Business Name

Northern Reflections

2012 Volume 1 **Newsletter Date August 2012**

Inside this issue:

Message from the President

Dear CCSQA/FCSQA members,

With the Standards Council of Canada getting established as the OECD recognized monitoring authority in Canada, various exciting discussions are rising in the Quality Assurance community. For this reason, the CCSQA/FCSQA Board has been actively working this year on creating effective means of communication with its members, looking for new and convenient ways of networking and keeping in touch with the fast-growing field of Quality Assurance.

If you haven't already, we encourage you to visit our website at www.ccsqa.org to learn more about our membership benefits, current events, newsletters and even post your organization's job opportunities, which is free for our members.

I would also like to take this opportunity to thank our Secretary, Irina Mosesova and Past-President Robert Di Lonardo for collaborating with the SQA in creating the CCSQA members Listserv, the link to it which can also be found on our website.

In just few minutes you can register and participate in polls related to current regulatory topics as well as share your thoughts on the future of the Chapter. This year we paid particular attention to social networks and are inviting you to join us in the effort to grow our Chapter and help us bring you services you're interested in.

Are you a member of Linkedin? Then, you can also find us under the group name "Canadian Chapter of the Society of Quality Assurance | CCSQA". Add our group and you will be able to stay in touch with other members of the Chapter, participate in our group discussions and share your thoughts, articles, and job opportunities.

Want to show us your writing skills? Then don't hesitate to send us your fun and creative articles for inclusion in our next newsletter!

We are currently working on our annual meeting, which is scheduled to be held this fall. As providing membership values and benefits are important to us, I invite you to share your thoughts on the desired topics of discussion for the meeting, thus allowing us to provide you, valuable members, the content you desire. Have a particular topic you'd like to share with us? We are always looking for speakers and would love to see your presentation at the annual meeting. As we are aware that our members are scattered all over Canada and it can be difficult for some of you to meet us in the eastern area, we are looking into hosting webinars of our meetings or separately as regulatory training so stay tuned!

The CCSQA/FCSQA Board would like to thank you all for your input and wish you a fun summer! Enjoy the newsletter!

Sami Bassil,

CCSQA President

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

Meet your SCSQA/CCSQA Board

Sami Bassil:

President

Auditor II, Charles River Laboratories Preclinical Services Montreal.

Five years experience in Quality Assurance specializing in FDA and OECD GLP .

Ritta Jadeja:
Vice President

GMP Trainer for Patheon, Mississauga, ON.

20 years of Quality Assurance and Compliance experience

in both GLP, GCP and GMP regulations

Robert DiLonardo:

Past President

Senior Specialist, Global Computer Validation Quality Assurance at Charles River Laboratories Preclinical Services Montreal. Over 6 years experience as a Quality Assurance Professional specializing in GLP and Computer System Validation

Irina Mosesova:
Secretary

Auditor II, Charles River Laboratories Preclinical Services Montreal.

Seven years experience in FDA and OECD GLPs and in computer system validations.

Janine Johnson:

Treasurer

Safety Manager, Safety and Risk Management, Pfizer Canada, Kirkland Quebec. 15 years of QA and regulatory experience in GLP, GCLP, GCP and Pharmacovigilence.

Tanja McAulay:
Director

Quality Assurance and Systems Manager, CIRION Biopharma Research, Laval Quebec. 13 years of Quality Assurance specializing in GLP, GCP and GCLP.

David Gregoire:

Director

Director, Quality Assurance at Algorithme Pharma, Laval Quebec. More than 15 years experience in Quality Assurance in GLP, GCP and GMP regulations.

Paul Sidney:

Director

Senior Director, Quality Assurance and RA for Charles River Preclinical Services, Senneville, Quebec. More than 25 years of preclinical expertise in Quality assurance specializing in GLP regulations.

Joe Kusain:

Director

Principal Auditor, Quality Assurance at CiToxLab.

More than 15 years of preclinical experience in Quality Assurance specializing in GLP regulations.

Get Involved! The board is always looking for new Ideas and Topics and welcomes new volunteers. Contact a board member at info@ccsqa.org

List of Chapters of the SQA around the World!

