2007 is a great year to be a member of NCCSQA. WELCOME to all new and returning members. You cannot beat this educational, training and networking value for your $15 investment!

A hearty thanks for your time and contributions to all our retiring 2006 Officers and Directors: Edie McMillan, Past President; Cathleen Rubens, Secretary; Ellen Colclough, Treasurer; Patrick Sabourin, Membership; Michelle Holbrook, Publicity and Website Liaison; and Betty Hyatt and Celine Clive, Membership Co-chairs.

The Chapter elected an energetic and talented group of new Officers and Directors; please give a warm welcome to them: Dr. Marcella Sarzotti-Kelsoe, President-Elect (Duke University); Jann Sorrell, Secretary (GSK); Jeanne deWard, Treasurer (Charles River Laboratories Pathology Associates); Dr. Richard Patterson, Membership (R J Patterson & Assoc.); Angela Berns, Publicity and Website Liaison (Schwarz Biosciences); and Anita Simkins, Program Co-Chair (Kendle International). The Executive Committee appointed Michelle Holbrook, Program Co-Chair (Kendle International) to replace Celine Clive's remaining one year term due to resignation.

(continued on page 2)
**Presidents message continued from Page 1.**

Guy Gardner, our 2006 NCCSQ A President, was elected 2007 Chair-Elect by SQA’s RQAP membership. This starts a 3-year, chair leadership position on the Council on Professional Registration, which administers the RQAP-GLP and RQAP-GCP registration programs and their examinations. We congratulate Guy on this accomplishment following his excellent leadership in our Chapter’s very successful 2006 RQAP-GLP study program.

Hopefully you have found our Chapter’s new partnership with SQA for financial and administrative services to make the clerical aspects of your membership go more smoothly. New features this year are the ability to pay for membership in both organizations at the same time, as well as to pay for Chapter membership and quarterly meetings by credit card. SQA now issues our Chapter notices sent by email, maintains our membership database, and does our bookkeeping. All these new services are funded by SQA, i.e., at no cost to NCCSQ A (except for credit card processing fees). Please let the appropriate Officer or Director know of any problems you might encounter with any of these new services; your patience is appreciated as we iron out any kinks in them.

Your Executive Committee expanded NCCSQ A’s scholarship program this year with two new awards. The winners of the two $500 reimbursements for SQA meeting training are Nancy Peters (Rho, Inc) and Austin Alwood (etrials Worldwide). The new $1,000 reimbursement for SQA meeting expenses not covered by one’s company was won by Carrie Ingalls (RTI). And NCCSQ A has contributed $500 to SQA to help underwrite entertainment expenses at the opening reception on April 30 5:30-7:30 pm at the SQA annual meeting in Austin, TX. Michelle Holbrook is in charge of our Chapter’s poster at that meeting. Be sure and stop at our poster, and pick up your special gift.

I am looking forward to seeing you at all your Chapter’s activities. Let’s make 2007 a banner year!

Stu Mertz
Editor’s Corner

Please remember that we will publish member news, articles, open positions and accomplishments.

The Member’s only portion of the NCCSQA website has lots of helpful information about upcoming NCCSQA events. If you’ve forgotten or lost your User ID or password please contact me and I’ll refresh your account.

Angela.Berns@SchwarzBiosciences.com

The deadline for contributions for the 2nd Quarter Newsletter is June 11 2007
See and Hear Your Executive Council at Work

The NCCSQA Executive Council meetings are open to all members. The Council meets 11:00 am - 1:00 pm on the second Thursday of every month at the GSK Venture Center, Conference Room V-136, 4117 Emperor Blvd, Durham (RTP), NC.

