

# 25 YEARS OF SQA

Presented by  
Patricia O'Brien Pomerleau  
SQA Past President  
SQA 25<sup>th</sup> Anniversary Meeting  
San Diego, CA  
April 21, 2009

# 25 YEARS OF SQA

- Changes
- Future
- SQA Past Presidents

# 25 YEARS OF SQA

## CHANGE

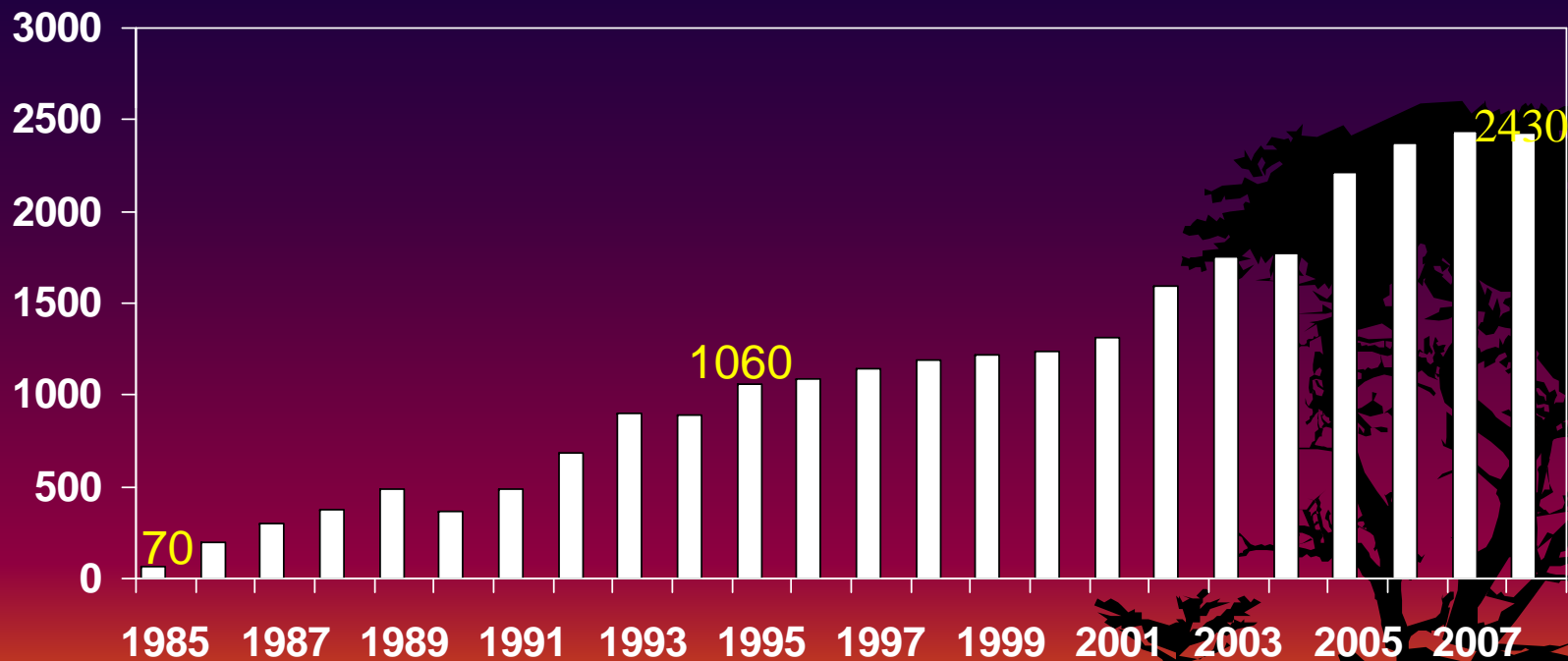


# 25 YEARS OF SQA

## CHANGE



# Society of Quality Assurance Members 1985 to 2008



# 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**



## SQA Mission and Vision



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

- [My Committees](#)
- [All Committees](#)
- [My Specialty Sections](#)
- [All Specialty Sections](#)
- [Inspectional Experiences](#)
- [Employment Opportunities](#)