The SQA now has chapters globally including in Nigeria and India. The CCSQA is proud to be the northern chapter representing this great nation. There are more than 2,500 active and affiliate SQA members from around the world representing all areas of compliance.

CCSQA (Canada)

ICSQA (India)

MARSQA Mid-Atlantic USA

MWSQA Midwest USA

NCARSQA National Capital Area USA

NRCSQA Nigeria

NCCSQA North Carolina USA

NERCSQA New England USA

PRCSQA Pacific RIM USA

RMRCSQA Rocky Mountain USA

*Map of Canada and SQA location as published by the SQA. Note: The CCSQA board is not sure why B.C. is a different colour than the rest of Canada but B.C. is definetely an important part of the CCSQA!

Regulatory News

FDA

The following new guidances have been issued/revised by the FDA. For a full list, see

http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm

- Guidance for Industry on Biosimilars: Q & As Regarding Implementation of the BPCI Act of 2009 Draft Issued: February 2012
- Scientific Considerations in Demonstrating Biosimilarity to a Reference Product Draft Issued February 2012
- Quality Considerations in Demonstrating Biosimilarity to a Reference Protein Product –Draft Issued February 2012
- S6(R1) Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals– Revised and issued 17 May 2012
- S2(R1) Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use– Issued June 6, 2012

EMEA

Guideline on bioanalytical method validation—EMEA effective February 01, 2012

Health Canada

Health Canada recently released a new final guidance on April 18th, 2012 entitled "Pre-market Evaluation of Hepatotoxicity in Health

Products". This guidance was initially drafted for comments in February 2011 and 125 comments were received and incorporated when appropriate.

The purpose of this document is to provide guidance to sponsors to facilitate the detection, assessment, mitigation and reporting of hepatoxicity induced by human health products prior to issuance of market authorization pursuant to the Food and Drug Regulations. This guidance is expected to support the safe and effective use of health products by health care professionals, patients, and consumers.

A full link to this guidance document is provided below:

http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/hepatotox_guide_ld-eng.php

Did you know???

In 1862, President Lincoln launches the Department of Agriculture and the Bureau of Chemistry. These were the predecessor of the Food and Drug Administration.

New SQA List Serv Forum

SQA has recently rolled out a new initiative. It is called listserv -forum with document library.

Any member of a Chapter, Specialty Section or Committee is eligible to participate. You just need to go to the SQA website at www.SQA.org and log in with your name and password. As a paid member of the CCSQA, you will have access to a members only area and are automatically a listserv member with this feature. If you need assistance logging on or password retrieval, contact sqa@sqa.org.

As a Chapter member with paid dues, you automatically have been included as a member of new listserv-forum with document library. It has been set up to promote professional development by encouraging discussion of QA topics among members of our Chapter.

This list serve is automatically included with your CCSQA membership.

All you have to do is log on to the SQA website, and access the members only section, then Member List serv. There is one for all of the CCSQA members.

There are also other list servs you can join depending on your area and expertise such as the professional registration list serve, and other specialty committees you may be a part of.

To join a list serve or to remove your list from the list serv all you have to do is click on "my settings" and remove or update how you want to be notified (ie email, or not.

Some features of this listserve will allow you to:

· E-mail your entire group using a single e-mail address;

· Opt to receive a daily digest of messages instead of receiving each message as it is sent;

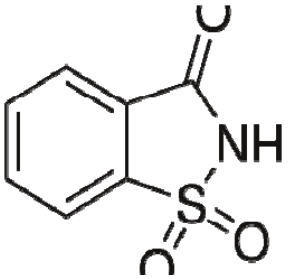
· Reply to a listserv message directly via e-mail without going online;

· Browse, search and/or reply to messages in the online forum where listserv message automatically are captured

· View an online list of the chapter or listserve members;

· Send messages to individual members of the group via the online interface;

- Use your existing SQA logon to access all SQA listserv-forums of which you are a member.



Saccarin

Did you know???

In 1971, Artificial sweetener saccharin, (trade marked as Sugar Twin or Sweet`n`low) which was included in FDA's original GRAS (generally recognized as safe) list, is removed from the list pending new scientific studies.

Then, In 1977, Bowing to industry pressure, the Saccharin Study and Labeling Act is passed by Congress to stop the FDA from banning the chemical sweetener.