To ensure our meeting space is an adequate size and to comply with the security rules of our site host, please let us know of your intent to attend via email to NCCSQA Secretary Jann Sorrell (jann.b.sorrell@gsk.com) by 5pm one week prior to the meeting. If you have items you'd like to add to our agenda, you may send them to Stu Mertz at stu@peakqc.com

We look forward to seeing you! The remaining meeting dates for 2007 are:

- 12 April  Notify by 05 April
- 10 May  Notify by 03 May
- 14 June  Notify by 07 June
- 12 July  Notify by 05 July
- 09 August  Notify by 02 August
- 13 September  Notify by 06 September
- 11 October  Notify by 04 October
- 08 November  Notify by 01 November
- 13 December  Notify by 06 December

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### 2007 NCCSQA Executive Council

#### Educ/Prog. Co-Chair
Michelle Holbrook  
Phone: 919-257-6670  
holbrook.michelle@kendle.com

#### Educ/Prog. Co-Chair
Anita Simkins  
Phone: 919-389-7313  
asimkins@nc.rr.com

#### Membership Chair
Richard Patterson, Ph.D.  
Phone: 919-846-3832  
qaman100@earthlink.net

#### Bylaws Chair
Beth Furr  
Phone: 919-998-2563  
Fax: 919-998-1415  
Beth.furr@quintiles.com

#### Issues & Methods
Evangelia Evdaimon  
Phone: 919-313-3963  
evdaimon@infostrength.com

#### Publicity Chair
Angela Berns  
Phone: 919-767-2662  
Fax: 919-767-3174  
Agela.berns@schwarzbiosciences.com
From your Membership Chairperson - Rich Patterson

There are 162 members in NCCSQA as of March 15. This is slightly ahead of the membership numbers last year at this time. The largest number of NCCSQA members work with GLPs, but members that work with GCPs exceed 30% of our membership.

In the QA Communiqué, the Membership Chair usually lists members who we are no longer able to contact in an attempt to update our records and re-establish contact. In this issue, we have news on Lisa Olsons move! On the same topic, if your information does change, you can update that by contacting me at qaman100@earthlink.net or by using the membership link on nccsqa.org. Unfortunately, we do not currently have the capability for you to make your changes online, but it is on our “to do” list for the near future.

2007 is the first year for SQA to provide administrative support to NCCSQA Membership. I think this is working well, but we have had a few surprises along the way and have had to iron out a few details. By the end of March, the Member Directory on nccsqa.org should be updated. It is possible that your member information could contain an error or you might lose access to the members-only area on the website. If your member information is incorrect, contact me at qaman100@earthlink.net or by use the membership link on nccsqa.org. If you lose access, please use the link on the homepage of nccsqa.org for help. If you have any questions about membership, please contact me.

Where are you now ??????

Lisa Olson is now Associate Director, QA at i3, focusing on computer system compliance and electronic record integrity issues at a global level. Contact information is:
1001 Winstead Drive, Suite 200
Cary, NC  27513
LISA.OLSON@I3RESEARCH.COM
919-678-4580
Five laboratories were working in a vacuum conducting Phase I-II immunogenicity testing on HIV vaccines. The NIH mandated that laboratories conducting this testing must follow GLPs. Marcella was asked to lead this effort.

How do you apply GLPs to clinical trials? BARQA has GCLP guidelines but there is nothing in the US.

A GCLP Committee was created. This committee addressed SOPs, templates, a numbering system, study plans, assay validation, proficiency testing and equipment validation.

- SOPs—now have over 100
- Equipment validation—followed GMP Regulations but were told this was overkill.
- Proficiency testing—nothing available for immunogenicity testing. CLIA or CAP addressed only partially these issues.

Audits:

- Notified labs in advance in the beginning of the program.
- Looked at each lab.
- Three people from the GCLP committee audited each lab
- Facility and in-process audits conducted

Currently use electronic SOPs and audit reports.

The five labs are now up to speed.

Problems encountered:

- Convincing scientists to document and formalize assay validation prospectively.
- QA considered “Police”
- QA overcommitted
- Personnel resistant to new procedures
- GCLPs are guidelines, not rules. Unclear what FDA expects.
The roundtable was a lively discussion from all parties. Several different topics got raised. No conclusions were drawn, but all agreed that QA has a difficult road, and discussions of this sort are helpful periodically to get us re-charged.

