Canadian Chapter of the Society of Quality Assurance
CCSQA
FCSQA
Filiale Canadienne de la Society of Quality Assurance

Newsletter / Journal

Volume 2, Issue 1 April 2003

INSIDE THIS ISSUE

2003 CCSQA Board of Directors

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Special Thank You to Rena Liu-Critchley and Rosemary Jotcham for volunteering to be the nominating committee in 2002.

President's Message

CCSQA President - Keith Burch

Hi everyone. Welcome to the new members that have joined this year and a big thank you to the members that have renewed. We all have to help to recruit new members and bring forward ideas to continue programs that will support our membership and make it useful to us all.

Thanks to Janine for working so hard leading the education committee and getting this newsletter out. We are trying to make our web site more useful too, we need some input on content and entries in our web site. For example would you object to job seeking or job placement businesses using our chapter website as an advertising tool?

A point of interest to our membership is an announcement that Agriculture Canada will be setting up ten of their research stations to become a GLP compliant facility and perform minor use studies. If Agriculture Canada trains people to do the Quality Assurance work, I'm sure they will benefit from membership to CCSQA. We have some of our members instructing and training the personnel at these sites. When ever possible I encourage all of our members to share our web site with others and let them know how easy it is to join the CCSQA.

I would like to see the CCSQA develop a list of people willing to instruct and or host training seminars. Due to the distances between major centres in Canada, these training seminars may be with just a few people and don't have to be elaborate or extravagant.

My best wishes to all and let's press on…. I hope to hear from members that have a view or opinion with some of the issues I mentioned above.

Financial Report

CCSQA Treasurer **-** Shelley Antel

2002 Year End Balance	630.84
100% from membership dues	
March 31, 2003 Balance	1091.60
100% from membership dues	
2003 Expenses to April 30, 2003	
2003 February Board Meeting (phone)	71.91
CCSQA Post Office Box	96.28
(paid for 1 year)	
++++++++++++++++++++++++++++++++++++	
Anticipated Income for 2003 (renewals)	400.00
Anticipated Expenses for 2003	
CCSQA Web Page Renewal	170.00
3 Board Meetings (phone expenses)	220.00
Training Workshops/Meetings	500.00
Budgeted Carryover to 2004	433.00

Education Committee

Members: Janine Johnson - jjohnson@cato.com
Debbie Dragoon - dragood@wyeth.com
Nahid Bibak - nahid_bibak@viridae.com

We have received some great suggestions for training topics from the Membership Survey that was sent out with your membership renewal. Some topics suggested were:

- Computer Validation - clinical and non-clinical
- IQ/OQ/PQ of Instruments
- Clinical QA support for Data Management
- Training Techniques
-

The education committee will be looking for presenters on these topics and please let us know if there are any other topics you would be interested in.

Marianne Vanderwel, Pfizer Canada Inc., has graciously agreed to present at an Evening Discussion Seminar (EDS) in June on the Canadian Clinical Trial Inspectorate.

Stay Tuned for Details in May.

Photos for 2003 SQA Annual Meeting Photography Contest

Historical Committee Report
Celeste Rose, RQAP-GLP

Join us in documenting SQA History! Are you planning to take pictures at upcoming national or regional chapter SQA-sponsored events? Have you taken pictures at any of the past SQA events? Would you like to enter them in the 2003 Photography Contest?

The SQA Historical Committee is actively seeking photographs for the 2nd Annual Photography Contest at this year's SQA Meeting in Washington, D.C. in October 2003. The photographs will then become part of SQA history via inclusion in the SQA Historical Photograph Archive!

We invite you to submit photos from any past or upcoming SQA events for the Photography Contest and for SQA Historical Archives. The 2nd Annual Photo Contest will be held at the 2003 SQA Annual Meeting. Photos will be judged on composition, clarity, and integrity by a selected panel. The submitted photographs will be prominently displayed on poster or table at the 2003 Annual Meeting. The winner will be announced at the Meeting and an award for the Best Photograph will be presented. The winner will receive a small prize and his/her name in the SQA newsletter. So get those cameras out and say "Cheese…"

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 events.
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).

