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

Newsletter / Journal

Volume 4, Issue 1 July 2005

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2005 CCSQA Board of Directors

Anne Beaubien - Envirotest Laboratories - President

Janine Johnson – Cato Research - Past-President

Deborah Dragoon – Wyeth – Vice-President

Penny Kirsch - Envirotest Laboratories - Treasurer

Joanne Tyas – ITR Lab - Secretary

Michael Maddix - Wyeth - Director
David Gregoire- Pharmascience - Director
Shelley Antel – Genetech - Director
Paul Sidney – Charles River Laboratories, Preclinical CTBR - Director

President's Message

Anne Beaubien

I would like to take this time to thank everyone for renewing your membership or signing up for a first time. We are a small group but a very enthusiastic one. This was most evident at the SQA conference in Orlando, Florida. Canadians definitely had a presence, the largest I think I have ever seen before. I am sorry if I was unable to talk to you or introduce myself. We had a table at the World Fair with a great crossword puzzle as well as pin the tail on the beaver. It is amazing the number of people that have never played the game, most noticeably our fellow QA attendees from Asia. They loved our prizes and the great maple syrup candies.

This fall our chapter is going to be presenting our own conference with what we hope will be topics of interest to Canadians from a Canadian perspective. I am amazed at the hard work the committee is doing and the time that everyone is putting in. I hope you show your appreciation by attending it.

We want to have our members benefit from being a member and the only way we can do that is if we know how you feel. Please give us any feedback on what we need to improve upon, what you would like to see or just to give us a pat on the back.

Send your comments to anneb@envirotest.com

Financial Report

CCSQA Treasurer – Penny Kirsch

December 20, 2004 Balance 3297.39

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Income

$1029.16 - Membership renewals

Expenses

$40.09 Accutel Conferencing Systems

$211.33 Bell Conferecing Inc.

$198.03 SQA Meeting Expenses

$119.63 PO Box

TOTAL **$569.08**

May 20, 2005 Balance $3757.47

DID YOU HEAR ???

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

Joint Chapter Meeting Invitation

Please join the Pacific and Rocky Mountain Regional Chapters of the Society of Quality Assurance for their joint charter meeting, Don't Gamble on Compliance!, Las Vegas, NV Sept. 26 - 27, 2005.

The Pacific and Rocky Mountain chapters have joined ranks to produce an outstanding educational opportunity. Don't Gamble on Compliance!, joint chapter meeting, will be held at The Tropicana Resort and Casino, located in the heart of the famous Las Vegas Strip, on September 26 - 27, 2005.

This outstanding educational opportunity of two full days of GLP and GCP presentations are planned on topics such as equipment validation, scientific and regulatory GLP/GCP issues, a holistic approach to compliance, review of regulatory 'gray areas', facility inspections, medical devices, multi-site studies, roles of study directors and contributing scientists, perspectives from a recent FDA inspection, and ethics. Two regulatory agency (FDA) speakers have been confirmed.

This Pacific and Rocky Mountain Regional Chapters joint chapter meeting promises to be an exceptional experience, in the city of exceptional experiences, Las Vegas. The joint chapters invite all to plan on attending this outstanding educational opportunity, at The Tropicana Resort and Casino, located in the heart of the famous Las Vegas Strip on September 26 - 27, 2005.

For meeting information and reservations, contact Michelle Seary at: mrse@chevrontexaco.com or call 510-242-2067

For reservations at The Tropicana Resort and Casino, http://www.tropicanalv.com or call 1-800-634-4000 Ask for the PRCSQA/RMRCSQA Fall Meeting rate.

NAICC – National Alliance of Independent Crop Consultants annual meeting report.

Keith Burch, *Tech Ag*. ICMS Inc. QA

I decided this year to attend the NAICC annual convention held in Los Angeles, instead of attending SQA in Florida. As it turned out, the dates for SQA conflicted with a previous engagement. (Our band Strange Brew II was playing for a Rotary Convention) and just ask my wife, she will tell you that "The band comes first…." And that isn't usually spoken in the nicest tone of voice….