**Mission Statement:** 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 Statement:** SQA 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
- Over 2,400 Members
- Volunteers
  - SQA Headquarters
- Professional Management Firm, CMG
  - SQA Headquarters
- Newsletter
- Newsletter and On-Line Availability
- Official QA Journal and On-Line Availability

# 25 YEARS OF SQA

- **GLP**
- **GLP, GCP, ICH**
- **GLP, GCP, ICH, GMP, OECD, ISO.....**
- **Membership Directory**
- **On-Line and Search Capabilities; Members Update Personal Information**
- **Classified Adds**
- **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](http://www.sqa.org))
  - postings
  - URL links
  - members only site
  - shared documents
- Regulatory Q & A
  - on-line
  - web-based list serve
- International Members
  - 39 Countries (2008)

# 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)
- RMRCSQA ( Rocky Mountain Regional Chapter)
- SRCSSQA (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](#)
- [Tellers 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](#)

[My Committees](#)

[All Committees](#)

[My Specialty Sections](#)

[All Specialty Sections](#)

[Inspectional Experiences](#)

[Employment Opportunities](#)



start

Microsoft PowerPoint ...

SQA: Committees - Mi...



Internet



1:09 PM

# 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
- Surveys on-line
- Corporate Sponsors
- Platinum and Silver Supporters

# 25 YEARS OF SQA

- Professionals
  - Registered QA Professional (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

- **1<sup>st</sup> 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**



**25th SQA Annual Meeting and Training - 24 April 2009**

- Committees
- Committees
- Specialty Sections
- Specialty Sections
- Inspectional Experiences
- QA Journal
- Regulatory Documents

### SQA Members-Only Website

Welcome, Patricia O'Brien Pomerleau, RQAP-GLP!

### 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](mailto: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 25th 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)

		<b>COMMITTEES*</b>																
<b>Goal</b>	<b>Objective</b>	<b>AIBC</b>	<b>BoPs</b>	<b>CPR</b>	<b>CRC</b>	<b>EdCom</b>	<b>EMCC</b>	<b>FC</b>	<b>Hist</b>	<b>IRC</b>	<b>LC</b>	<b>MRDC</b>	<b>NomCom</b>	<b>Prog</b>	<b>RCPC</b>	<b>RFC</b>	<b>SAB</b>	<b>TC</b>
1	1.A									X								
2	2.A									X							X	
	2.B											X						
	2.C				X						X	X						
3	3.A		X			X				X				X		X		
4	4.A	X	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X
5	5.A		X															
	5.B								X									
	5.C												X					
	5.D					X						X	X				X	
	5.E													X				
	5.F								X						X			
	5.G														X	X		
	5.H					X												
	5.I		X															
	5.J				X													
	5.K								X									
5.L											X							

**\*Key to Committee Abbreviations**

AIBC- Articles of Incorporation and Bylaws Committee; BoPs- Board of Publications; CPR- Council on Professional Registration; CRC- Corporate Relations Committee;  
 EdCom- Education Committee; EMCC- Ethics and Membership Credentials Committee; FC- Finance Committee; Hist- Historical Committee;  
 IRC- International Relations Committee; LC- Liaison Committee; MRDC- Membership Retention and Development Committee; NomCom- Nominating Committee;  
 Prog- Program Committee; RCPC- Regional Chapters' Presidents Committee; RFC- Regulatory Forum Council; SAB- Strategic Advisory Board; TC- Tellers Committee

**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*													RCC- Regulatory Communications Coordinator HQ- SQA Headquarters BoD- SQA Board of Directors		
Goal	Objective	AHSS	BCSS	BASS	BTSS	CSS	CVIC	GLPSS	GMPSS	MDSS	SASS	USS	RCC	HQ	BoD
1	1.A											X		X	X
2	2.A												X	X	X
	2.B											X		X	X
	2.C													X	X
3	3.A													X	X
4	4.A	X	X	X	X	X	X	X	X	X	X	X	X	X	X
5	5.A													X	X
	5.B													X	X
	5.C													X	X
	5.D													X	X
	5.E													X	X
	5.F													X	X
	5.G	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	5.H													X	X
	5.I													X	X
	5.J													X	X
5.K													X	X	
5.L													X	X	