Topics of discussion included:

- QA and the business receive conflicting messages of costs, earnings, and the bottom line over quality
- Many indicated that they may actually expect more of internal staff than vendors, because internal staff work in this industry and are “supposed to know better”
- Some in the business units see QA as a “professional wrist-slasher” or “the enemy” or QA “makes people look stupid.” May be more helpful for QA to be partners – helping people get their SOPs right, can reduce external client opinions and perhaps observations
- QA can help by re-framing discussions. One example is not to cite 21 CFR Part 11, but rather to talk about procedures, controls, and data integrity.
- Someone indicated that non-compliance just seems to keep going on – “non-compliance is viral.” (I love this!)
- It may be helpful to explain to the business that QA will have to defend the activities and documentation in front of the FDA. Or that they are “there to watch your back.”
- Frustrations include the business not being held accountable for non-compliance (or for not fixing problems) – non-compliance and audit observations are not part of performance appraisals, thus can have no real effect on individuals. Would be different if these were in MBOs.
- Rewards to the business units are for meeting timelines and budgets, but these types of rewards do not hit QA.

Continued on Page 8……
Continued…..“The Politics of Auditing”

- In relation to accountability for findings, sometimes the people who performed the work are not even there anymore when the audit occurs.
- Problems result and continue when only one instance (in an audit observation, for example) is addressed, vs. looking at systemic problems.
- A challenge is auditing people who used to be your co-workers.
- Federally funded research is difficult – investigators are not used to the regulated environment and see QA as challenging their “science.”
- Deviations can be allowed, but the use of deviations can easily get out of control.
- A corporate group auditing a compliance group was concerned about the lack of independence of the reporting structure and the fact that the group had no escalation process.
- It may be a good idea to do face-to-face dissemination of findings to internal groups, where possible. Take them back to and remind them of their procedures. Again reinforce the fact that QA is here to help not make life more difficult.
- Some indicated that audit reports are sent to vendors certified mail, with a signature guarantee, to avoid claims that it was never received.
- Should senior management metrics count number of audits? Is it not more important to track number of closeouts, number of follow ups?
- People are often afraid to answer in audits or afraid to admit they do not know.

QA can build relationships with business units to help them with approaches – this can facilitate people being more likely to call with questions. Education on what an audit is can be helpful.

Submitted by Lisa Olson
NCCSQA 2007 1st Quarterly Meeting

GAMP Training for Quality Assurance Professionals
Tuesday, March 27, 2007
GlaxoSmithKline, Elion Hitchings Auditorium
12:30pm – 1:00pm Registration
1:00pm-4:00pm Program

Program Topics & Speakers
GAMP IT Infrastructure Control and Guidance
Gail Utnage, GSK Validation Manager
GAMP Good Practice: Validation of Laboratory Computerized Systems
Lorrie Schuessler, GSK Program Manager
Principles of risk Management and Application in the Development and Management their of Audit Programs: The GSK Approach
Edie McMillan, GSK Program Manager

*Directions to Elion-Hitchings Auditorium
From Raleigh: Take I40 West and take exit 279B to get on the Durham freeway (highway 147). Take the Durham freeway north to exit 6 (Cornwallis road); less than 0.5 miles. Make a right onto Cornwallis, Elion-Hitchings building will be immediately on the left. Elion Hitchings Auditorium is on the first floor, security guards at the door will direct you.
From Chapel Hill: Take I40 East and take exit 279B to get on the Durham freeway (highway 147). Take the Durham freeway north to exit 6 (Cornwallis road); less than 0.5 miles. Make a right onto Cornwallis, Elion-Hitchings building will be immediately on the left. Elion Hitchings Auditorium is on the first floor, security guards at the door will direct you.
From Durham: Take the Durham freeway south to exit 6 (Cornwallis road). Make a right onto Cornwallis, Elion-Hitchings building will be immediately on the left. Elion Hitchings Auditorium is on the first floor, security guards at the door will direct you.
NCCSQA 2007 1st Quarterly Meeting

To register, e-mail your registration information to nccsqa_prog@yahoo.com by 10:00 am on March 20, 2007.

