

Newsletter / Journal

Volume 3, Issue 1

July 2004

INSIDE THIS ISSUE

- 1 President's Message
- 2 Election Results / Nomination Committee
- 3 Financial Report
- 4 What's New at HPFB
- 5 What's new on the CCSQA WWW
- 6 Upcoming SQA and CCSQA Events
- 7 Featured Articles and SQA News
- 8 Welcome New Members!!!
- 9 Membership Committee Update
- 10 Websites of Interest
- 11 Advertisements
- 12 Comments and Contributions

2004 CCSQA Board of Directors

Out of a possible 55 votes only 17 were received by the February 29, 2004 deadline. Our quorum of 20% was met. Out of these 17 ballots all nominees were accepted by a majority vote (>50%). Therefore the new board was inaugurated at the March 9 CCSQA Board Meeting. The 2004 CCSQA Board is as follows.

President - Janine Johnson jjohnson@cato.com
Vice-president - Anne Beaubien anneb@envirotest.com
Secretary-Maria Tzamouranis MTzamouranis@itrlab.com
Treasurer - Penny Kirsch penny_kirsch@yahoo.com
Past-President - Keith Burch burch@icms-inc.com
Director - Stephan Cote scote@amgen.com
Director - Nahid Bibak nahid_bibak@viridae.com
Director - Paul Sidney psidney@ctbr.com
Director - Michael Maddix Maddixm@wyeth.com

President's Message

CCSQA President – Janine Johnson

I am writing this the day after the close of the SQA conference in Reno, NV. There were 33 Canadians listed on the Attendee List. Of those 12 were current members and 4 were board members. We had a poster at the meeting, lunch tables, and a bowling night. Many Canadians who came to visit the board members hanging around the poster asked questions about the Chapter. I let everyone know that our annual training meeting will be held in Ottawa again this year on October 1 and 2.

I would like to thank Debbie Dragoon for organizing the bowling night and Keith Burch and Stephan Cote for helping out with the poster and greeting CCSQA/FCSQA members and non-members at the meeting.

Thank you for all your support of the chapter and I hope to see you in Ottawa in October.

Update: At the time of publishing the newsletter we have five confirmed speakers, and the registration forms, with a tentative agenda, will be released in mid-July.



Financial Report
 CCSQA Treasurer – Penny Kirsch

2003 Year End Balance	877.51
Income for 2004	1172.74
100% from membership dues	
+++++	
2004 Expenses to June 29 2004, 2004	
CCSQA Post Office Box	112.72
CCSQA Web Page Renewal	160.77
2 Board Meetings (phone expenses)	118.61
2004 SQA Meeting Expenses	79.00

TOTAL EXPENSES	471.10
June 29, 2004 Balance	1579.15

What’s New on the CCSQA WWW ??

Deborah Dragoon – Wyeth

We had 581 Web site visits for a total of 2888 hits since January 2004 with the most visits/hits occurring in April. The average hit per hour for May was 2. The average hit per day for May was 8. According to the Web Page Statistics, career opportunities and officer's list were some of the top links visited.

Please submit requests for Web Page content to Ms. D. Dragoon at dragood@wyeth.com.

What’s New at the HPFB????

See attached Addendum for more links!!!

Medical Device Compliance and Enforcement Directive

http://www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/pol_0045_md_tc_e.html

Supersedes: New document

Date issued: February 11, 2004

Date of implementation: March 1st, 2004

Guidance on the Medical Device Inspection Programme

http://www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/md_inspection_guide_tc_e.html

Supersedes: New document

Date issued: February 6, 2004

Date of implementation: March 1st, 2004

IMPORTANT NOTE: This guidance document is intended to provide medical device manufacturers, importers and distributors with guidance related to the assessment of their compliance with the Food and Drugs Act and Medical Devices Regulations during inspections under the Health Products and Food Branch Inspectorate, Medical Device Inspection Programme.

This and other HPFB news can be found at

www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/new_e.html



Editor’s Favorite Quote:

By Harry Truman

“I never did give anybody hell. I just told the truth and they thought it was hell”

SQA Historical Committee

By Victor I. Green, RQAP-GLP

ENTER AND WIN - THE SQA PHOTO CONTEST!

