

# Newsletter / Journal

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December 2003

## INSIDE THIS ISSUE

- 1 President's Message
- 2 Election Results / Nomination Committee
- 3 Financial Report
- 4 Featured Articles
- 5 Membership Committee Update
- 6 Upcoming SQA and CCSQA Events
- 7 Job Board
- 8 What's In It For Americans (WIIFA)
- 9 Websites of Interest
- 10 Advertisements
- 11 Comments and Contributions

## 2004 CCSQA Board of Directors Nominations

**Penny Kirsch** - Envirotest Laboratories -  
Treasurer

**Michael Maddix** - Wyeth - Director

**Paul Sidney** - CTBR Bioresearch Inc. - Director

**Note: The CCSQA board did not receive any nominees for the position of Vice-President. The current vice-president may perform both roles in 2004 if a nominee is not found.**

**If you have any suggestions for a vice-president nomination please write to [jjohnson@cato.com](mailto:jjohnson@cato.com)**

## President's Message

### **CCSQA President** - Keith Burch

This chapter has completed our second year now and although there is always more to be done we have accomplished a lot. We knew going into creating a Canadian Chapter that we would have geographical distances to bear. It is difficult for us to meet face to face and yet we had a good turn out for the education seminar held in Ottawa. With the smaller group, everyone was able to speak and participate. The feeling around the table was that this was indeed a worth while seminar, which will be continued next year.

Our membership has grown but there are many Quality Assurance people out there in various industries that we have not been able to reach. This is where all our members need to participate in sharing the opportunity for others to join and benefit from membership in the Society of Quality Assurance. With more members we will be able and need to provide more regional meetings throughout Canada.

I thank Vice President Janine Johnson who filled in for me when I was away for work. Thank you to all the executive directors for their time and dedication to the Chapter. I encourage every one of our members to pitch in and dedicate some time to helping with the various programs that Janine wants to accomplish as President of the Canadian Chapter in 2004. This quote is from a John Amatt presentation; "It's not what you go through in life that makes you what you are; it's how you react to the world you're going through." I feel that together, sharing thoughts and ideas in this Chapter, can and will make the journey more enjoyable.

**See you in Reno for the SQA convention in April.**

Financial Report  
**CCSQA Treasurer** - Shelley Antel

<b>2002 Year End Balance</b>	630.84
100% from membership dues	
<b>Income for 2003</b>	<b>1191.90</b>
<b>(membership dues and carryover from meeting)</b>	
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<b>December 31, 2003 Balance</b>	877.51
+++++	
<b>2003 Expenses to December 31, 2003</b>	
CCSQA Post Office Box	96.28
CCSQA Web Page Renewal	160.00
4 Board Meetings (phone expenses)	75.00
Promotional Items (CCSQA Bags for meetings)	500.00
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<b>TOTAL</b>	<b>831.28</b>
<b>Budgeted Carryover to 2004</b>	360.62

Quality Initiative for Research  
 Excellence at Capital Health

**Mary Kate Needler –**  
*Research Auditor, Capital Health*

Capital Health is pleased to introduce QIRE (pronounced “choir”), our new Quality Initiative for Research Excellence.

QIRE is designed to promote a culture of research excellence through continuous quality improvement. The initiative is rooted in Capital Health’s core values of collaboration, accountability, respect, and excellence. QIRE will use a multifaceted, supportive, and team approach to ensure that:

- Researchers are appropriately qualified, have access to ongoing training and internal expertise, and actively seek opportunities for improvement;
- Best practices are identified and shared, and successes are celebrated;
- Internal policies and procedures are comprehensive, appropriate, and effective;
- Research is conducted according to the highest scientific and ethical standards and complies with local, national, and international requirements.

We are currently reviewing Capital Health’s research-related policies, procedures, and practices to ensure that our internal systems are optimal. Specialized educational programs and other initiatives will ensure that investigators, research staff, and Research Ethics Board members receive the support they need to carry out world-class clinical research. QIRE will include a comprehensive internal audit program, allowing us to measure performance against requirements. Feedback from the audit program will be used to inform decision-making, enabling further quality improvement.

Capital Health has taken a leadership role in developing a network of Canadian academic health care centers that have (or are developing) internal audit programs for research conducted at their facilities. This informal network is facilitating information sharing and collaboration across the country.