The NAICC convention is run very much like SQA convention with training on the days just prior to the convention. On Monday Jan 17th there was an all day training session on dangerous goods. On Tuesday the 18th again dangerous goods training and there was also Quality Assurance training presented by Renee Daniel of Perspective Consulting. Wednesday Jan 19th there were committee and board meetings, workshops on computer programs for Ag research, moderator workshops and again dangerous goods training. You can see that crop researchers and consultants have to deal with more and more regulations to be able to handle dangerous goods. We in Canada must be aware of the rules when sending materials across the border.

The convention started Jan 20th with quite a variety of sessions that you could pick with most sessions split for consultants or researchers. Francisca Liem from the USEPA was one of the first speakers for the researchers session as regulatory issues is very much a concern for all Ag Professionals. Following Francisca was a presentation of the proposed changes to APHIS Crop Regulations by John Turner of the USDA. There were many other sessions dealing with crop pest detection, protection and environment issues.

January 21st brought a host of sessions covering adjuvants, to air application, to soil chemistry and management, food safety and anatomy of a lawsuit.

Gary Coukell seen here,

general manager of ICMS Inc. was the moderator for the afternoon researchers session on; recording devices, improved sampling methods in field soil dissipation studies and measuring instruments for agriculture. There was also a session on managing employees and an ethics session.

The last day, Jan 22 was a half-day with round table discussions. There was also a session on Excel training by Dr. Charles Green. More and more studies are going to electronic data. But some companies are still using paper but having data transcribed to electronic to facilitate updating the Study Director and early preparation of final reports. This data is considered supplemental data but we as QA may have to audit it as well.

One of the main reasons I wanted to attend NAICC was to meet many of the Study Directors that I send my reports to. There were also a lot of QA people from various companies as well. We had our company trade booth there which gave us an excellent opportunity to network with a lot of clients and sponsor companies. If you want more information on the speakers and program NAICC will soon have the proceedings posted on their web site at www.naicc.org

I feel it's important to be involved in as many aspects of this profession as possible and I do enjoy and will continue to attend the SQA meetings where we may learn more QA skills and to interact with peers.

I also find the CCSQA meetings that we have had in Ottawa the last two years very informative. The smaller group setting is an excellent setting to have everyone interact with each other and the presenters. I look forward to seeing you all at our next CCSQA meeting.

….Keith

Membership Committee Update

CCSQA Past President - Janine Johnson

Membership by the Numbers:

57 members as of 03 June 2005 (15 new and 42 renewed)

CCSQA Membership Renewals are Due !!!

The new member and renewal forms can be found on the CCSQA website **www.ccsqa.org**

Upcoming CCSQA / SQA Events

CCSQA Membership Meeting/Training

September 30/October 1, 2005 in Montréal, PQ

The 3rd Annual Meeting of the Canadian Chapter of the Society of Quality Assurance will be held in Montreal at the Holiday Inn Dorval Airport on 30 September and 1 0ctober 2005. If you are interested in participating in the planning of this meeting, please contact the chair of the annual meeting program committee, ***Janine Johnson*** *at* jjohnson@cato.com ***or 514-856-2286 x 259.***

SQA's 22nd Annual Membership Meeting

http://www.sqa.org

The 22nd Annual Meeting of the Society of Quality Assurance will be held in Phoenix, Arizona in April 2006 . If you are interested in participating in the planning of this historic meeting, please contact Hugh Hauser hugh.hauser@covance.com (608)242-2618 or MaryEllen Lander lander.Maryellen@endo.com (610)558-9800 ext. 4218,
Co-Chairs of the 2006 Program Committee.

JOB POSTINGS

QA AUDITOR

The successful candidate will be responsible for performing QA related functions and ensures compliance with applicable regulations. Duties will include: conducts internal QA inspections; conduct study, process/method and facility based audit and audit study plans, raw data and final reports. Monitor corrective actions identified during audits, maintain inspection/audit records, and maintain control documentation.