The SQA Historical Committee invites YOU to take pictures at this year's SQA-sponsored events, then submit them and/or any photos from past SQA events for entry in the SQA Photography Contest at the 21st SQA Annual Meeting and 1st International QA Conference in Orlando, FL in 2005.

There will NOT be a SQA Photo Contest at the 2004 Annual Meeting. Use this opportunity to capture a memorable image of a meeting this year and submit it to us following the guidelines below.

Photo Contest Guidelines:

1. All photos must be taken during an SQA event: SQA Annual Meetings, SQA regional Chapter Meetings, SQA-sponsored training sessions or other SQA event.
2. Photos must be of SQA members attending the event.
3. Photos may be submitted in print format or in digital format recommended to be submitted in .jpeg format).
4. Type or legibly print your name and affiliation, phone number, names of individuals in the photograph, (left to right and front to back) on two small sticky labels. Also, include the name/ date/location of the SQA event (month and year are okay, if you do not know the full date). If the photo is submitted digitally, assemble the information and submit the label information with the digital image.
5. Secure one of the labels (from step 4) to the back of the photograph and submit the other label with the photograph. The extra label (or information submitted with digital photograph) will be used for display of the photograph.
6. Photos may be submitted via mail address to the attention of: **Celeste Rose, RoseTECH Consulting, Inc., 1135 Dorothea Dr. Painesville, Ohio 44077**. Photos will not be returned, but will become part of the SQA Historical Photo archives.
7. Digital photos may be sent via e-mail to Celeste Rose at crose@rosetechconsulting.com
8. The deadline for submission of photos via mail or e-mail is **January 15, 2005**.
9. Photos may also be submitted in a manila envelope to the SQA Historical Committee at the time of the Annual Meeting in Orlando, FL

Upcoming CCSQA / SQA Events

CCSQA Membership Meeting/Training

October 1 and 2, 2004 – Embassy West

The 2nd Annual Meeting of the Canadian Chapter of the Society of Quality Assurance will be held in Ottawa, Ontario on October 1 and 2. If you are interested in participating in the planning of this meeting, please contact **Janine Johnson** at jjohnson@cato.com or 514-856-2286 x 259.

1st Global Quality Assurance Conference and 21st SQA Annual Meeting

Hilton in the Walt Disney World Resort, Orlando, FL USA , 20 - 24 February 2005

This historic event will be co-sponsored by the British Association of Research Quality Assurance (BARQA), the Japan Society of Quality Assurance (JSQA) and SQA. For more information on BARQA and JSQA, please see the National Societies page. Please check back for further details on the Annual Meeting and International Conference.

<http://www.sqa.org/newsite/public/meeting-am-fut.asp>

Council on Professional Registration

The GLP Quality Assurance Professional Registry Examination consists of 150 multiple-choice questions. Candidates are allowed three hours to complete the examination. Individuals passing the examination will be credentialed as Registered Quality Assurance Professionals in GLPs (RQAP-GLP).

Individuals with expertise in GLP quality assurance write the questions and review them for relevancy, consistency, accuracy, and appropriateness. The SQA then prepares the examinations, with advice and assistance from the professional testing agency (Applied Measurement Professionals, AMP) that is contracted to assist SQA with development, administration, scoring, and analysis of the examination.

The GLP Quality Assurance Professional Registry Examination is administered annually. For 2004, SQA has added an additional administration primarily for quality assurance professionals outside the United States. The examination schedule for 2004 and 2005 follows.

2004-2005 Examination Schedule

Examination Dates	Application Postmark Deadline	Test Center Locations
Tuesday, 9 November 2004 (afternoon)	21 September 2004	Liverpool, UK Orlando, FL (SQA Annual Meeting Site)
Saturday, 19 February 2005	27 December 2004	Chicago, IL Philadelphia, PA San Diego, CA

For Saturday examinations, examinees must report at 8:30 am. The examination begins at 9:00 am. SQA reserves the right to cancel a test center due to insufficient registration. If SQA cancels a test center, the candidates who selected that center will be notified and may choose another test center or submit a written request for a full refund. The request for a refund must be sent to SQA Headquarters and be postmarked at least seven days prior to the administration of the examination.