The act does require a label warning that saccharin has been found to cause cancer in laboratory animals.

It is still widely used today as an artificial sweetener in drinks, candies, cookies, etc.. today!

Health Canada GCP News

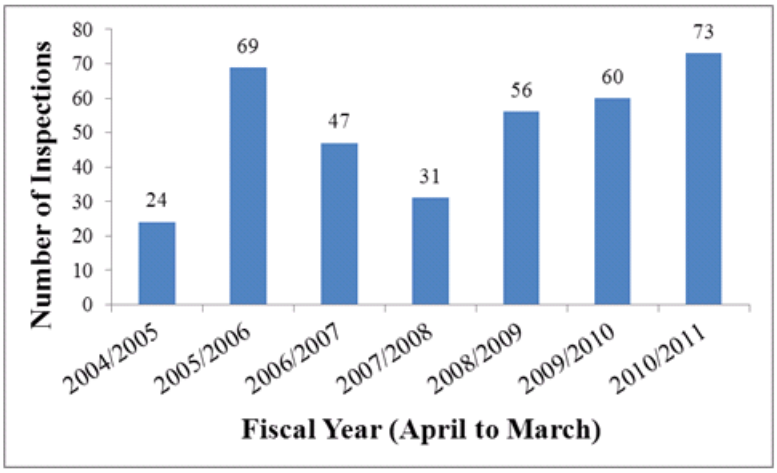
Health Canada has recently released a summary report on the GCP and Ethics Board inspections performed in Canada from 2004 to 2011. The document can be found online on the www.hc.gc.ca website at the following link:

http://www.hc-sc.gc.ca/dhp-mps/compli-conform/clini-pract-prat/report-rapport/2004-2011-eng.php. The title of the document is « Summary Report of Inspections of Clinical Trials Conducted from April 2004 to March 2011 »

A brief exerpt is found below summarizing the number of inspections performed and the number of non-compliant or compliant rating at the site. Please refer to the full PDF version of the article for more information. A link to this article has also been provided on the CCSQA listserve by one of our members.

The listserv can be accessed through the SQA members only log in (refer to page 5 of current news letter for listserv information).

Table 1 Distribution of good clinical practices (GCP) inspections and research ethics board (REB) assessments in Canada (April 2004 to March 2011)



The annual number of inspections conducted is based on the resources available to the program, in accordance with the organization's priorities for that year. It is also determined by other factors (for example, complexity of the sites and/or trials inspected), and could potentially be impacted by other activities, such as compliance verifications, in a given year.

Of the 329 inspections, 303 (92%) were assigned a compliant ("C") rating while 26 (8%) inspections at 11 sites were assigned a non-compliant ("NC") rating. In some cases, sites were inspected with respect to more than one protocol; hence an "NC" rating was issued for each study. Some establishments also received a subsequent "NC" rating during an inspection conducted in follow up to a previously issued "NC" rating. In each of these cases, the Inspectorate issued an Exit Notice with an accompanying notice of intent to suspend the study's authorization, thereby requiring the sites to implement timely corrective actions to achieve compliance with the Regulations, protect the rights and safety of the trial subjects, and to maintain the validity of the clinical trial data. Corrective actions are required for each observation whether the overall inspection rating is "C" or "NC." No ratings were issued in regards to REB assessments.

Locations for the RQAP Examinations in Canada

Computer-based testing (CBT) format is planned for 2012 testing.

The GLP Quality Assurance Professional Registry Examination consists of 165 multiple-choice questions, 15 of which are un-scored for use in future exams. Candidates are allowed three and one-half (3.5) hours to complete the examination. Individuals passing the examination will be credentialed as Registered Quality Assurance Professionals in Good Laboratory Practice (RQAP-GLP).

Individuals with expertise in GLP quality assurance write the questions and review them for relevancy, consistency, accuracy, and appropriateness. The SQA then prepares the examinations, with advice and assistance from an independent professional testing services provider that is contracted to assist SQA with development, administration, scoring, and analysis of the examination.

The GLP Quality Assurance Professional Registry Examination is administered twice annually. See notes in the Application and Candidate Handbook section below for further information. The examination schedule for 2012 follows.