**\*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; CVIC- 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;  
USS- 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
- Director
- Director
- Director
- Director
- Director
- Executive Director
- James Ault
- Catherine Bens
- Nancy Gongliewski
- Debra Green
- Nicki Iacono
- John Yergler
- Elliot Graham

# 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

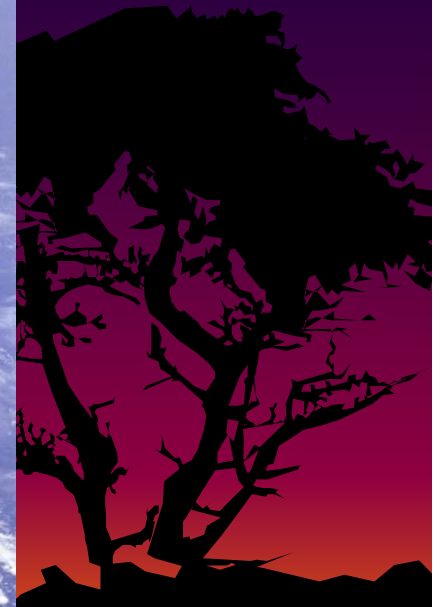
- **Future Initiatives**

**#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 20<sup>th</sup> Anniversary Annual Meeting



# Ann Smith, Founding President 1984



Allied Corporation  
Corporate Health,  
Safety and Environmental Sciences  
P.O. Box 2332R  
Morristown, New Jersey 07960

October 5, 1984

Ms. Patricia O'Brien Pomerleau  
Manager, Quality Assurance Unit  
Revlon 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,

A handwritten signature in cursive script, appearing to read 'Ann C. Smith'.