Eligibility Requirements

To be eligible for the GLP Quality Assurance Professional Registry Examination, applicants must fulfill one of the two following requirements:

1. Have the equivalent of four years of full-time experience working as a quality assurance professional prior to the examination date; OR
2. Have a baccalaureate degree AND the equivalent of two years of full-time experience working as a quality assurance professional prior to the examination date.

Examination Fee

The examination fee in 2004 and 2005 is \$275 (USD).

Application and Candidate Handbook

To apply for the GLP Quality Assurance Professional Registry Examination, access the Candidate Handbook from the link on this page, and complete the application form included in the Handbook. The application must be postmarked as indicated above. The Candidate Handbook describes examination policies and procedures. It provides a content outline, a list of study references, and sample questions. An application form is included as well as a form to request special accommodations. Alternatively, a Candidate Handbook or an application form may be obtained from Applied Measurement Professionals [telephone, (913) 541-0400; e-mail, info@goAMP.com]. Candidates should receive a response within two business days of sending an inquiry to AMP.

More information can be found at: <http://www.sqa.org/newsite/public/rqapglp-about.asp>

Membership Committee Update

CCSQA President - Janine Johnson

Membership by the Numbers:

**60 members as of July 16, 2004
(23 new and 37 renewed)**

The 2004 CCSQA Membership Directory was sent to all active members in May 2004. Updates to membership will be presented in the next Newsletter.

Our goal, as in previous years, is 75 members. We need your help to reach our goal, please renew your membership or reach out to other QA professionals you know and tell them about the CCSQA.

The new member and renewal forms can be found on the CCSQA website. <http://www.ccsqa.org/>

WELCOME NEW MEMBERS!!!

Ms. Diane Motink

QA Associate II
Apotex Research Inc.
200 Barmac Drive,
Mississauga, Ontario
L5M 4N3

Tel: 416-749-9300

Fax: 416-401-3867

E-mail: dmotink@apotex.com

Ms. Margo Morrison

Senior QA Associate
MDS Pharma Services
1980 Matheson Boulevard East, Suite A
Mississauga, Ontario
L4W 5N3

Tel: 905-206-8884

Fax: 905-212-2746

E-mail: margo.morrison@mdsps.com

SQA and Regional Chapter Membership Survey!

<http://www.zoomerang.com/recipient/survey.zgi?p=WEB2M9DGLWYR>

This survey is being facilitated by the Society of Quality Assurance (SQA) Membership Retention and Development Committee (MR&DC). The purpose of the MR&DC is to evaluate current membership needs and benefits, create new and improved benefits to serve the needs of the individual members, and develop/increase the base of individual membership in all areas of research regulated by Good Clinical Practices, Good Laboratory Practices and Good Manufacturing Practices and their associated regulations around the world. The MR&DC shall also consider the inclusion of any new regulatory areas as may be developed from time to time in the global arena. This survey will allow your input so that we can identify your needs and communicate them to both Regional Chapter and SQA leaders.

There are five sections of this survey: demographics and membership data; regional chapter membership; new specialty section interests; animal health specialty section interests; and professional registration interests. There are a total of 29 questions, which should involve less than 15 minutes of your time. If you don't have interest in all of the survey areas, please answer only the areas that are of interest to you, and question 29. The very last question of the survey invites you to tell us what we haven't covered and how else we can serve your needs.

Because the survey is being distributed to SQA members in addition to the regional chapter members, you may be invited to complete the survey more than once. Please only respond to the survey one time.

The survey will close Friday, 23 July 2004. Thank you for your participation.

Sincerely,
SQA Membership Retention and Development Committee

Websites of Interest

Privacy Acts (Canada and US)

- **Canadian Personal Information Protection and Electronic Documents Act (PIPEDA)**

Canadian Privacy Act

http://www.privcom.gc.ca/legislation/02_07_01_e.asp

Provincial Privacy Acts and Oversight Offices

http://www.privcom.gc.ca/information/comms_e.asp

Canadian Institute of Health Research - Privacy

http://www.cih-irsc.gc.ca/publications/ethics/privacy/index_e.shtml

- **United States Health Insurance Portability and Accountability Act (HIPAA)**

Office of Civil Rights <http://www.hhs.gov/ocr/hipaa/finalreg.html>

Centers for Medicare and Medicaid Services

<http://www.hipaa.com/>

US Department of Health and Human Services

<http://aspe.os.dhhs.gov/admsimp/>

OECD GLPs and Guidance Documents

OECD Principles on Good Laboratory Practice

[http://www.olis.oecd.org/olis/1998doc.nsf/LinkTo/env-mc-chem\(98\)17](http://www.olis.oecd.org/olis/1998doc.nsf/LinkTo/env-mc-chem(98)17)

