



Newsletter / Journal

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2007 CCSQA Board of Directors

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Vice President: Paul Sidney

Past-President: Deborah Dragoon

Secretary: Joanne Tyas

Treasurer: Janine Johnson

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Michael Maddix

Penny Kirsch

Andrew Hargrave

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Do not hesitate to contact any of the members of the board if you have questions.

www.CCSQA.org

PRESIDENT'S MESSAGE

Greetings! 2007 has been a year of many changes in our profession, and in our relationship with the SQA. The new system of central management of chapter resources at first appeared to present some challenges for us, but with careful negotiation with the very receptive and helpful SQA head office staff, we have worked out an arrangement for our Canadian Chapter that is mutually beneficial. We now have access to more resources for communication while retaining our financial autonomy, unlike our sister chapters in the U.S.

The SQA has now started a new wing of the RQAP designation that is close to my own heart - the RQAP-GCP. There are a growing number of GCP auditors joining the SQA, including within Canada, as the need for QA in clinical research is growing and growing all the time. I am hopeful to see more of our GCP colleagues join the CCSQA as they become aware of the opportunity for professional development that SQA membership can offer them, so that alongside our other GxP QA colleagues, we can work together to uphold the same underlying principles that serve good, ethical science.

The SQA conference is in Austin this year, and since Austin is the "performing music capital of the world", it is appropriate that the theme of this year's conference is "music". We have a good contingent attending from our chapter that will raise awareness of the activities of QA professionals in the great white north.

Our conference this Fall will be again in Montreal, and I look forward to seeing familiar and new faces there!

On a final note, I wish to thank my fellow CCSQA board members for their tireless efforts to support the ongoing growth of our chapter. Truly they are an excellent group of people to work with!

All the best, Andrei

Financial Report

CCSQA Treasurer – Janine Johnson

2006 Beginning Balance \$4,298.21

Income for 2006

2006 Membership dues 61 @ \$20 \$ 1,220.00

Annual Meeting \$ 5,700.00

Job Posting \$ 25.00

US Dollar Credits \$ 21.61

Repayment of Service Fees \$15.00

Total Income: \$ 6,981.61

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2006 Expenses to December 31, 2006

Teleconferencing \$ 559.37

Post Office Box and Postage \$ 183.07

Annual Meeting Expenses \$ 5,049.51

Website Fees \$ 166.89

Bank Fees \$ 1.60

Total Expenses: \$ 5,960.44

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Ending Balance 31 December 2006 \$5,319.38

Past President's Message

As we approach the middle of 2007, let's reflect and think about the direction of our chapter. Our initial goal was to have representation from each province. Our membership has continued to grow (demographics across 7 provinces and 3 states).

Our current leadership comes to you with an impressive GCP background. One of the Board Members is a GMP auditor. As we move forward, let's continue with the established diversity.

International chapters are initiating in other countries. These chapters are looking for advice from our experience. One of our key initiatives from this past year has been to establish a GLP Monitoring Authority in Canada. Mr. Paul Sidney has been instrumental in establishing initial contacts to achieve this goal. Establishing a GLP Monitoring Authority will meet one of the EMEA requirements thereby giving Canadian research a better name.

Support the chapter by volunteering. Share your expertise with your peers. Dr. Brennan and the Board are open to your suggestions.

Deborah Dragoon

DID YOU HEAR ???

If you did, please let us know so we can share with the group.



Canada Quiz

1. What is the capital of Yukon?
2. Who was the first Prime-minister of Canada?
3. Who wrote Anne of Green Gables?
4. In which Ontario city would you find "the big nickel"?
5. What is Canada's smallest province?
6. This Canadian invented the snowmobile?
7. What is the name of the vast treeless area in Canada's north?
8. She became the first woman to lead the new democratic party?
9. One branch of the Canadian government is called the house of commons, what is the other branch called?
10. This portion of mainland Canada is part of the province of Newfoundland?

Answers on the last page
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Canadian Personal Information Protection and Electronic Documents Act (PIPEDA)

Janine Johnson, GlaxoSmithKline
Biologicals North America

- Effective: January 1, 2004
- PIPEDA is similar but not equivalent to HIPAA (US)
- It governs privacy of all personal information collected and distributed within and across provincial borders.

EXCEPTIONS:

- As of December 2003 Quebec Privacy Law has been officially promulgated as the governing law for collection, use and distribution of personal information within Quebec.
- As of October 2004 the Personal Information Protection Acts of British Columbia and Alberta has been officially promulgated as the governing law for personal information within their respective provincial borders.
- As of November 2005 the Personal Information Protection Acts of Ontario has been officially promulgated as the governing law for personal information within their respective provincial borders.

Distribution of personal information outside of these Provinces and for all other Canadian Provinces must follow PIPEDA, which is based on 10 guiding principles taken from the Canadian Standards Association Model Code for the Protection of Personal Information which has been a recognized national standard since 1996. The following is a paraphrase of those principles with my personal interpretation of how it affects us.

