSQA (New England Regional Chapter)
- PRCSQA (Pacific Regional Chapter)
- RMRCQA (Rocky Mountain Regional Chapter)
- SRCRSAQ (Southern Regional Chapter)
25 YEARS OF SQA

• SQA Committees
Committees

Please follow the links listed below to see overviews of each committee. If you are a member of at least one committee, you can also go to My Committees for a linked list of your committees. See also the Committee Chairs and Board Liaisons.

Appointed Committees:
- Board of Publications
- Finance Committee
- Nominating Committee
- Regional Chapters' Presidents Committee
- Tertiary Committee

Elected Committees:
- Articles of Incorporation and Bylaws Committee
- Education Committee
- Ethics and Membership Credentials Committee

Volunteer Committees:
- Corporate Relations Committee
- Historical Committee
- International Relations
- liaison Committee
- Membership Retention and Development Committee
- Mentoring Program Committee
- Program Committee
- Regulatory Forum Council
25 YEARS OF SQA

• SQA Specialty Sections
  Animal Health
  Beyond Compliance
  BioAnalytical
  BioTechnology
  Clinical
  Computer Validation
  Initiative Committee
  GLP
  GMP
  Medical Device
  Scientific Archiving
  University
25 YEARS OF SQA

• SQA Memorandum of Understanding
• BARQA (British Association of Research QA)
• JSQA (Japan Society of QA)
• DARQA (Dutch Association of Research QA)
• DGGF (German Society of Good Research Practices)
• DKGQA (Danish QA Group)
• GIQAR (Italian Society of Research QA)
• KSQA (Korean Society of QA)
• SARQA (Swedish Association of Research QA)
• SEGCIB (Spanish Society for QA in Research)
• SofaQ (French Society of QA)
• SPAQA (Swiss Professional Association of QA)
25 YEARS OF SQA

- Training at Annual Meetings
- Training at Annual Meeting
- Training Outside Annual Meeting
- Training at Other Professional Organization’s Meetings
25 YEARS OF SQA

• Annual Meeting Program Committee
  - VP Responsibility

• Annual Meeting Program Committee
  - Chairperson Responsibility

• Annual Meeting Program Committee
  - Co-Chairpersons Responsibility
25 YEARS OF SQA

• Surveys
• Corporate Sponsors

• Surveys on-line
• Platinum and Silver Supporters
25 YEARS OF SQA

• Professional QA (RQAP) – GLPs [513]
  - FDA, EPA
  - OECD
  - 2008 Exam in US, Canada, UK
  - computer-based testing

• Registered QA Professional – GCPs [89]
  - FDA
  - ICH
  - 2008 Exam in US, Canada, UK
  - computer-based testing
25 YEARS OF SQA

- 1st Global QA Conference
  - 2005, Orlando, FL

- 2nd Global QA Conference
  - 2008, Edinburgh, England

- 3rd Global QA Conference
  - 2011, Kyoto, Japan
25 YEARS OF SQA

• SQA Historical Committee
  - paper Archives
  - poster
  - paper photos

• SQA Historical Committee
  - ppt Presentations
    - - 2 with photos (2009)
  - paper and digital Archives
  - paper photo album display (2009)
  - Annual Meeting Program booklets display (2004 & 2009)
  - poster with photos of 25 SQA Presidents (2009)
  - Timeline of SQA History (2009)
  - input into Plenary presentation “25 Years of SQA” (2009)
SQA HISTORICAL
COMMITTEE MEMBERS - 2009

Carlos Castro, Chairperson, Midwest Research Institute
Alenda Branch, Auxilium Pharmaceuticals
Anthony Scott Brewer, Ethicon Endo-Surgery, Inc.
O.J. Cartwright, FDA, Center for Veterinary Medicine, Office of Research
Sherry Garrett, Pfizer Inc.
Victor Green, AAI Pharma
Angelo Jacala, Celgene Corporation
Sharon Little, NHRC Department of Respiratory Research
Patricia O’Brien Pomerleau, The Hamner Institutes for Health Sciences
Ernest Pile, Schering-Plough Pharmaceutical Corp.
Mike Struharik, RxGen
Welcome, Patricia O'Brien Pomerleau, RQAP-GLPL

What's New
(Also see the calendar available through the Meetings & Training and Resources & Opportunities menus above.