Ann C. Smith  
Past Chair  
Organizing Committee

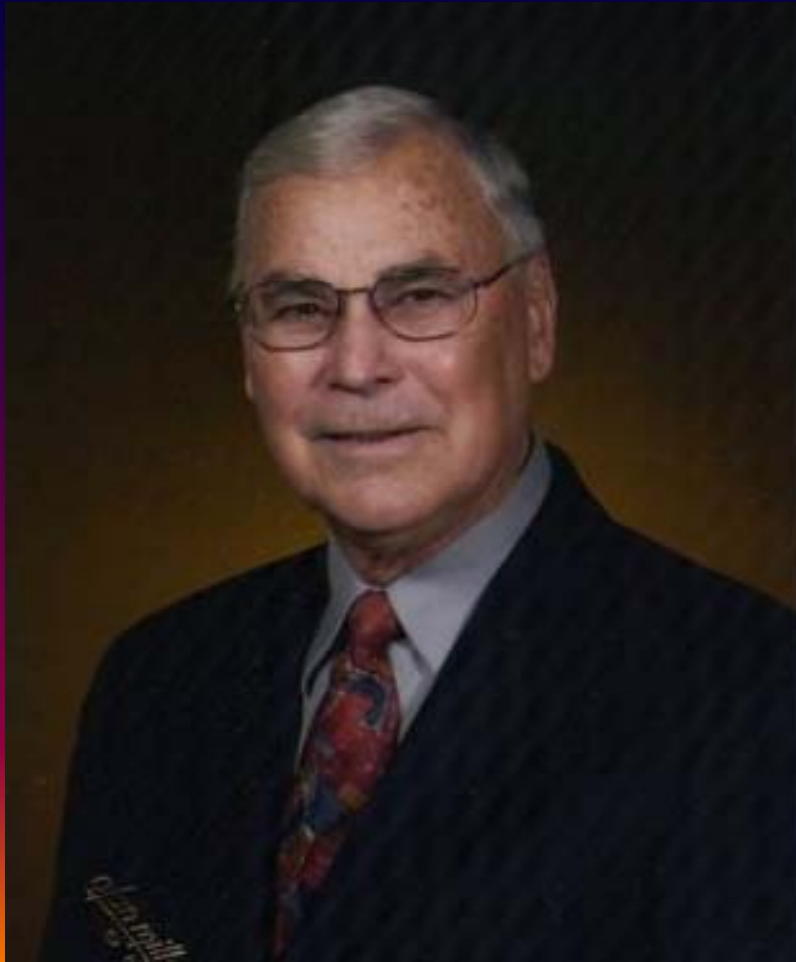
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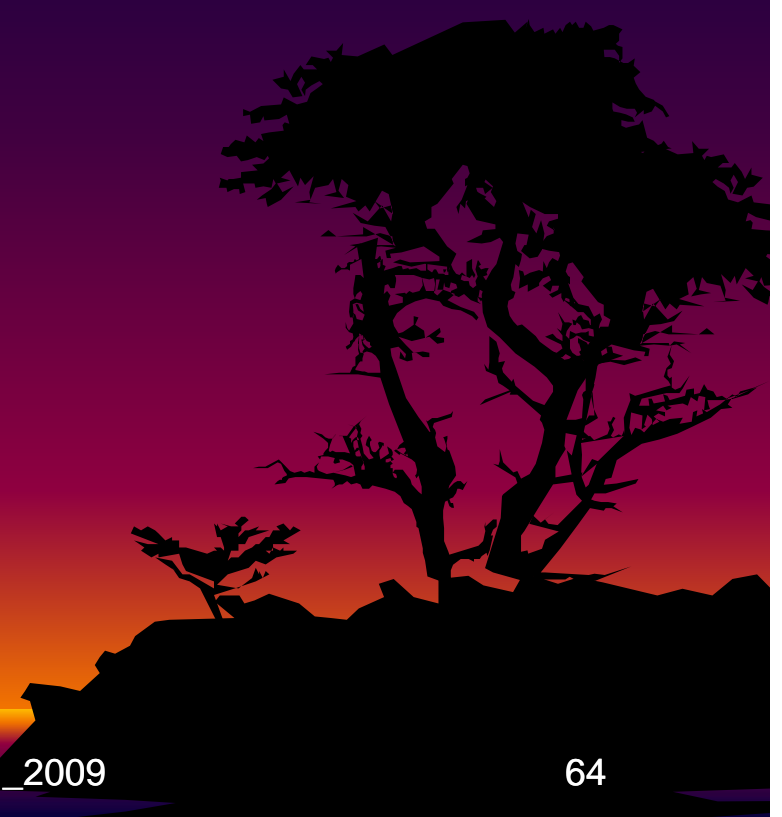
# Frederick G. Snyder, President 1984 - 1985



# William R. King, President 1985 - 1986



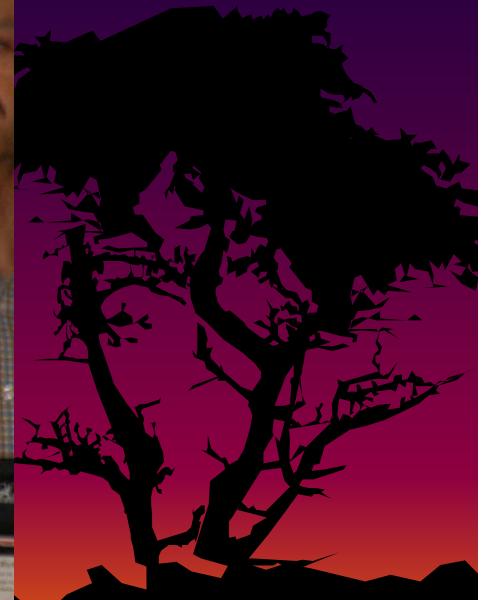
# Joseph B. Townsend, President 1986 - 1987