The successful candidate must have a minimum B.Sc. in scientific discipline, preferably in Chemistry and a minimum of 3 years laboratory experience. Knowledge of GLP, GCP and SCC/CAEAL (ISO/IEC 17025) regulations would be an asset. Excellent written and communication skills, detail-oriented are necessary. You must be able to work independently and as a team.

Interested candidates may submit resumes and applications to Human Resources Department @resumes@cantest.com.

We would like to take this opportunity to thank all candidates for applying, however, only suitable candidates will be contacted.

CANTEST is a full service analytical laboratory company specializing in environmental, food, industrial, bioanalytical and animal forensic drug testing. The head office is located in the 50,000 square foot CANTEST Life Sciences Centre in Burnaby, BC – the largest of it's kind in the province with over 200 professional and support staff.

CANTEST has a 35 year history of providing professional services to a wide variety of private and public sector organizations. The company is 100% Canadian, employee owned and well positioned for growth.

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

A CRITICAL ROLE, A VITAL MISSION.

Ottawa. **Canadian Blood Services** (CBS) ensures all Canadians have access to a safe, secure, and affordable supply of quality blood, blood products and alternatives. With over 4,440 employees and 17,000 volunteers coast to coast, CBS collects approximately 850,000 units of blood annually and processes it into the components and products that are administered to thousands of patients each year. CBS is currently seeking a **Director of Quality Systems Support** and a **Director of Quality Assurance**.

Executive Director, Quality Systems Support

In this position, you will provide leadership, management and direction in the development, application, and improvement of quality systems and programs. As the ideal candidate, you have a University degree in a related discipline and at least 12 years of progressive management experience in the operations or quality field of a pharmaceutical or other Health Canada regulated industry. You have demonstrated expertise in the development, implementation, monitoring and improvement of a quality management system in a stringent regulatory environment. You possess strong interpersonal and communication skills, strong organizational and management skills, an ability to investigate and troubleshoot, and have an excellent grasp of risk management.

Director, Quality Assurance

In this position, you will play a key role in providing leadership, direction and support in the design, implementation and monitoring of the performance of quality assurance activities across the organization. Working with sites across the country, you will ensure that systems and processes are developed, implemented, maintained and improved in accordance with CBS' rigorous quality, regulatory and legislative standards requirements. You will also be responsible for ensuring ongoing compliance for CBS' quality assurance activities, training, and monitoring of performance indicators. As the ideal candidate, your academic background in pharmacy or biological sciences, combined with significant experience in developing and implementing a quality assurance program in life sciences manufacturing, have prepared you well for this position. Your superb communications, team building and critical thinking skills will make you a success.

To explore either of these opportunities, please contact Doug Tetzner in our Ottawa office at (613) 742-3205 or forward your resume in confidence to doug.tetzner@rayberndtson.ca

MDS Pharma Services

Computer Validation Specialist

As the computer validation specialist, you will produce and execute plans to audit computerized systems at MDS Pharma Services, as assigned and assure completion of these projects on scheduled time.

Your main responsibilities will include:

- Performing audits of computerized systems and related validation deliverables in order to identify deviations and potential problems according to SOPs, company standards, rules and regulations
- Performing internal, process or supplier audits
- Perform audit for other business units or for third parties
- Evaluate changes to systems and their related risks
- Training on computer system validation and on computer system related rules and regulations

To qualify you must possess:

- B.Sc. in Computer Science or in a relevant scientific field (Engineering, chemistry, biochemistry, etc.) or Certificate in IS, MIS, Programming or Computer Analyst, with a strong background in quality assurance.
- Minimum of five years experience in computer system validation or computer system quality assurance or software quality assurance, or a combination of those fields acquired in a regulated environment.

Skills:

You must have excellent interpersonal and strong leadership skills. You must be assertive, organized and very thorough as well as keeping calm under pressure by working under tight deadlines. Extensive knowledge of CRO related regulations (GCP; GLP; FDA; ICH…) including 21 CFR Part 11 are required. Excellent written and spoken English and French is an asset. You must be able to work occasional overtime hours if required and must be willing to travel.

