CCSQA Newsletter

Northern Hemispheres

Volume 1, Issue 1 Newsletter Date June, 2009

Inside this issue:

Special points of interest:

- *Advertise with CCSQA*
- *Send us your suggestions and comments for future articles*
- *Suggest the CCSQA membership to your colleagues to spread the word. Also membership to the CCSQA gives you 1 point towards your RQAP.*

Message from the President

Greetings fellow members of the CCSQA! It is now summertime and not only are all the plants and trees back to life but we are bringing back to life a couple of essential communication tools for the membership.

My primary objective as president was to ensure that the membership receives value for their dues. So firstly, as you can see this newsletter has been reborn! It has been awhile since one was published but it was a goal of ours at the CCSQA board to make sure that we publish information to the membership on a regular basis.

Inside this newsletter you will find information about the current Board of Directors; who we are and how you can reach us. There is also an update on GLP monitoring in Canada that we first learned about last year at the fall meeting. We also have included information about some future meetings: the International Global Regulatory Compliance Challenge Symposium sponsored by the Regulatory Forum of the SQA and our annual Chapter meeting that will be held this November – mark your calendars!

One of the objectives of this newsletter is to provide a space for articles that would be of interest to the QA professional. So in this edition we have articles on laboratory accreditation and ISR; two very current and important topics in our industry. I hope you will find these articles interesting and useful so as to encourage you to want to share your experiences or information and contribute an article for upcoming editions.

Last but certainly not least, there is up to date information about the changes that are being made to update the chapter's web-site. We hope that once updated you will bookmark this site and make it your primary choice when seeking information that will help you as a Canadian QA Professional.

As you can see we have been busy with some things to ensure that we can provide advantages for being a CCSQA member. We are not at rest and will continue to work hard for the members. We also welcome participation; you have our contact information on page two so please don't hesitate to lets us know what you think and if you have any suggestions for us.

Please enjoy the read and we will touch bases again in the fall.

Canadian Chapter of the Society of Quality Assurance

CCSQA

FCSQA

Filiale Canadienne de la Society of Quality Assurance

Meet your CCSQA Board

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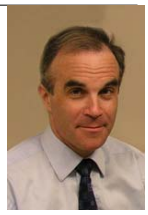

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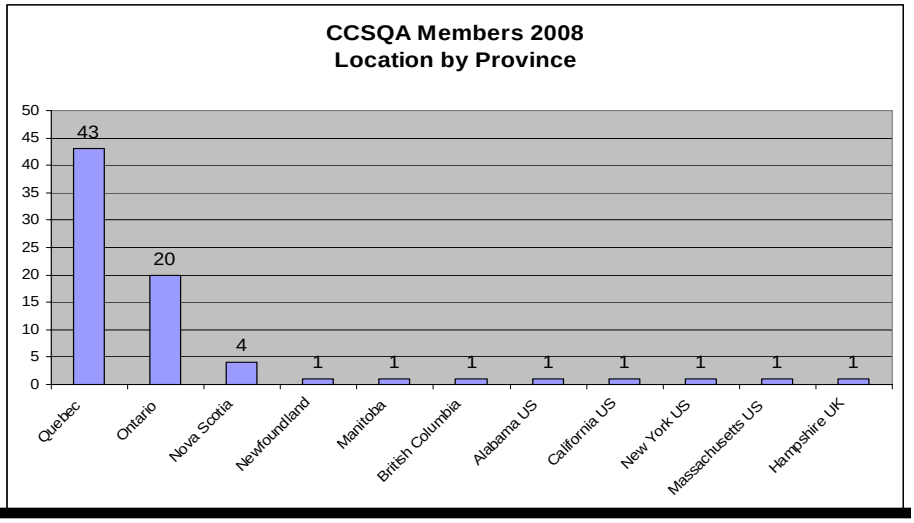
Did you know? The CCSQA has members from all across Canada and even in the USA!



CCSQA Website is on the move!

The CCSQA Board is working very closely with the SQA to produce and update a new and fresh website for our members. Details to follow soon. Our goal is to provide an up to date tool that all members can access to obtain information, post articles or job openings, ask questions, and bring all of us closer together. As Canadians, we are lucky to have a large and spacious country however it does present its challenges and our members span from the pacific west coast to Atlantic Canada. The Website will allow all members to communicate easier and have the latest information.

Once we have details on the new website and its implementation, we will distribute the news to all members right away.

"Experience is the name that everyone gives to their mistakes" Oscar Wilde

Canadian Monitoring Authority Update

As was presented at the fall chapter meeting last year, Health Canada is moving ahead and developing a system for GLP monitoring for both pharmaceutical and biotech products.