Name: Company:
Phone: E-mail:
Address:

2007 Membership fee/dues. If joining NCCSQA, please also fill out the 2007 Membership Form located at www.nccsqa.org/membership.htm $15

Program registration for 2007 members ........................................ $15
Program registration for 2007 non-members ............................... $35

Total enclosed

After registering by e-mail, please send payment using one of the following payment methods:

Option 1: Mail this completed registration form, a check (payable to NCCSQA including name of registrants on the check) or a completed credit card payment form and if applicable, a membership application (new members only) to the address listed below by March 20th.

Option 2: Mail this completed registration form and bring a check or completed credit card payment form to the Meeting Registration Table on event day.

Note: Credit Cards and payment forms are not processed at the Registration table, they are mailed to SQA.

Registration will be taken at the door
Our client, a rapidly expanding specialty pharmaceutical company in RTP, is actively recruiting for a highly competent, seasoned and versatile drug development professional for key role driving the Quality Assurance efforts in clinical development.

Selected candidate will combine the requisite technical/scientific knowledge (listed below), with sound operational judgment, expert project management skill and developmental staff management style. Broad experience handling GCP compliance for pharmaceutical company needed. GLP background also desirable. Environment is highly empowered, innovative, entrepreneurial and quality-driven. Seek top candidate who thrives in such setting. Company is prepared to pay top dollar to attract and retain its candidate. Full relocation available.

Ideal Candidate will offer:

- Degree in related field as well as 8+ years in GCP compliance, including 3+ years in a leadership role
- In-depth knowledge of the US Federal regulations related to clinical research ((21 Parts 50, 56, 312) and ICH Good Clinical Practice Guidelines
- Experienced in preparing standard operating procedures (SOPs) for the clinical compliance function
- Ability to review clinical protocols, informed consents, monitoring and data management plans and independently make recommendations for improvements, where necessary

Role will be responsible for:

- Establishing and maintaining all clinical quality compliance functions within the organization and will be expected to develop proper standardized procedures consistent with current ICH regulatory requirements as well as monitor the quality, efficiency, uniformity and compliance to these standards in partnership with internal and external staff
- Planning and initiating appropriate internal and external audits in support of all domestic and international clinical development programs
- Conducting training of internal and contract staff to optimize successful, regulatory-compliant activities. Similar skill sets for GLP compliance would be desirable,
Quality Assurance - GCP Compliance Auditor:

Our client, an Atlanta-based pharmaceutical firm undergoing tremendous growth, is actively recruiting for a GCP Compliance Specialist to join its expanding Quality Assurance team. This is a newly created position and firm is prepared to pay top dollar (including relo) to attract and retain the best candidate. In addition to the requisite technical/scientific skills listed below company seeks a collaborator who will work well in a dynamic and empowered setting.

The selected candidate will conduct vendor, clinical site, file and/or data audits to ensure compliance with GCPs as well as conduct internal audits to ensure compliance with Company SOPs, GCPs, cGMPs and other applicable regulatory requirements. Role will also involve preparing audit reports and corrective action plans, coordinating external consultant audits, reviewing internal documentation for compliance to Company SOPs, GCPs and other applicable regulatory requirements, assisting in the preparation for and execution of international or domestic regulatory agency inspections, develop, implement and revise Quality Assurance SOPs and performing other tasks as assigned by management personnel.

The ideal candidate will offer a BS degree in Life Sciences as well as 3 to 5 years of experience in the pharmaceutical (or related) industry including 2 years working with GCP and/or GLPs and at least 1 year in an auditing function. Seek an achiever looking for a next great opportunity. Growth potential is tremendous.

GCP Quality Auditor - Pharmaceutical, Direct Hire:

Our client, a pharmaceutical firm located in Research Triangle Park, is actively recruiting for a GCP Quality Auditor to join its rapidly expanding Quality Assurance team. The Firm is experiencing tremendous growth and is eager to bring on a top-notch clinical professional for a key role handling its GCP function. This position is a direct hire position, will require 50% travel and is paying up to the mid $70’s plus bonus, benefits, etc.