Principle 1: Accountability

"An organization is responsible for personal information under its control and shall designate an individual or individuals who are accountable for the organization's compliance with established privacy principles"

Interpretation: The organization should assign a person responsible for privacy (senior management level) and then have location specific contacts, if the company has offices in more than one province

Principle 2: Identifying Purposes

"The purpose for which personal information is collected shall be identified by the organization at or before the time the information is collected"

In defining purpose the following should be considered: What information is gathered and why; how information is handled and used; and when, how, and why information is available to third parties.

Principle 3: Consent

"The knowledge and informed consent of the individual are required for the collection, use, or disclosure of personal information, except where exempted by law". This consent may include both explicit and implied forms of consent.

Interpretation: Signing a contract, non-disclosure agreement or informed consent is explicit, whereas submitting a CV for consideration for an open job posting would be implied consent for that purpose. All disclosures of medical information require an explicit consent.

Principle 4: Limiting Collection

"The collection of personal information shall be limited to that which is necessary for the purposes identified by the organization. Information shall be collected by fair and lawful means."

Principle 5: Limiting Use, Disclosure and Retention

"Personal information shall not be used or disclosed for purposes other than those for which it was collected, except with the informed consent of the individual or as required by law. Personal information shall be retained only as long as necessary for the fulfillment of those purposes."

Interpretation: All employees and business associates should be trained on the policy, and to be careful about inadvertent disclosure of personal information. (Sources of non-intended disclosure: faxes, e-mails)

Principle 6: Accuracy

"Personal information shall be as accurate, complete, and up-to-date as is necessary for the purposes for which it is to be used."

Interpretation: The best example where this would have the most affect is maintaining a database of information containing personal information. If we do disclose information we need to ensure the information disclosed is current. (Limiting the information - principle 4 - collected would reduce the amount of effort in maintaining accuracy.) A risk assessment as to what harm would be caused by the disclosure of inaccurate information should be performed when designing databases.

Principle 7: Safeguards

"Personal Information shall be protected by security safeguards appropriate to the sensitivity of the information"

Interpretation: Electronic and physical safeguards of information. The biggest threat for inadvertent disclosure is though sending personal information via e-mail without an encryption. Our biggest hole for physical disclosure and inadvertent destruction is through the use of off-site storage and storage of clinical trial information in our offices. We need to assess the sensitivity of the personal information collected and ensure that the most sensitive information has appropriate safeguards applied either through electronic encryption or by not storing this information at an off-site facility or in our unlocked offices.

Principle 8: Openness

"An organization shall make readily available to individuals specific information about its policies and practices relating to the management of personal information."

Interpretation: A privacy policy must include who is the company designated privacy contact so that anyone who is interested in our policy can ask questions on how they can see the personal information we have on them, what information we have, how we use that information, and who has access to their information. The privacy policy must be made publicly available. Certain companies are posting their policy on their webpage or are sending brochures to their clients.

Principle 9: Individual Access

"Upon request, an individual shall be informed of the existence, use, and disclosure of his or her personal information and shall be given access to that information. An individual shall be able to challenge the accuracy and completeness of the information and have it amended as appropriate."

There are certain exemptions to this in the regulation, such as for a child under 14 and for information being used in a legal proceeding...

Principle 10: Challenging Compliance

"An individual shall be able to address a challenge concerning compliance with the above principles to the designated individual or individuals accountable for the organization's compliance."

Interpretation: A process to address challenges to the policy should be defined in the policy document. Hopefully this will never happen, but if it does the privacy contact should know what steps they need to take to resolve it.

- **Enforcement:** Usually a company will only be investigated if a complaint is made to the privacy commissioner of Canada.
- The Commissioner cannot impose fines for contraventions. However, the Federal Court, which is the next level of review, has the power to award damages to a complainant.
- Fines for violation under Quebec law are from 1-20K and the individual identified in an organization as responsible could also be held legally liable.

For more information go to:
http://www.privcom.gc.ca/index_e.asp

CCSQA Membership Renewals are Due !!!

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

OR contact Janine at janine.j.johnson@gskbio.com

Upcoming CCSQA / SQA Events**SQA's 23rd Annual Meeting**
<http://www.sqa.org>

The 23rd Annual Meeting of the Society of Quality Assurance will be held in Austin, Texas in April 2007

Watch for news this summer on the CCSQA annual meeting.

Comments & Contributions

Please forward any comments or contributions for the CCSQA Newsletter to Deborah Dragoon

[\(dragood@wyeth.com\)](mailto:dragood@wyeth.com)

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

Answers to Canada Quiz

1. Whitehorse
2. John A. Macdonald
3. Lucy Maud Montgomery
4. Sudbury
5. PEI
6. Armand Bombardier
7. Tundra
8. Audrey McLaughlin
9. The Senate
10. Labrador