# Jane E. Goeke, President 1987 - 1988



# Patricia D. Royal, President 1988 - 1989



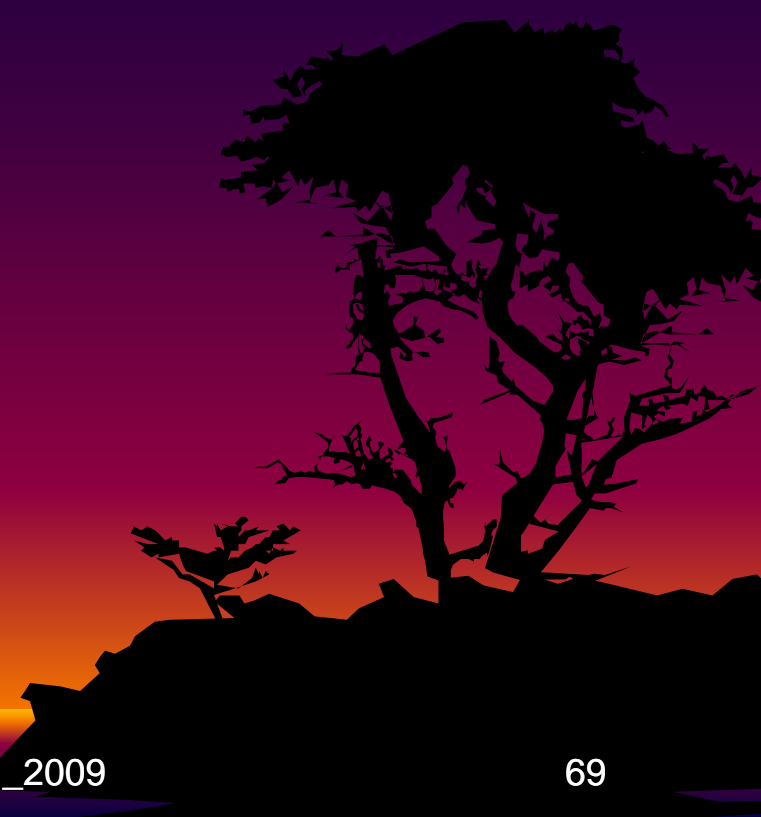
# Pamela H. Errico, President 1989 - 1990



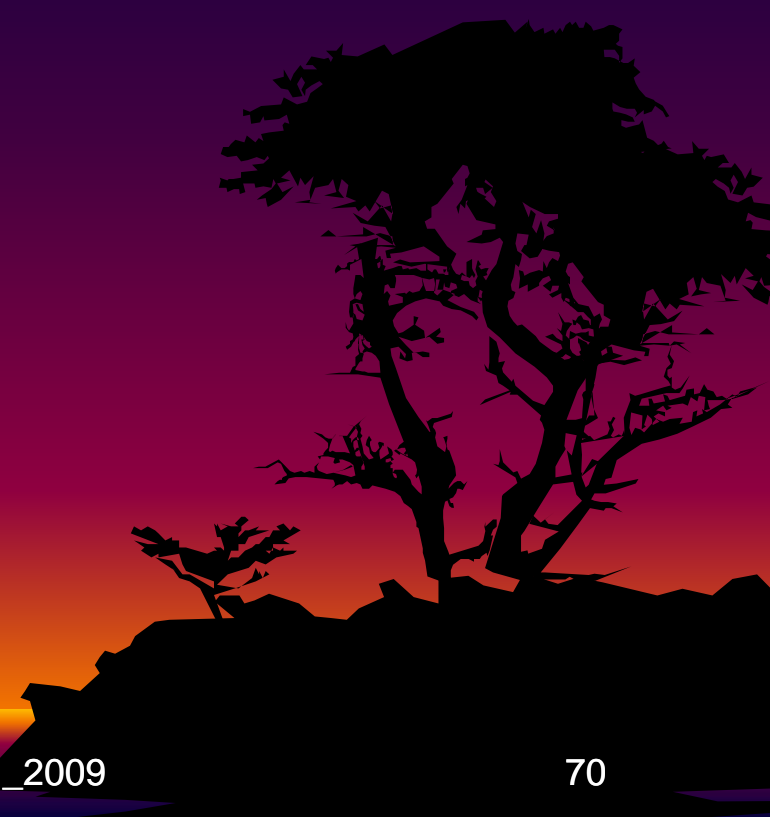
# Richard M. Siconolfi, President 1990 - 1991