There has been significant progress made, but information isn't yet ready to be released for consultation. The directive is being evaluated by the Therapeutic Drugs Directorate and Biologics and Genetic Therapies Directorate, and hopefully it will be approved in the very short term and that a Minister-sanctioned announcement will be made very soon.

One of the possibilities for monitoring GLP may be through the Standards Council of Canada's PALCAN GLP certification program. This program is currently the only GLPMA in Canada at the moment.

Once we receive any news about this we will pass it along to the membership – stay tuned.

Did you know? Your membership to the CCSQA counts as 1 point towards your RQAP

Accreditation to ISO15189 to Harmonize Laboratory Testing

Studies show that roughly 70% of medical decisions are based on laboratory testing results. Physicians use these results to make diagnosis and decide treatment options. Therefore private and public laboratories must ensure precision and accuracy for all patient testing.

Accreditation agencies such as the CAP (College of American Pathologists) certify laboratories in the world with their strict standards however are not mandatory in Canada for laboratory testing. In the USA, they have been approved to accredited laboratories for CLIA (clinical laboratory improvement act). The CLIA is the regulations from the FDA specifically relating to clinical laboratory testing in the US.

Ontario was the first province to mandate its private and public laboratories to an ISO standard of quality for medical testing (ISO 15189).

The Canadian Ministry of Health issued a directive in 2005 that by December 2008, all hospital and private biomedical laboratories in Quebec should be accredited according to ISO15189. This has since been extended.

Many laboratories in other provinces are not waiting for the mandatory licensing and are working towards ISO 15189 currently.

The ISO 15189 requires specific standards of quality to include SOPs, validation, proficiency testing, quality assurance, and training among others.

These requirements will ensure quality standards across all biomedical laboratories and subsequently, accurate testing for all of us!

CCSQA Fall Annual Meeting and Training Sessions

The CCSQA Fall meeting is already in the planning stage. Yes, we know summer is already coming fast and now you are finally getting to enjoy the nice weather but your CCSQA board is working hard to plan the fall meeting.

It will be held in November in Montreal. Our membership is scattered, and since Canada is such a large country we are trying to focus on the areas where we have the most member volume so it will be easier to attend. No worries for our west and east coast friends, we are working hard to initiate a web conference, where you will be able to attend by webinar. If this is a success it will allow members of the society to attend from all areas of this wonderful country. News of this will be posted soon.

We need you to help make this meeting a success. We encourage everyone and anyone to volunteer to become a speaker to share you areas of expertise and experience! If you volunteer and are selected as a speaker, you will receive entrance to the meeting free of charge!

If you or someone you know would be interested in speaking, contact a member of the CCSQA board.

Remember the success of this meeting is a result of all of us working together as one society.

Did you know?

In 2007, the FDA's CDER (Center for Drug Evaluation and Research) recalled a total of 988 products? www.FDA.gov/FY07 FDA Recalls all classes.pdf

AAPS Annual Meeting Update and ISR

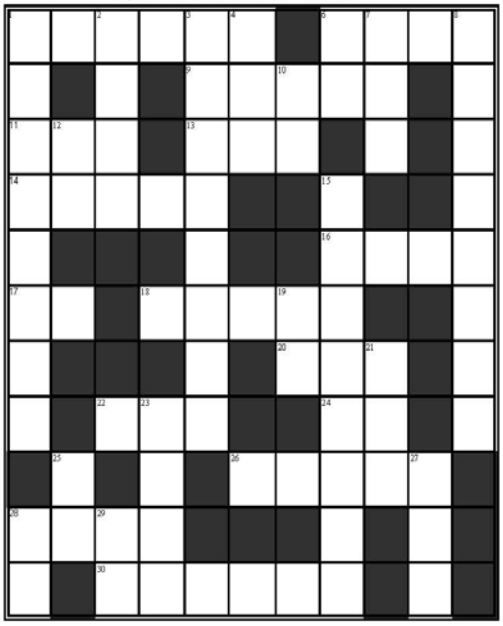
The AAPS annual meeting was held in Crystal City in February 2008 and one of the main key topics that year were ISR (Incurred Sample Reanalysis). ISR is the measurement of the active product in incurred (natural) samples. The FDA's point of view is that spiking a matrix with a test article (to prepare Quality Controls that are used in validation) may not exactly mimic the actual sample conditions that are found in incurred samples. The human body metabolizes and creates additional challenges that spiking in pure matrix may not capture. It was found in FDA submissions that in multiple studies, the validations may have been executed flawlessly, however when sample analysis was initiated, the method was not precise and accurate. Therefore the FDA is now requesting that in study sample analysis reproducibility is now tested. The AAPS conference focused on this issue and how the industry is making this happen. It is an FDA expectation that this will be done according to the speakers at the AAPS conference. The FDA has not published any official regulation or guidance on this at this moment. The industry consensus is that the ISR should be performed at least once for each animal species per method for toxicology studies and for each and every clinical study per method. The typical % of ISR samples that are to be tested according to the speakers is at least 5% of the study samples. There are alternative approaches that were discussed of how to do this, the majority of speakers indicated a preference to do the ISR analysis on an ongoing basis. Meaning as you analyze samples from one batch, you will randomly insert repeat samples from your previous batch. This way you will be able to measure the ISR reproducibility on an ongoing basis. The acceptance criteria is the ISR results must match the original results by ≤20% for small molecule and ≤30% for large molecules for each sample repeat. In addition, overall (the total of the ISR analysis when tabulated at the study conclusion), at least 80%(small molecule) or 70% (large molecule) of your repeated samples must be within this criteria.