The selected candidate will conduct clinical site, file and/or data audits to ensure compliance with GCPs, SOPs, cGMPs and other applicable regulatory requirements. In addition, this person will prepare audit reports and corrective action plans, coordinate audits, review (QC) internal documentation for compliance to Company SOPs, GCPs and other applicable regulatory requirements; assist in the preparation for and execution of international or domestic regulatory agency inspections; develop, implement and revise Quality Assurance SOPs; and perform other tasks as assigned by management personnel.

The ideal candidate will have 2-5 years of experience in clinical research and/or the pharmaceutical industry and have at least 1-2 years of experience conducting GCP audits. RAC &/or CQA certifications a plus.
Quality Assurance - Clinical/Clinical Trial Material (Top $$):
Seeking very sharp and capable Quality Assurance professional for key position with growing specialty pharmaceutical company in RTP. Initial focus will be on managing Quality related to Clinical Trials Materials and will later evolve to include broader QA responsibilities. Identifying a skilled, knowledgeable and versatile quality assurance professional is a top priority at this time.

Specific tasks will include:

Coordinating and performing external audits of CTM raw material manufacturers, packaging manufacturers, contract laboratories, Contract Research Organizations and other vendors/suppliers as directed. Assisting in evaluations of quality systems employed by a supplier/contractor and, when directed, assist supplier/contractors in improvements.

Qualifying new Clinical Trial Material suppliers/contractors and Contract Research service providers and assuring those suppliers/contractor/service providers are operating in conformance to cGMPs, GLPs, GCPs, and established standards.

Creating, reviewing and approving CTM drug product master formulae and manufacturing procedures, CTM drug product standards and specifications, quality standards, packaging specifications and regulatory documentation.

Conducting and reviewing investigations relating to CTM customer complaints, deviations, and failure investigations and support resolution of supplier and production quality issues encountered during Clinical Trial Material production.

Seek candidate with excellent current skills and desire to expand/grow knowledge/experience base.

Selected candidate will offer 2-3 years in Compliance/Auditing and some exposure to quality in a CTM setting. In addition, seek a "roll up your sleeves/get the job done" workstyle. This company is undergoing tremendous expansion. Our selected candidate will be a quick study who can shift gears readily, prioritize effectively and modify work plan to suit shifting needs. Demonstrated ability to develop positive relationships with vendors and coworkers important.

Accurate attention to detail, experience with batch record review, auditing mentality and broad understanding of drug development, pharmaceutical production and quality are all critical. This position offers great growth potential for the right candidate. 4 year degree expected.

The position will pay industry-leading base, plus generous bonus, benefits, stock, etc.. Specific wage will depend upon relevant experience and skills. Immediate opening. Local candidates only.
Opportunities

Manager of Quality (GXP) Training - Pharmaceutical:

Our client, an Atlanta-based pharmaceutical company, is actively recruiting for a top-notch training professional to drive GXP training. Role will involve leading technical programs including GCP, GMP, GLP & SOP training. Company is experiencing exponential growth. Seek seasoned and accomplished trainer who will contribute to the development of an expanded program to accommodate said growth.

Role will involve managing the administrative/logistical aspects of the program as well as course development and delivery. Incumbent will liaise with department heads to ensure training programs meet their needs. Incumbent will liaise with department managers to ensure staff attends programs as appropriate. Seek smart trainer who develops collaborative and productive relationships with all stakeholders.

Successful candidate will combine 5+ years in Training Management role with 5+ years in R&D setting. Must understand quality principles in a drug development setting and offer demonstrated ability to successfully instruct in said areas. This is a newly created position due to growth. Seek very sharp and competent candidate who can help grow the training function.

Company is prepared to pay full relo for top candidate. Please forward Word resume.
Position Title: Quality Assurance/ Quality Control Auditor

POSITION SUMMARY
Responsible for activities involving Quality Assurance/ Quality Control and compliance with applicable regulatory requirements. Responsible for ensuring that clinical trials are conducted in compliance with Good Clinical Practices (GCP's) and other applicable regulatory requirements. Ensure that trial data is generated, documented and reported in compliance with Good Clinical Practices (GCP's) and other applicable regulatory requirements.