Examination Dates	EARLY Application Postmark Deadline	Late Application Postmark Deadline
1 October - 3 November 2012 via Computer-Based Testing (CBT)	19 August 2012	2 September 2012 (+50$ late fee)

Locations for the Computer Based Exam in Canada for 2012

⇒ Failsafe Canada Inc #110, 3025 - 12th St NE Calgary Canada

⇒ Academy of Learning - Gateway Blvd #154, 6325 Gateway Boulevard Edmonton Canada

⇒ Pearson Professional Centres-Vancouver, Canada 4190 Lougheed Hwy Commerce Court Buildin Burnaby Canada

⇒ Winnipeg College of Science & Technology Inc 696 Portage Ave Winnipeg Canada

⇒ Memorial University of Newfoundland Division of Lifelong Learning, MUN St.John's Canada

⇒ Sylvan Learning Centre 6440 Quinpool Rd Halifax Canada

⇒ Durham Business & Computer College 1099 Kingston Road Pickering Canada

⇒ Pearson Professional Centres-Toronto, Canada 21 St. Clair Avenue East Toronto Canada

⇒ Itplanit 151 Slater St, Ottawa Canada

⇒ Everest College-Business, Health Care, Technology 250 York St London Canada

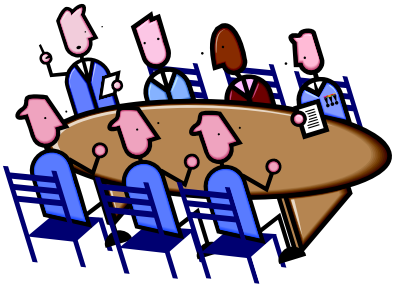
⇒ triOS College 110 King St E Kitchener Canada

⇒ Canadian Computer Distributors 1737 Walker Rd. Windsor Canada

⇒ Sylvan Learning Centre 18A Superior Crescent Charlottetown Canada

⇒ Pearson Professional Centres-Montreal, Canada 7705 17e Avenue Montreal Canada

⇒ Academy Of Learning 1202A Quebec Ave Saskatoon Canada



OECD Working Group Needs You!

Written by Joe Tyas

The OECD Discussion Group was developed to serve as a forum for industry involved in the organisation and conduct of GLP studies, to communicate and comment on concerns that impact on their business.

Membership of the OECD Discussion Group is comprised of organisations who have been nominated by their government's permanent representative on the OECD GLP Working Group and the Canadian Chapter of the Society of Quality Assurance (CCSQA) was nominated to represent the Canadian Industry.

The OECD's Working Group on GLP will identify topics of possible concern to industry, and invite comments from industry. The comments will be compiled and reviewed by a subgroup of the Working Group, and then discussed at the next meeting of the Working Group and actions will be proposed as appropriate.

The topics identified so far by the OECD Discussion Group have focused on the harmonisation of GLP standards across the OECD GLP community and address the suitability of current GLP requirements for emerging technologies. Comments were provided by the members and the Working Group met on 29-31 May 2012 to discuss the comments. The summary of the Working Group meeting discussions have since been posted on the OECD Discussion Group website and have been made available to the members of the group.

There is now an opportunity for CCSQA members to comment on issues related to quality assurance activities, the identification and characterisation of test items and issues relating to advances in IT technology.

The CCSQA Board encourage CCSQA members to provide comments.

A summary of the issues noted has been published and is provided on the next page (Page 9) of this newsletter.

The CCSQA Board will also advise CCSQA members of future topics as they are proposed.

Feedback from the members is important as it will help to harmonise and improve GLP practices between OECD member countries which will ultimately benefit Canadian businesses involved in GLP studies.

Don't hesitate to contact a CCSQA board member with your comments and we will ensure they are forwarded to the OECD discussion group.

Summary of OECD Working Group Issues

OECD Discussion Group on Harmonisation Issues.

Feedback to industry members following discussions at the 26th Meeting of the Working Group on Good Laboratory Practice.

Following the creation of the web-based discussion forum and the listing of the first two topics, over 100 responses were posted by industry representative before the agreed closing date for submissions. The OECD Secretariat and the sub group responsible for the progression of this project reviewed all responses prior to the 26th Working Group meeting and grouped those responses which had a common theme.