To learn more, please contact:

Mary Kate Needler  
 Research Auditor, Capital Health  
 Room B23A, Centre for Clinical Research  
 5790 University Avenue, Halifax, N.S. B3H 1V7  
 Telephone: (902) 473-8549  
 Email: [marykate.needler@cdha.nshealth.ca](mailto:marykate.needler@cdha.nshealth.ca)

**DID YOU HEAR ???**

**The HPFB released Annexe 2 to the cGMP guidelines: manufacture of Drugs used in Clinical Trials on December 15, 2003.**

**The drug GMP and Establishment Licensing (EL) enforcement directive was release on December 1, 2003.**

*This and other HPFB news can be found at*

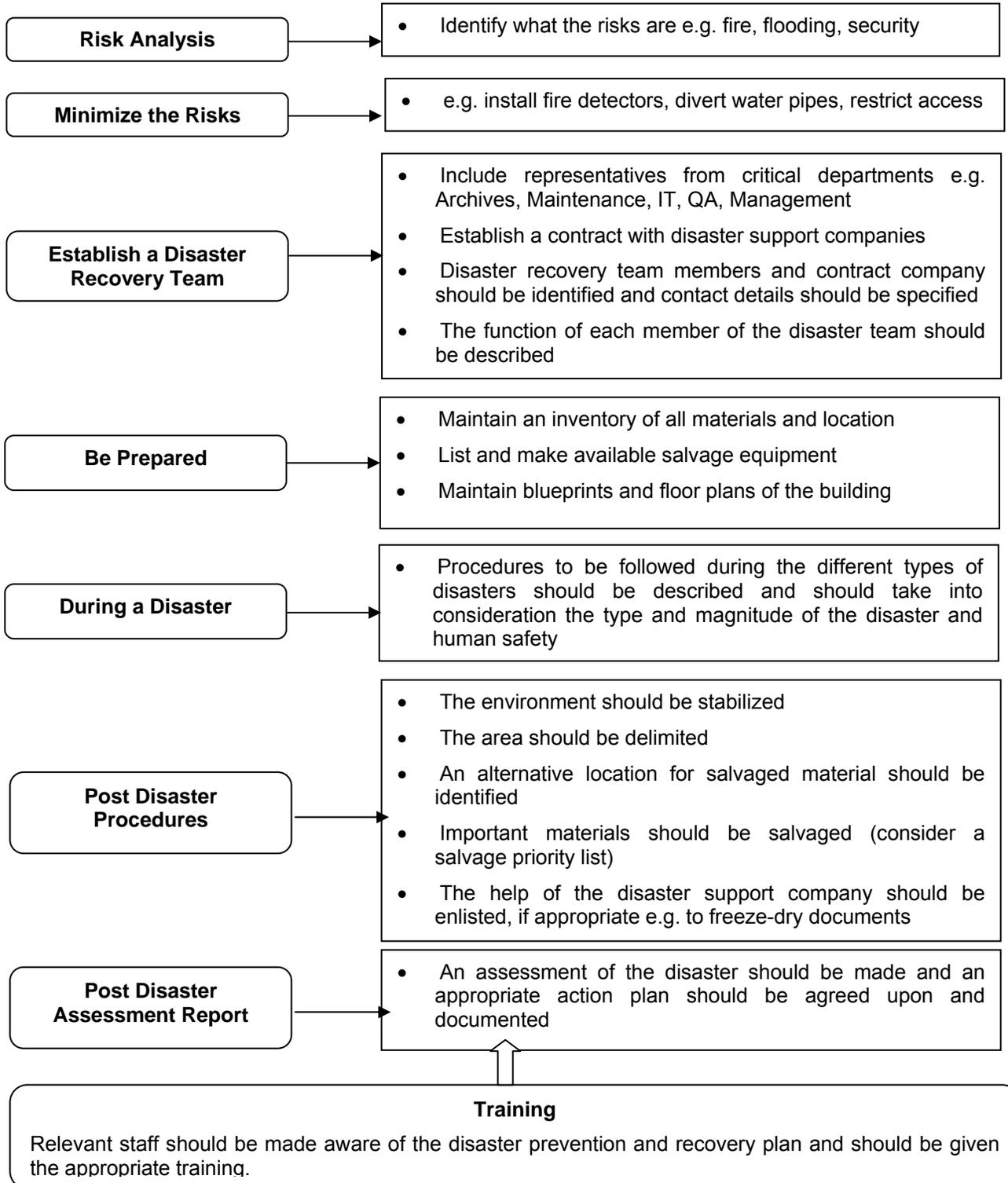
[www.hc-sc.gc.ca/hpfb-gpsa/inspectorate/new\\_e.html](http://www.hc-sc.gc.ca/hpfb-gpsa/inspectorate/new_e.html)



## Points To Consider When Preparing and Implementing a Disaster Prevention and Recovery Plan for the Archives

*Mabel Rusitti, Archives Supervisor and Joanne Tyas, QA Manager - ITR Laboratories Canada, Inc.*

Disaster prevention is an essential part of a good business. The value of a disaster prevention and recovery plan is to provide the ability to react to a disaster efficiently and with speed. Key elements for consideration are detailed below:



## Council on Professional Registration Report – November 2003

**Chair Elect, CPR - Fran Pattillo, RQAP-GLP**

What a wild year! The Council on Professional Registration (CPR) and the Council's Registration Examination Committee has been (un-) believably busy finalizing and offering (via AMP) the first examination that incorporates questions pertaining to the Organization for Economic Cooperation and Development (OECD) Principles of GLPs. The 2003 examination was offered Saturday, October 11, 2003 in Seattle, Chicago, and Montreal. The exam was also offered at the SQA Annual Meeting in Arlington, VA, on Sunday, October 12, 2003. Eighty-nine (89) candidates sat for the 2003 exam, a 46% increase from the year before. Based upon the preliminary results (candidate test results are not yet available), the exam was more difficult than previous exams and had an even higher reliability index than previous exams. Were good, and getting better!