Historical Committee Report (continued)

Photo Contest Guidelines:

4. Type or legibly print your name and affiliation, phone number, names of the individuals in the photograph (left to right and front to back) on two small sticky label. Also include the name/date/location of the SQA event (month and year are ok if you do not know the full date). If photo is submitted digitally, assemble the information and submit the label information with digital picture.
5. Secure one of the labels (from step 4) to the back of the photograph and submit the other label with photograph. The extra label (or info submitted with digital photo) will be used for display of the photograph.
6. Photos may be submitted via mail addressed to the attention of:
   Celeste Rose, RoseTech Consulting, 1135 Dorothea Drive, Painesville, Ohio 44077.
7. Digital photos may be sent via email to Celeste Rose at *crose@rosetechconsulting.com*.
8. The deadline for submission of photographs via mail or email is September 15, 2003.
9. Photos may also be submitted in a manila envelope to the SQA Historical Committee at the time of the Annual Meeting in October 2003.
10. All photographs received will become the property of SQA.

DID YOU HEAR???

The UK agency that monitors for GLP, the Medicines Control Agency (MCA) and the Medical Device Agency (MDA) will be called the Medicines and Healthcare products Regulatory Agency (MHRA) as of April 2003.

21 CFR Part 11: New FDA Guidance Document Issued in February 2003

Joanne Tyas, QA Manager
ITR Laboratories Canada, Inc.

As part of the GMP initiative ("Pharmaceutical cGMPs for the 21st Century: A Risk-Based Approach" www.fda.gov/oc/guidance/gmp.html) the FDA have stated that they intend to re-examine the 21 CFR Part 11 rule and in February 2003 a new draft guidance document for 21 CFR Part 11 was issued (www.fda.gov/cber/guidelines.htm#part11). At the same time the previous draft guidance documents and enforcement policy guide were withdrawn.

The draft guidance provides information on how the Agency intends to exercise enforcement discretion with regard to the following 21 CFR Part 11 requirements during this re-examination of the rule; validation, audit trails, legacy systems, copies of records and record retention. During the re-examination, however, the Agency intends to enforce all other aspects of Part 11 including requirements for electronic signatures.

The draft guidance document clarifies the definition of a Part 11 record and states that the FDA intend to interpret the scope of Part 11 narrowly to encourage technological advancement and limit unnecessary cost to the industry. There is an emphasis on the need for maintaining compliance with the predicate rule. Risk based approaches may be taken based on the potential of the system to affect product quality, safety and record integrity.

It is interesting to note that for legacy systems the Agency do not intend to take regulatory action for systems that were in place before 21 CFR Part 11 was issued (20 August 1997). It is also recognised in the records and record retention section that in certain instances hybrid systems can exist where electronic versions are printed out and signed.

At this stage it is not clear how large or small the changes will be to 21 CFR Part 11. What is certain, however, is that 21 CFR Part 11 is still in place. Some may have misunderstood the situation and believe that the 21 CFR Part 11 rule itself has been withdrawn. This is certainly not the case and it is important that progression in this area should continue.

The new draft guidance provides information on the FDA's current thinking towards 21 CFR Part 11, however, the fact that this is a draft document should also be taken into consideration.

Council on Professional Registration Report

Chair, CPR - Tammy White, RQAP-GLP

Sixty-one (61) quality assurance professionals sat for the 2002 GLP Quality Assurance Professional Registry Examination.The passing point for the October 2000 examination was 99 raw score units out of 150 possible points and did not change for the October 2002 administration. Raw scores were converted to scaled scores such that a raw score of 99 was equal to the minimum passing scaled score of 75 pre-established by the SQA. After final scoring was completed, score reports were generated, checked for accuracy, and mailed to candidates on November 18, 2002. Each score report included the candidate's raw score and scaled score, the minimum passing scaled score, and sub-scores by content area to facilitate candidate understanding regarding test performance strengths and weaknesses.

2002 EXAM RESULTS

0Candidate Group	Total Number	Number Passing
All	61	51
First time	56	49
Repeat	5	2

Led by Debra Wallace, the CPR is also updating the GLP Quality Assurance Professional Registry Examination Candidate Handbook. The CPR is ensuring that the Handbook is up-to-date and additional details are being added to clarify examination eligibility requirements and re-registration criteria and procedures. The Handbook is available via the RQAP-GLP link on the SQA web site, or from AMP. The RQAP-GLP link will also be updated. Also, also… all (16) of the Council Polices is currently being reviewed and updated.

The 2003 examination will be offered Saturday, October 11, 2003 in Seattle, Chicago, and Montreal, and at the SQA Annual Meeting in Arlington, VA, on Sunday, October 12, 2003. For additional details, and an application for the examination (Candidate Handbook), please go to the RQAP-GLP site.