# Elisse A. Rosen, President 1991 - 1992



# Arthur F. Uelner, President 1992 - 1993



# Linda H. Borkowski, President 1993 - 1994



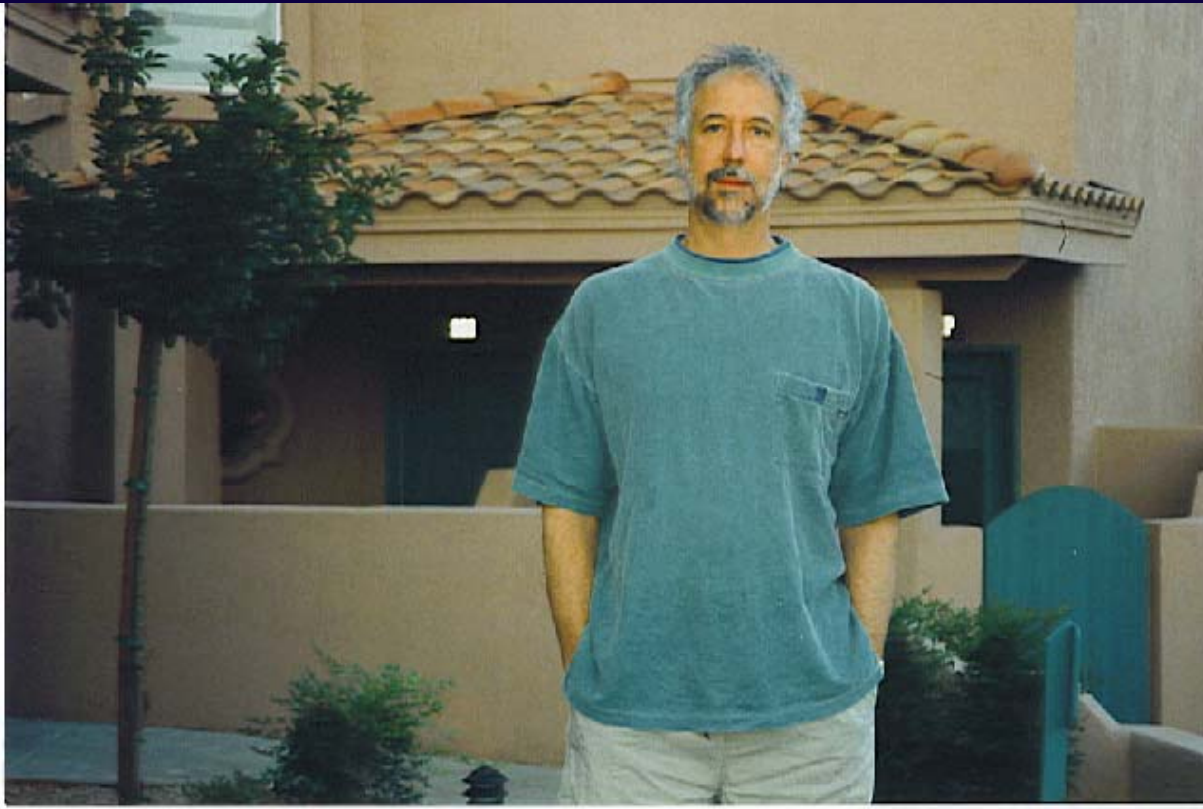
# Patricia O'Brien Pomerleau, President 1994 - 1995