Quality Assurance and GLP

[http://www.olis.oecd.org/olis/1999doc.nsf/LinkTo/env-jm-mono\(99\)20](http://www.olis.oecd.org/olis/1999doc.nsf/LinkTo/env-jm-mono(99)20)

Compliance of Laboratory Suppliers with GLP Principles.

[http://www.olis.oecd.org/olis/1999doc.nsf/LinkTo/env-jm-mono\(99\)21](http://www.olis.oecd.org/olis/1999doc.nsf/LinkTo/env-jm-mono(99)21)

The Application of GLP Principles to Field Studies.

[http://www.olis.oecd.org/olis/1999doc.nsf/LinkTo/env-jm-mono\(99\)22](http://www.olis.oecd.org/olis/1999doc.nsf/LinkTo/env-jm-mono(99)22)

The Application of the GLP Principles to Short Term Studies.

[http://www.olis.oecd.org/olis/1999doc.nsf/LinkTo/env-jm-mono\(99\)23](http://www.olis.oecd.org/olis/1999doc.nsf/LinkTo/env-jm-mono(99)23)

The Roles & Responsibilities of the Study Director in GLP Studies.

[http://www.olis.oecd.org/olis/1999doc.nsf/LinkTo/env-jm-mono\(99\)24](http://www.olis.oecd.org/olis/1999doc.nsf/LinkTo/env-jm-mono(99)24)

The Application of the Principles of GLP to Computerised Systems.

[http://www.olis.oecd.org/olis/1995doc.nsf/LinkTo/ocde-gd\(95\)115](http://www.olis.oecd.org/olis/1995doc.nsf/LinkTo/ocde-gd(95)115)

The Role and Responsibility of the Sponsor in the Application of the Principles of GLP.

[http://www.olis.oecd.org/olis/1998doc.nsf/LinkTo/env-mc-chem\(98\)16](http://www.olis.oecd.org/olis/1998doc.nsf/LinkTo/env-mc-chem(98)16)

The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies.

[http://www.olis.oecd.org/olis/2002doc.nsf/LinkTo/env-jm-mono\(2002\)9](http://www.olis.oecd.org/olis/2002doc.nsf/LinkTo/env-jm-mono(2002)9)

Advertisements

GET NOTICED!!! Advertise HERE!

Advertisements are posted for 60 days on our webpage <http://www.ccsqa.org/> and in each issue of our newsletter (average of 2 per year). The following rates are for non-members; members will receive a 25% discount off the published rates.

Full Page	(7in x 9 in)	150\$
1/2 Page	(3.5in x 9in)	100\$
Business Card	(3.5in x 2in)	50\$

Newsletter only rates are as follows:

Full Page	(7in x 9 in)	75\$
1/2 Page	(3.5in x 9in)	50\$
Business Card	(3.5in x 2in)	25\$

All ads must conform to the dimensions listed in the rates. The publisher is not liable for advertisements printed from faulty ad materials.

Newsletter Specifications:

Arial, 10 point, normal font
Wordperfect or Microsoft Word file format
High Resolution (at least 300 dpi)

Webpage Specifications:

Microsoft Word file format (The file will be converted to PDF prior to posting on the webpage)
High Resolution (at least 300dpi)

Note: Advertisements may be modified due to size limitations on the webpage and electronic transfer to members. Submitters will be notified and asked to approve any modifications, prior to publication.

Please refer to our webpage <http://www.ccsqa.org/> for submission requirements and payment information.

Comments & Contributions

Please forward any comments or contributions for the CCSQA Newsletter to Anne Beaubien (anneb@envirotest.com):

- GLP/GCP contributions.
- Regulatory questions.
- Advertisements or Job Posts.
- Upcoming events. ■