An extra huge THANKS! goes out to the Examination Committee - lead by Linda Massey-Felder, RQAP-GLP, and comprised of Trisha Franz, RQAP-GLP, Missy Miller, RQAP-GLP, Deb Garvin, RQAP-GLP, Judith McDowall, RQAP-GLP, Mary Shawgo, RQAP-GLP, and Kevin Yount, RQAP-GLP. In addition to their 'real day/night jobs,' this group made time to participate in generating one of the best exams since the examination program began 10 years ago. All of the Council Officers also shared in the fun. Alaska, no rest for the "volunteers." With the next SQA Annual Meeting roughly five months away, the CPR has already started putting together the 2004 exam. The 2004 exam will only be offered at the meeting site, Reno, NV, on Saturday, April 24, 2004. For additional details, please visit our site at: <http://www.sqa.org/newsite/cpr/rqapglp-exam.asp>

The site provides the updated "GLP Quality Assurance Professional Registry Examination Candidate Handbook," study references, contact information, etc. Please note that *the deadline for submitting exam applications is February 23, 2004.*

The Registration Examination Committee needs your help! The Committee is in need of additional "volunteers" to help with the facilitation of future examinations. If you're RQAP-GLP certified, and would like to help, please contact Judith McDowall ([jmcdow@biotechnicalservices.com](mailto:jmcdow@biotechnicalservices.com)) directly.

## Council on Professional Registration Report – continued

Re-registration for those QA professionals RQAP-GLP certified after successfully passing either the 1997 or 2000 examination is on going. Out of the 141 individuals due to re-register, to date, 111 (79%) have submitted their re-registration paperwork.

The Council's Nominating Committee is currently putting together a ballot for the 2004 elections. The Membership will be electing a new Chair-Elect and a new Secretary/Treasurer. On January 1, 2004 Fran Pattillo, RQAP-GLP will become the Chair the CPR and Tammy White, RQAP-GLP will become Past Chair. The Council, and the Membership, extends a sincere thanks to Tammy for leading the CPR through a very trying year. The CPR also wants to take this opportunity to thank Gene Burnett, RQAP-GLP (current past chair) and Debra Wallace, RQAP-GLP (current Secretary/Treasurer) for their terms of excellent service on the Council. Any group is only as good as the sum of their members and this crew was truly blessed by all the hard work and dedication of our members.

### **CPR Council:**

**Tammy White, RQAP-GLP**  
Chair, CPR

**Fran Pattillo, RQAP-GLP**  
Chair Elect, CPR

**Debra Wallace, RQAP-GLP**  
Secretary/Treasurer, CPR

**Gene Burnett, RQAP-GLP**  
Past (out in the) Chair, CPR

## Membership Committee Update

**CCSQA Vice President** - Janine Johnson

### Membership by the Numbers:

55 members as of December 31, 2003  
(30 new and 25 renewed)

We did not quite reach our membership goal for 2003 (75) but we are hopeful that as the word gets out we will reach this goal in 2004. Membership renewals will be posted on the CCSQA website in early January. An e-mail prompting you to renew will be sent out once the form has been updated.

**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/>

## 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. Amgen continues to grow with our successes. We currently have the following opportunity at our Thousand Oaks, California facility.

### **GLP Compliance Advisor II**

### **GLP Compliance Advisor III**

Amgen's compensation package features comprehensive benefits and relocation assistance. To apply, please visit the Amgen Career Center at [www.amgen.com](http://www.amgen.com) or email your resume to [smaguire@amgen.com](mailto:smaguire@amgen.com)

The full job posting can also be found on the CCSQA website at [www.ccsqa.org](http://www.ccsqa.org).

## Upcoming CCSQA / SQA Events

### **CCSQA Membership Renewals Due April 30, 2004**

### **SQA's 20<sup>th</sup> Annual Membership Meeting April 25-29, 2004 Reno Hilton, Reno, NV USA**

[http://www.sqa.org/AM2002/Annual\\_mtgs\\_main.htm](http://www.sqa.org/AM2002/Annual_mtgs_main.htm)

*The 20th Annual Meeting of the Society of Quality Assurance will be held in Reno, Nevada in April of 2004. If you are interested in participating in the planning of this historic meeting, please contact either **Moir Bandoli** ([mbandoli@bioanalytical.com](mailto:mbandoli@bioanalytical.com)), 812/985-5900 x 121, Chair of the 2004 Program Committee.*

### **CCSQA Membership Meeting/Training October 2003**

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

## 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](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](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](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/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 Janine Johnson (jjohnson@cato.com):

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