Pesticides: Consumer Protection to be Boosted via Harmonisation of Maximum Residue Levels

March 14, 2003
European Commission - Press Release
DN: IP/03/383
http://europa.eu.int/comm/food/fs/ph_ps/pest/intro_en.pdf

Today the European Commission adopted a proposal for a Regulation aiming to harmonise at the European level the maximum residue levels (MRLs) of pesticides permitted in products of plant and animal origin.

The consequence of this draft Regulation entering into force will be that all MRLs for plant protection products will become harmonised after a transitional 'phase-in' period, and will thenceforth only be set at the European level. It removes all trade inconsistencies that result from the current situation whereby Member States can set their own national MRLs in the absence of Community MRLs. In addition to consolidating and simplifying existing legislation, a primary objective of the Regulation is to define the roles of the different actors in the process of setting MRLs. The European Food Safety Authority (EFSA) will be responsible for risk assessment, while the Commission will provide risk management by setting the MRLs, taking EFSA's opinions into consideration. The Commission already has an active programme of annual residues monitoring in place, which will be able to feed EFSA with additional data for risk assessment.

Next steps:

The Commission will now submit the draft Regulation for approval by the European Parliament and Council as well as notifying its trading partners in the World Trade Organisation and in the Cotonou agreement with the ACP-countries. The proposal will hopefully enter into force before January 2005.

The proposed Regulation replaces and simplifies the four existing basic Council Directives on pesticide residues, namely Directives 76/895/EEC, 86/362/EEC, 86/363/EEC and 90/642/EEC.

Membership Committee Update

CCSQA Vice President - Janine Johnson

Membership by the Numbers:

41 members as of December 31, 2002

19 new and 17 renewals as of April 30, 2003

To reach our membership goal for 2003 (75) we need to have 22 renewals and 15 new 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/

We need volunteers to help plan the Regional Meeting-EAST please contact me at jjohnson@cato.com by May 16.

Upcoming CCSQA / SQA Events

CCSQA Membership Renewals Due
April 30, 2003

CCSQA Annual Meeting of Members
East Coast - Summer 2003
West Coast - Fall 2003

19th SQA Annual Meeting

http://www.sqa.org/AM2002/Annual_mtgs_main.htm
Marriott Crystal Gateway, Arlington, VA USA
12 - 16 October 2003

Program planning for the 2003 Annual Meeting in Washington D.C. has begun. The Program Committee is looking for session topics that meeting attendees will find relevant and interesting. If you have session topic ideas or would like to chair a session, please contact either ***Delinda Kindig*** *(d.kindiq@lilly.com), 317/277-4376 or* ***Patty Runge*** *(prunge@epl-inc.com), 703/471-7060 x 237, CoChairs of the 2003 Program Committee.*

JOB BOARD

As the largest biotechnology company on the planet, Amgen offers the chance to truly innovate and contribute to the big picture in science. Our R&D focus on nephrology, oncology, inflammation and bone disease, and neurology has already produced six marketed products with a promising pipeline of new human therapeutics to come. A world-class sales force, global manufacturing operations, and clinical development sites on three continents complete our picture as a Fortune 500 company and a leading biotechnology company committed to improving people's lives. And Amgen continues to grow with our successes. We currently have the following opportunity at our Thousand Oaks, California facility.

GLP Compliance Advisor II, Job ID# amge-00000879

GLP Compliance Advisor III, Job ID# amge-00000880

Amgen offers an exceptional compensation and benefits package. To apply, please visit the Amgen Career Center at www.amgen.com.

The full job posting can also be found on the CCSQA website at www.ccsqa.org.

What's In It For Americans (WIIFA)

CCSQA Director - Deborah Dragoon

If your company does business in Canada either to market in Canada or to research in Canada you can benefit:

- Interact with other QA professionals in your discipline
- Learn about Canadian regulations
- Interact with personnel outside your scope (GLP, GCP, GMP, EPA, FDA, OECD)
- Share perspectives on changes to the regulations
- Keep abreast with the current regulations and upcoming changes
- Utilize the CCSQA Web Page (Coming Attraction)
- Utilize the CCSQA for Questions and Answers
- Networking, networking, networking

Join today! ■

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.cihr-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/admnsimp/

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

Quality Assurance and GLP
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

The Application of GLP Principles to Field Studies.
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

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

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

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

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 Janine Johnson (jjohnson@cato.com):

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