PRINCIPAL ACTIVITIES
Conduct vendor, clinical site, file or data audits to ensure compliance with GCP's.
Conduct internal audits to ensure compliance with Company SOP's, GCP's, and other applicable regulatory requirements.
Prepare audit reports and corrective action plans.
Coordinate external consultant audits.
Review (QC) internal documentation for compliance to Company SOP's, GCP's, and other applicable regulatory requirements.
Assist in the preparation for and execution of international or domestic regulatory agency inspections.
Develop, implement and revise Quality Assurance SOP's.
Perform other tasks as assigned by management personnel.
Travel 60%

REQUIREMENTS
• A bachelor's degree in a Life Science preferred or relevant work experience.
• Certified Quality Auditor (CQA) and/or Regulatory Affairs Certification is preferred but not required.
• 3 to 5 years experience in the pharmaceutical or biotechnology industry or clinical research environment.
• 3 years experience as a QA Auditor
• Experience and knowledge of GCP's/ SOP's preferably within a pharmaceutical or research environment.
• The ability to multi-task, troubleshoot, problem solve, research, and make sound decisions based on scientific evidence and regulatory requirements.
• Ability to work well independently and as a part of a team with people at all levels within the organization is essential.
• Strong attention to detail.
• Excellent verbal and written communication skills are a must.
• Computer/ PC proficiency in MS Word, Excel, Power Point, and Project.
Knowledge and experience in auditing clinical trial data, Electronic Data Capture (EDC) systems and 21CFR11 computer system validation is strongly preferred.

Please contact Chris Loughner via e-mail at cloughner@abraxisbio.com in regards to this position. Thank you in advance for you interest in Abraxis Bioscience.
i3 assists the world's leading pharmaceutical and biotechnology companies with integrated scientific solutions throughout the pharmaceutical product lifecycle. i3 services include therapeutically specialized, full-service contract research; data capture, analysis, and reporting; strategic consulting and expertise in epidemiology, health economics, and outcomes; and certified medical education.

**Senior Quality Assurance Auditor:**
- Conducts all types of internal/external audits of sites including but not limited to; contract laboratories, databases, reports, processes and systems in a clinical research environment.
- Works within the quality assurance team to ensure that the quality of the research conducted by the organization is maintained.
- Assists in the training of a team of quality assurance associates/assistants.
- Effectively documents audit findings in an audit report and obtain responses in a timely fashion.
- Reports and presents to clinical staff and investigators the findings of audits and provides advice on resolving problems identified.
- Facilitates customer audits of the company and or projects.
- Answers queries and provides advice to Ingenix personnel and third parties on difficult issues regarding current GCP, SOP and quality assurance requirements where necessary.
- Acts as quality assurance project manager for assigned projects.
- Reviews audit reports for other quality assurance personnel.
- Assists in preparing investigational sites for inspection by regulatory authorities.
- Minimum of four (4) years auditing experience in medical/pharmaceutical field. Knowledge of GCP, GMP, GLP and ICH guidelines.
- Preferred location: Basking Ridge, NJ
NORTH CAROLINA CHAPTER of the SOCIETY of QUALITY ASSURANCE

OUR MISSION
To disseminate current information on regulatory policies and trends, provide multi-faceted educational opportunities, and to act as a resource for our members who are respected quality assurance professionals.

2007 Application for NCCSQA Membership
For more information, see www.nccsqa.org

Name: ____________________________
Title: ____________________________
Company: _________________________
Address: __________________________
______________________________
City: _____________________________ State: ______
Zip code: ________________
Telephone: (___) __________________
Fax: (___) ________________________
E-mail: __________________________

Area of Expertise (you may select up to two categories):
Category: GLP GMP/QSR GCP 21 CFR Part 11
Arena: FDA Drugs EPA FDA Devices FDA Animal Health

Scope of interests (you may select more than one category and arena):
Category: GLP GMP/QSR GCP 21 CFR Part 11
Arena: FDA Drugs EPA FDA Devices FDA Animal Health

SQA Member: Active Affiliate Not
Certifications: RQAP CQA CQIA RAC
Other (specify): ____________________________