Unemployed SQA Members
If you have lost your job and have not yet paid your 2009 membership dues, please contact sqa@sqa.org and request a hardship status application form. The Board will consider membership hardship requests on an individual need basis.

POGO Releases Report on FDA CDRH GLP Compliance Program
The Project on Government Oversight (POGO) has released a report condemning the performance of the FDA's CDRH GLP compliance program. Entitled "The FDA's Deadly Gamble with the Safety of Medical Devices", the report can be accessed at http://www.pogo.org/pogo-files/reports/public-health/safety-of-medical-devices/ph-fda-20090218.html

JSQA Case Studies: the GLPSS assisted the Japanese Society of Quality Assurance to provide interpretation for 66 case studies based on GLP study situations...Details and full report

NOW OPEN - Online Registration for the 29th SQA Annual Meeting and Training 19-24 April 2009 in San Diego, CA....Register Now

OECD Issues New and Updated Test Guidelines...Details
SQA STRATEGIC PLAN

• **Goal 1**: Provide International Forum for Exchange and Dissemination of
  - information and knowledge pertaining to QA

• **Goal 2**: Advance Profession by Facilitating Interactions with
  - governmental organizations
  - academia
  - industry

• **Goal 3**: Increase Awareness of Global Regulatory Issues that Affect Our
  - professional communities
  - business communities
SQA STRATEGIC PLAN

• **Goal 4**: Promote
  - honesty
  - integrity
  - ethical conduct of SQA members

• **Goal 5**: Strengthen SQA’s Structure, Operation and Communications to Better Serve
  - growing and developing membership
## Society of Quality Assurance Strategic Plan Goals and Objectives

with recommendations from the Board of Directors for ownership

(Please reference the Strategic Plan for the specific Goal, Objective and proposed Tactics)

<table>
<thead>
<tr>
<th>Goal</th>
<th>Objective</th>
<th>AIBC</th>
<th>BoPs</th>
<th>CPR</th>
<th>CRC</th>
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*Key to Committee Abbreviations*

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# Society of Quality Assurance Strategic Plan Goals and Objectives

with recommendations from the Board of Directors for ownership

(please reference the Strategic Plan for the specific goal, objective and proposed tactics)

## Specialty Sections*

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*Key to Specialty Section Abbreviations

AHSS- Animal Health Specialty Section; BCSS- Beyond Compliance Specialty Section; BASS- BioAnalytical Specialty Section; BTSS- BioTechnology Specialty Section; CSS- Clinical Specialty Section; Covic- Computer Validation Initiative Committee (Specialty Section); GLPSS- Good Laboratory Practices Specialty Section; GMPSS- Good Manufacturing Practices Specialty Section; MDSS- Medical Device Specialty Section; SASS- Scientific Archiving Specialty Section; USSS- University Specialty Section
25 YEARS OF SQA

- Interactions with Regulatory Agencies
  - Regulatory Forum Discussions
  - Regulatory Liaisons
  - Annual Meetings and Regional Chapter Meetings
    - Regulatory Agency Invited Speakers and Participants
  - SQA Documents/Position Papers Sent to Agencies on Issues
25 YEARS OF SQA

• Interactions with Regulatory Agencies
  - SQA Appointee to OECD GLP Workshop
  - SQA Appointee to Environmental Laboratory Advisory Board (ELAB)
  - SQA Appointee to Task Force on Proposed EPA GLP FIFRA and TSCA Consolidation
  - SQA Appointee to Task Force on FDA GLP Modernization Efforts
SQA OFFICERS AND BOARD OF DIRECTORS - 2009

- President
- Vice President
- Secretary
- Treasurer
- Immediate Past President

- Jeff Cummings
- James F. McCormack
- Moira J. Bandoli
- Joyce L. Henry
- MaryEllen Lander
SQA OFFICERS AND BOARD OF DIRECTORS - 2009

