

**\*\*\* NCCSQA \*\*\* 2007 Annual Report**

Also submitted to SQA pursuant to SQA RCPC SOP RP-02-01.02 Section 5.16  
by Stu Mertz, 2008 Past President; approved by Executive Council June 12, 2008

<b>OFFICERS</b>																			
President (& SQA RCPC member)	Stuart Mertz Jr, PhD																		
President Elect (& Program Committee member)	Marcella Sarzotti-Kelsoe, PhD																		
Past President	Guy Gardner (resigned January '07)																		
Secretary	Jann Sorrell																		
Treasurer	Jeanne deWard																		
<b>BOARD &amp; Committees &amp; Staff</b>																			
Membership	Rich Patterson, PhD																		
Publicity/Website	Angela Berns																		
Issues & Methods	Evangelia Evdaimon, Monica Fanjoy, Guy Gardner, Betty Hyatt, Edie McMillan, Jenny O'Brien, Lisa Olson, Marcella Sarzotti-Kelsoe																		
Bylaws	Beth Furr, JD																		
Program Co-Chairs	Michelle Holbrook & Anita Simkins																		
Nominating Committee	Stu Mertz, Edie McMillan, Carrie Ingalls																		
RQAP-GLP (Ad hoc)	Stu Mertz, Carrie Ingalls, Shelly Woody																		
Administrative Assistants	SQA staff members																		
Historian (archivist)	Celia Keller																		
<b>NCCSQA ACTIVITIES &amp; TANGIBLE BENEFITS IN 2007</b>																			
1	<p>Monthly Executive Council Meetings on 2<sup>nd</sup> Thursday of each month except August, at GSK Venture Center, Durham, NC (except December at local restaurant this year).                      Monthly Regional Chapter President's Committee (RCPC)(NCCSA President or designee) conference-call meeting on 3<sup>rd</sup> Wednesday of each month to exchange ideas and for sharing of chapter business and activities among chapters and provide input to SQA Board of Directors</p>																		
2	<p>Monthly QA ISSUES &amp; METHODS ROUNDTABLE DISCUSSIONS except December, at GSK Venture Center, Durham, NC                      Issues &amp; Methods Schedule for 2007.                      Special THANKS are extended to our volunteer Facilitators and Coordinators !!</p> <table border="1"> <thead> <tr> <th>Date</th> <th>Topic</th> <th>Facilitator</th> <th>Coordinator</th> </tr> </thead> <tbody> <tr> <td>January 9</td> <td>Veni, Vidi, Erravi, Vici - Phase 1 Clinical Trials for Vaccines</td> <td>Marcella Sarzotti-Kelsoe</td> <td>Evangelia Evdaimon</td> </tr> <tr> <td>February 13</td> <td>Auditing Clinical Labs – What is the Standard</td> <td>Betty Hyatt</td> <td>Betty Hyatt</td> </tr> <tr> <td>March 13</td> <td>The Politics of Auditing</td> <td>Edie McMillan, Angela Berns</td> <td>Lisa Olson</td> </tr> </tbody> </table>			Date	Topic	Facilitator	Coordinator	January 9	Veni, Vidi, Erravi, Vici - Phase 1 Clinical Trials for Vaccines	Marcella Sarzotti-Kelsoe	Evangelia Evdaimon	February 13	Auditing Clinical Labs – What is the Standard	Betty Hyatt	Betty Hyatt	March 13	The Politics of Auditing	Edie McMillan, Angela Berns	Lisa Olson
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**NCCSQA ACTIVITIES & TANGIBLE BENEFITS IN 2007 (continued)**

Date	Topic	Facilitator	Coordinator
April 10	Measurement and Monitoring of Quality. Examples of Statistical Methods or Other Techniques	Evangelia Evdaimon	Evangelia Evdaimon
May 8	Blessing or Curse – Effective E-mailing	Austin Alwood	Jenny O'Brien
June 12	Quality Relationships – QA and Purchasing, etc	Vicki Scroggins-Johnson	Marcella Sarzotti-Kelsoe
July 10	Continuous Improvement as an Inspection Readiness Tool	Jenny O'Brien	Evangelia Evdaimon
August 14	Long Distance Quality – Impact and Issues of Working Remotely	Betty Hyatt	Edie McMillan
September 11	Portrait of a Successful QA Manager	David Brodish	Lisa Olson
October 9	Digital Images as Raw Data – Issues and Concerns	Lisa Olson	Edie McMillan
November 13 (Canceled due to insufficient attendance)	Risk Assessment, Risk Management - Strategies to Protect Quality	Edie McMillan	Evangelia Evdaimon