Please send your resume to:

Isabelle Acoca
Talent Sourcing Consultant
isabelle.acoca@mdsinc.com
www.mdsintl.com

MDS Pharma Services is an equal opportunity employer that offers a competitive "value proposition" which includes Employee Share Ownership Plan, Retirement Program, Flex Benefits Program, Recognition, Training, etc. Only selected candidates will be contacted.

MDS Pharma Services

Quality Assurance Auditor, Quality Assurance

Under the guidance of the Supervisor, Quality Assurance, the role of the Auditor is to ensure compliance to protocols, SOPs and applicable regulations, through audits of scientific records and inspections of studies in progress.

Your main responsibilities will include:

- Auditing reports to assure that the results accurately reflect the raw data generated during the study.
- Ensuring consistency of data handling/reporting throughout the project.
- Ensuring consistency in application of scientific standards across the company.
- Contributing to the QA Monthly report by highlighting all significant findings in QA reports.
- Interacting with internal clients to discuss QA observations and study related issues.
- Ensuring that study timelines are met.

To qualify you must possess:

- B.Sc. in Chemistry, Biochemistry, or a related field
- Two to three years experience in a chromatographic analysis laboratory is required

We are looking for a detail-oriented and autonomous person. Excellent effective communication skills are necessary in matters of being tactful and diplomatic yet remaining firm.
Knowledge of statistical and chromatographic methods, GLP regulations and guidelines are critical for this role. Excellent written and spoken English is necessary; functional knowledge of French.

Please send your resume to:
Isabelle Acoca
Talent Sourcing Consultant
isabelle.acoca@mdsinc.com

MDS Pharma Services is an equal opportunity employer that offers a competitive "value proposition" which includes Employee Share Ownership Plan, Retirement Program, Flex Benefits Program, Recognition, Training, etc. Only selected candidates will be contacted.

A BRIEF SUMMARY of the EUROPEAN UNION (EU) and the EUROPEAN MEDICINES EVALUATION AGENCY (EMEA)
(Submitted by: Joanne Tyas and Rowena Franklin of ITR)

The European Union (EU) was established in the 1950s, after the Second World War, with the objective of bringing peace, stability and prosperity to the countries of Europe (http://europa.eu.int/index_en.htm).

Initially, the EU consisted of six European countries but several countries have joined since this time with the current members of the EU being highlighted in yellow on the map.

Source (http://europa.eu.int/index_en.htm).

The European Agency for the Evaluation of Medicinal Products (EMEA) coordinates the evaluation and supervision of medicinal products for human and veterinary use throughout the EU. It provides a centralized mutual recognition procedure through which companies can submit one single marketing authorization application, which, if approved, will be valid for all of the countries of the EU (http://www.emea.eu.int/).

Within the EMEA is the Agency's Inspections Sector. The Inspections Sector is responsible for co-coordinating any GMP, GCP or GLP inspections requested by the relevant committees of the EMEA marketing authorization applications and accordance with Community legislation (http://www.emea.eu.int/Inspections/index.html).

As part of its duties, the Inspections Sector operates a sampling and testing program, coordinates communication and action in response to suspected quality defects relating to centrally authorized medicines, and issues officially recognized certificates for medicinal products to confirm the status of centrally authorized medicinal products and the GMP compliance of their manufacturing sites. The Inspection Sector also mediates between Member States by chairing meetings of EU GCP and GMP inspectors and is involved in activities between various organizations from the European Community and non-European countries, which are designed to promote harmonization in application procedures and augment inter-market access (http://www.emea.eu.int/Inspections/index.html).

For more information on the EU and the EMEA, please visit the websites referenced in the text above.

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.

2005 Membership Listing Erratum

From:

Mrs. Sandra Milovic
E-mail: sandra.milovic@mdsinc.com

To:

Mrs. Sandra Milkovic
E-mail: sandra.milkovic@mdsinc.com

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

Comments & Contributions

Please forward any comments or contributions for the CCSQA Newsletter to Deborah Dragoon (dragood@wyeth.com):

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