- Director
  - James Ault
  - Catherine Bens
  - Nancy Gongliewski
  - Debra Green
  - Nicki Iacono
  - John Yergler
  - Elliot Graham

- Director
- Director
- Director
- Director
- Executive Director

- Director

25 YEARS OF SQA

- Volunteers
- Leadership
- Experiences
- Communication and Networking
- Professionalism
- Endurance
25 YEARS OF SQA

• * Future Initiatives
  #1: Further Develop SQA Relationships with Regulators
    - - contact regulators
    - - regulatory liaisons with Committees and Specialty Sections

*SQA President Jeff Cummings, Quality Matters, 25 (1): 1-2 First Quarter 2009
25 YEARS OF SQA

* Future Initiatives

#2: Enhance SQA’s Focus on Career Development for QA Professional

- - SQA University (SQA-U)
  - - - career map
- - Membership and Retention Development Committee
  - - - career center with resources
- - Mentoring Program
  - - - Committee
  - - - pilot program and roll-out

*SQA President Jeff Cummings, Quality Matters, 25 (1): 1-2 First Quarter 2009
25 YEARS OF SQA

• Future Initiatives
  #3: Global Regulatory Challenges Symposium 10/26-30/2009

#4: SQA Web-based Data Management System (iMIS)

#5:

#6:
25 YEARS OF SQA

*It will take an understanding that
- when we all work together
- when each of us looks beyond our own short-term interests
to the wider set of obligations we have
- to each other

THAT’S WHEN WE SUCCEED

*President Barack Obama, March 2009
25 YEARS OF SQA

IMAGINE

WHAT THE FUTURE HOLDS.....
25 YEARS OF SQA

Photo Tribute to SQA Presidents
6 Past Presidents in Nashville, TN - 1988
8 Past Presidents in New Orleans, LA - 1994
13 Past Presidents in Reno, NV – 2004
SQA 20th Anniversary Annual Meeting
Ann Smith, Founding President
1984

October 5, 1984

Ms. Patricia O’Drion Pomerleau
Manager, Quality Assurance Unit
Raylon Health Care Group
One Scarsdale Road
Tuckahoe, NY 10707

Dear Pat:

I enjoyed seeing you again at the Fifth Quality Assurance Roundtable this past week in Boston. I am very pleased and proud that we launched the Society of Quality Assurance at the meeting this week. It was accomplished as the result of the efforts of many people. As a member of the Options/Organizing Committee, your work was instrumental in getting the Society off the ground.

I would like to thank you personally for the hard work you have done through these last several years. It has been a pleasure to be able to work with you, and I look forward to working with you in the future.

Thanks again.

Sincerely,

Ann C. Seth
Past Chair
Organizing Committee

/sga
Frederick G. Snyder, President
1984 - 1985
William R. King, President
1985 - 1986
Joseph B. Townsend, President
1986 - 1987
Jane E. Goeke, President
1987 - 1988
Patricia D. Royal, President
1988 - 1989
Pamela H. Errico, President
1989 - 1990
Richard M. Siconolfi, President
1990 - 1991
Elisse A. Rosen, President
1991 - 1992
Arthur F. Uelner, President
1992 - 1993
Linda H. Borkowski, President
1993 - 1994
Patricia O’Brien Pomerleau, President
1994 - 1995
William M. Harrison, President
1995 - 1996
Gary A. Roy, President
1996 - 1997
Robert M. McCormick, President
1997 - 1998
Barry W. Benson, President
1998 - 1999
Ralph Anderson, President
1999 - 2000
Kenneth D. Dammers, President
2000 - 2001
Deborah Eyer Garvin, President 2001 - 2002
Laura E. Metzger, President
2002 - 2003
Paul E. Bork, President
2003 - 2004
Kevin F. Yount, President
2004 - 2005
John D. Yergler, President
2005 - 2006
Barbara A. Foy, President
2006 - 2007
MaryEllen Lander, President 2008 - 2009
Jeff Cummings, President
2009 - 2010
CONGRATULATIONS ON SQA’s SILVER 25th ANNIVERSARY!!!