There was much discussion on where these results are to be presented (whether in the validation report or sample analysis report). There was no clear answer, however the preference was in the sample analysis report. You will have to define in your SOPs how you will report this data. Whatever you decide to do at your organization, this must be predefined and documented. It is now an expectation of the industry for all Bioanalysis.

CCSQA FUN PAGE

Cross Word Puzzle (For beginners!)

QAU Crossword- Have Fun!!!



answers are available on last page

Across

1 Non-Regulatory procedural document
6 Regulated Procedures to follow
9 beads are sometimes coated with this...type of patio furniture
11 acronym for occupational health and safety
13 hospitals will soon require this accreditation (15189)
14 type of reward
16 sites will use this to collect specimens (2 words)
17 Chartered Accountant Accronym
18 all data needs to have this to be traceable
20 synonym for zero
22 regulatory body
24 complete an action
26 the GLPs were created to prevent this
28 (french) word used in finance
30 passwords and IDs are required to ensure the system is ___

Down

1 GLP studies require this document
2 if you don't win then you ___
3 these need to be established proir to analysis
4 do you have to write in pen?
6 (spanish) positive
7 The number of lines you put through the original data to do a GLP correction
8 labelled with conc, expiry date, + storage, according to GLPs
10 In the words of Star Trek's Captain Jean Luc Picard:"make it ___"
12 A department to help the employees and manage benefits
15 need to do this for equipment and methods
19 opposite of out
21 acronym for a marketing term
23 all authentication requires initials and this
25 acronym for a finance term
27 congress association for several pharmas and biotechs
28 when you want to carbon copy someone this is what you do
29 more than one person

How well do you know this Country?

1. Which Canadian province has the largest area?

2. This animal is Canada's national emblem?

3. What is the highest mountain in Canada?

4. This Italian explorer is credited with discovering Newfoundland around 1497A.D.?

5. What is Canada's most southernmost point?

6. This province is Canada's most densely populated?

7. What is the largest bay in Canada?

8. These French islands are located just south of Newfoundland?

9. In what year did Canada celebrate its 100th birthday?

10. Which province do we associate with the Douglas Fir?

Answers on back

"Time is that quality of nature that keeps events from happening all at once… Lately it doesn't seem to be working!" ***Anonymous***

Want to join the fun? Email me your quiz, puzzle or cartoon and it can go in the next CCSQA Northern Hemispheres Edition!!

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Quality Checklists: Friend or Foe

The use of checklists may be a QA auditor's best friend. They provide standardization for audits, ensuring all audits and inspections focus on the key areas and points of the GLPs and GCPs that are followed.

They are also very good training tools, a new auditor will feel at ease following his or her checklist knowing that he or she will not miss any key points.

Checklists may also narrow the scope of the audit if they are used too strictly. Remember that the regulations are never black and white. There may be situations that arise that are not part of the checklist and need to be audited.

Therefore when checklists are used, they must be used as part of an entire audit process which extends far beyond the checklist questions.

An auditor must observe, ask, listen and use all their senses to see what is around them and not only what the clipboard tells them to look at.

This comes with experience. As you grow as an auditor you will be able to use the checklists as a guide but most of all, use your senses and experience to observe, ask and note down observations.

This will ensure that the checklists will be used to their full potential, and not as a crutch.

Did you know? On 30 June 1906, President Roosevelt signed the Food and Drugs Act, which allowed the law to seize any unlawful food and drugs that did not meet applicable standards?

RQAP-GLP Examination

The CCSQA is happy to announce that the RQAP-GLP exam will be held this October at Concordia University in Montreal.

Further information regarding the RQAP (Registered Quality Assurance Professional) in GLPs is available on the SQA website. In brief this exam is written to cover all areas of the GLPs including the FDA, EMEA, OECD, FIFRA, EPA regulations among other topics.