<b>NCCSQA ACTIVITIES &amp; TANGIBLE BENEFITS IN 2007 (continued)</b>	
3	Quarterly Chapter Meetings and special meeting, including QA training programs and interactions with Regulators. Drawing for annual NCCSQA membership at each chapter meeting; Drawing for annual SQA membership at 4Q meeting.
	1Q, GAMP Training for Quality Assurance Professionals, March 27, GSK, RTP, NC
	2Q, Historical Occurrences of Ethical Misconduct and Applied Clinical Research Ethics, June 28, GSK, Durham, NC
	3Q, Workshop on Good Clinical Laboratory Practices (GCLP) Guidelines for International Clinical Trials: Interpretation & Implementation, October 9-10, Holiday Inn Brownstone Hotel & Conference Center, Raleigh, NC. Invited international panelists participating in closed session on Oct 9: Josephine Cox, Thomas Denny, Hanna Golding, John Hural, Isaac Rodriguez-Chavez, Gwenneth Stevens, Tim Stiles and Tony Tarragona-Fiol. Financial support provided in large part by Collaboration for AIDS Vaccine Discovery (Bill and Melinda Gates Foundation). White paper is planned to be issued in 2008. See brief write up in Regional Chapter News, "NCCSQA GCLP Workshop Review" by Dr. Marcella Sarzotti-Kelsoe, Quality Matters, Vol 23, No. 4, page 13, 4 <sup>th</sup> Q 2007
	Special Supper Mtg, EPA GLP Programs Update and Informal Discussions with EPA Investigators Robert Cypher and Dan Myers, November 13, Holiday Inn Brownstone Hotel & Conference. Center, Raleigh, NC
4Q & Holiday Party, 2007 A Year in Review: New Documents and Interpretations, November 30, Sheraton Imperial Center, Durham, NC	
4	<p><b>NCCSQA CONTRACTS:</b></p> <ol style="list-style-type: none"> <li>1. With SQA for Administrative &amp; Financial Services</li> <li>2. With Andrew Corcoran for programming of NCCSQA website</li> <li>3. With Earthlink for website hosting</li> <li>4. With Holiday Inn Brownstone Hotel &amp; Conf. Center, Raleigh, NC for 3Q and EPA Chapter meetings for facility and food services</li> <li>5. With Sheraton Imperial Center, Durham, NC for 4Q chapter meeting for facility and food services</li> </ol>
5	Quarterly NEWSLETTER "QA Communiqué" is issued by email: Three were edited and issued by the Publicity Committee Chair
6	<p>Website: <a href="http://www.nccsqa.org">www.nccsqa.org</a> Job Postings/Advertisement of QA positions; Members Only Directory, Chapter Activities, Historical documents, QA hyperlinks, and much more.</p> <p>Website Pilot w/SQA was approved</p>
7	RQAP-GLP Study Program (28 April 2007 exam in Raleigh). There was insufficient interest from the Chapter membership to warrant the time to conduct a formal program. However an Ad Hoc Committee (Stu Mertz, Carrie Ingalls, Shelly Woody) was organized and they compiled the study materials from the 2006 program into attachments to eleven emails, and distributed the 11 emails to 11 interested members. Also names of persons interested in organizing/participating in individual study groups were distributed by email.

<b>NCCSQA ACTIVITIES &amp; TANGIBLE BENEFITS IN 2007 (continued)</b>	
8	RQAP-GCP Study Program (28 April 2007 exam in Raleigh). Attempt was made to start a program for the first GCP exam (Linda Patterson, coordinator); however, there was insufficient interest from the Chapter membership.
9	Corporate Sponsor Program. Companies: GSK, EPL, Collaboration for AIDS Vaccine Discovery (Bill and Melinda Gates Foundation). In 2007, the Executive Council added recognition of in-kind contributions in addition to cash contributions.
10	Membership: List of 2007 membership is in SQA database. Membership in 2006 = 241; membership in 2007 = 217 2007 Membership by GxP (from membership dues forms): GLP 94, EPA 27, GCP 66, GMP 35. Membership administration was turned over to SQA Administrative services.
11	Participation in Annual SQA Meeting, Austin, TX, May 1-3, 2007: Donation to SQA for first night's social mixer: \$500 Membership Drawing for two NCCSQA-funded SQA-Meeting Training Scholarships up to \$500: Austin Alwood, Dan Ozaki Membership Drawing for one NCCSQA-funded SQA-Meeting Travel Scholarship up to \$1,000: Lise Richards Officer/Director Mtg Expenses Reimbursement up to \$1,000: Michelle Holbrook Author of NCCSQA Chapter Poster: Michelle Hollbrook Authors RQAP-GLP Poster: Stu Mertz, Carrie Ingalls and Shelly Woody
12	Elections & Miscellaneous Accomplishments/Highlights 1. Transition to using SQA Administrative and Financial Services has gone well and NCCSQA took a leadership position in this project including sharing of our successes with other chapters via RCPC. Full utilization of new and free SQA Administrative Services to Chapters for managing our financial accounts, membership drive and database, quarterly meeting registrations, informational emails and web-based voting has reduced the time for Exec Council and Committee Chair to conduct clerical tasks; thus permitting us to "focus on the business of training and professional development for Chapter members." We heartily THANK the SQA BOARD for funding of these administrative services. 2. NCCSQA Financial Policy was developed and tested in 2007, and approved by Executive Council on May 8, '08. 3. NCCSQA Executive Council Guidance Document, Version 1 was approved on July 10, 2007. This is a training manual for officers and directors and committee chairs; summary of NCCSQA procedures. It has been in development and testing as a draft document for several years. 4. Elections for 2008 positions were conducted by a new web-based electronic ballot system via SQA website. 5. We were very fortunate to have SQA Executive Director Elliott Graham attended March 8th Executive Council meeting
13	Bylaw Amendments: Several amendments were drafted, voted upon using new web-based electronic ballot system, approved by membership, and issued Jan 10, 2008