# William M. Harrison, President 1995 - 1996



# Gary A. Roy, President 1996 - 1997



# Robert M. McCormick, President 1997 - 1998



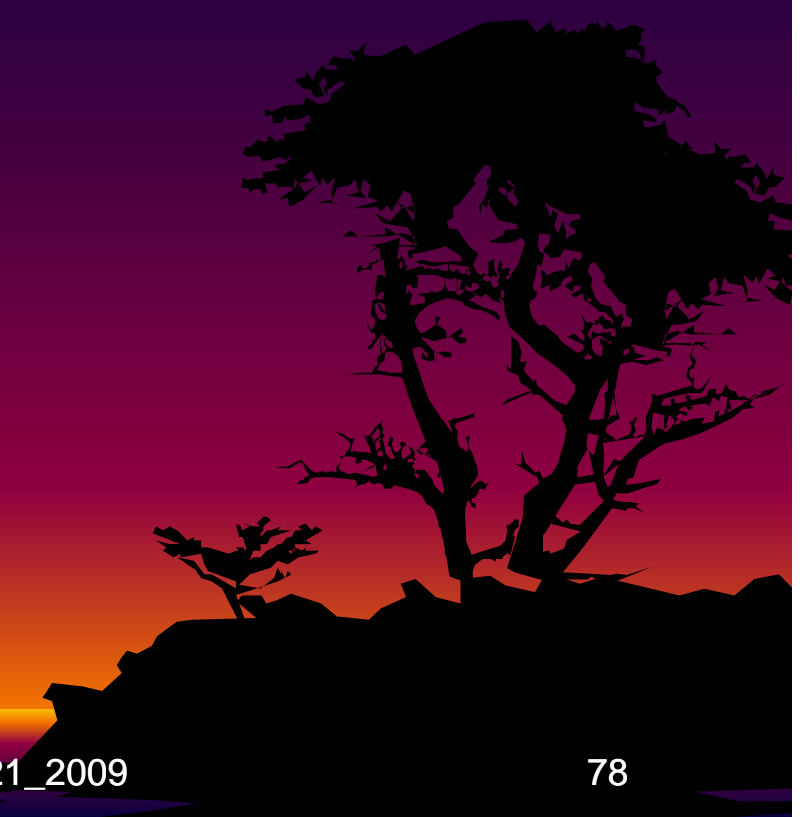
# Barry W. Benson, President 1998 - 1999



# 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



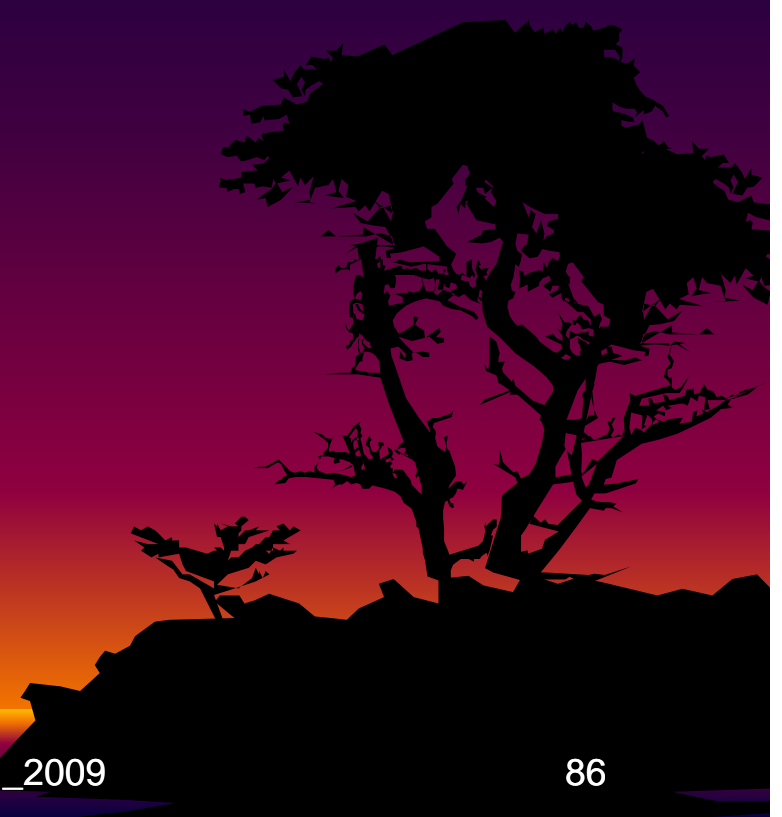
# Barbara A. Foy, President 2006 - 2007



# MaryEllen Lander, President 2008 - 2009



# Jeff Cummings, *President* 2009 - 2010



CONGRATULATIONS ON  
SQA's SILVER  
25th ANNIVERSARY!!!