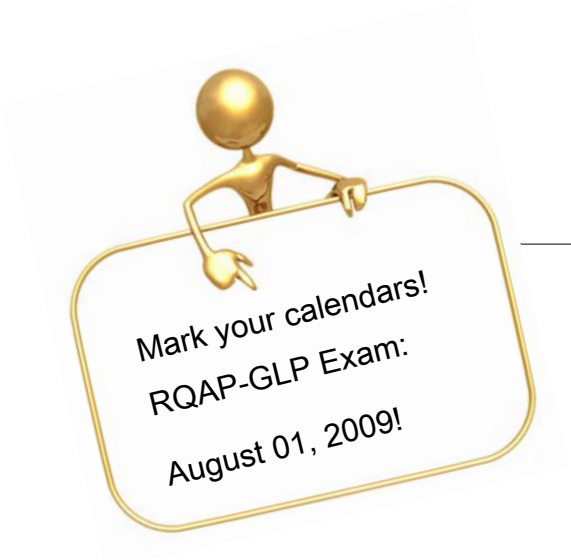
The study guide is available on the SQA website with details of what you should know. The RQAP also offers certification in GCPs.

The RQAP-GLP exam will be on August 01, 2009 in Montreal and will be paper based. The SQA also offers electronic exams in other locations.

You need to send your application to apply by June 27th.

There will also be a second location in October, just prior to the Global Regulatory Compliance Challenges symposium (see opposite page). This second exam session, will be paper based and offered on 17 October, 2009. Applications for the exam held in Philadelphia must be received by September 01.

For the Montreal RQAP-GLP exam, applications must be postmarked to the SQA prior to June 27th, 2009. Applications should not be sent to the CCSQA.



Society of Quality Assurance
Promoting Quality in the Regulated Research Community

Global Regulatory Compliance Challenges

A symposium sponsored by the Regulatory Forum of SQA

26-27 October 2009, Philadelphia, PA USA

Globalization heightens the need for an understanding of the regulatory framework and of achieving compliance in all corners of the world.

This symposium will explore global compliance issues encountered by regulators and the regulated community, with a focus on interactions with countries that are not members of the OECD, e.g., China, India, South American countries. Using real-life situations to illustrate the lessons learned and paths toward global regulatory compliance, the symposium will include formal presentations and interactive sessions about cultural and language challenges and compliance issues.

Topics will include, but are not limited to the following:

- **Understanding multisite study compliance across borders and continents;**
- **Establishing a GLP laboratory and achieving GLP certification;**
- **Qualifying a GLP contract research organization;**
- **Developing awareness of cultural differences; and**
- **Comparing differences between GLP implementation in facilities in OECD member and non-member countries - case studies.**

You will not want to miss this educational opportunity if you are working with facilities in OECD non-member countries and you are any of the following:

- **Quality Assurance professional**
- **Regulatory Affairs professional**
- **Study sponsor or monitor**
- **Study Director or scientist**
- **Facility management professional**
- **Regulator**

For more information, please visit www.SQA.org.

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Career or Classified Section:

Are you interested in posting a position of interest to the CCSQA membership directory? If so, send it to mcaulayt@cirion.com and we will post it in the next edition of the newsletter or by email to all members.

CALLING ALL QA JOURNALISTS!!!

If you would like to write an article for the next edition of the CCSQA journal, let us know, we are looking for QA journalists to share their experience and knowledge!

We are on the Web! Email us at www.ccsqa.org

CCSQA Newsletter

Do you have comments or suggestion for the newsletter, want to contribute? Contact me!
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E-mail: mcaulayt@cirion.com

Canada Quiz Answers:

Answers:

1. Quebec
2. beaver
3. Mount Logan
4. John Cabot
5. Point Pelee, Ontario
6. Prince Edward Island
7. Hudson Bay
8. St. Pierre et Miquelon
9. 1967
10. British Columbia

Cross word Puzzle Answers

Across
1
6
9
11
13
14
16
17
18
20
22
24
26
28
29

Down
2
3
4
6
7
8
12
13
##
21
23
25
27
28

Job Announcement Rates (invoiced quarterly or yearly)*

Size	Website only	Newsletter only	Both
1/4 page	$10/qtr or $40/yr	$10/qtr or $40/yr	$15/qtr or $60/yr
1/2 page	$20/qtr or $80/yr	$20/qtr or $80/yr	$35/qtr or $140/yr
full page	$30/qtr or $120/yr	$30/qtr or $120/yr	$55/qtr or $220/yr

Website ads are posted as Word or PDF documents. Take advantage of the full page ad by including a company logo and job description! Use our convenient annual invoicing to advertise your online career center for a whole year!

Newsletter ads must be in Word.

* Job postings are free for CCSQA members.