The areas which produced the highest number of remarks were related to quality assurance activities, the identification and characterisation of test items and issues relating to advances in IT technology.

A proposal was made to the GLP Working Group that in the first instance focus should be placed on these three areas. To this end it was agreed that three "issue groups" (subgroups of the Working Group) should be formed.

The initial remit of these groups will be to determine whether there is a need for additional guidance, or amendments to current guidance, for monitoring authorities and industry on the three subjects.

If it is decided that further guidance is required to ensure harmonisation of approach across the OECD GLP community the "issue groups" will start to draft documents which will be considered at the next Working Group meeting.

All other remarks posted by industry members will be considered and where possible a response will be posted on the discussion forum. However, it should be noted that responses will only be posted if consensus can be reached among Working Group members.

A number of the comments posted by industry members on the web site are quite specific and may just impact on inspection programmes in their countries. In such cases, industry members are encouraged to discuss local issues with their national monitoring authorities in an attempt to clarify issues and resolve any misunderstandings.

The Working Group members agreed that it would be appropriate to leave the current topics on the web site for the remainder of 2012 in order to give industry members a chance to review and reflect on the comments of other members and to amend and add to the comments that have already been submitted. Industry members are also asked to consider which of the remaining issues (those not related to QA, Test Item or IT) they consider to be the highest priority.

Please note that the web site will be open for additional comments on QA, Test Item and IT until the end of September 2012. The web site will be open for additional comments on all other issues relating to the two general topics until the end of December 2012.

The shortened deadline for the areas the Working Group have already decided to progress is designed to allow the "issue groups" to progress these projects as quickly as possible in order to make significant progress before the Working Group meets again in 2013.

Member Articles

We've always done it that way...."

Submitted by Ritta Jadega

Apparently this story is based on a true incident. A quality management consultant was visiting a small and somewhat antiquated English manufacturing company, to advise on improving general operating efficiency. The advisor was reviewing a particular daily report which dealt with aspects of productivity, absentee rates, machine failure, downtime, etc.

The report was completed manually onto a photocopied proforma that was several generations away from the original master-copy, so its headings and descriptions were quite difficult to understand.

The photocopied forms were particularly fuzzy at the top-right corner, where a small box had a heading that was not clear at all.

The advisor was interested to note that the figure '0' had been written in every daily report for the past year.

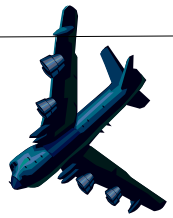
On questioning the members of staff who completed the report, they told him that they always put a zero in that box, and when he asked them why they looked at each other blankly.

"Hmmm.., I'm not sure about that," they each said, "I guess we've just always done it that way."

Intrigued, the consultant visited the archives to see if he could find a clearer form, to discover what was originally being reported and whether it actually held any significance.

When he found the old reports, he saw that the zero return had continued uninterrupted for as far back as the records extended - at least the past thirty years - but none of the forms was any clearer than those presently in use.

A little frustrated, he packed away the old papers and turned to leave the room, but something caught his eye. In another box he noticed a fol



der, promisingly titled 'master forms'.

Sure enough inside it he found the original daily report proforma master-copy, in pristine condition.

In the top right corner was the mysterious box, with the heading clearly shown.....

'Number of Air Raids Today'

The moral of this story is sometimes it is good to question why we have always done it that way!

This area of the newsletter is reserved for member articles. Don't be shy to nourish your budding writing skills and share your viewpoint with our members. Articles can be submitted on anything relating to the Quality Assurance Profession and can be creative and fun. Submit any works to newsletter@ccsqa.org.

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

Classifieds

Advertising/Job Announcements

Advertisements are posted on our webpage http://www.ccsqa.org/. In addition, if your advertisement is posted on the webpage at time we publish our newsletter, your advertisement will be included in the newsletter as well.

OPTIONS	DESCRIPTION
I. Pay-per-submission	This option allows you to pay per submission for a 30 day-period display on our website for **$25.00 CAD.**
II. Pay-period: 90 days	This option allows you to pay **$60.00 CAD** for 90 day-period with the opportunity to have a replacement submission every 30 days (i.e., three (3) postings within that period).
III. Pay-period: 6 months	This option allows you to pay **$100.00 CAD** for 180 day-period with the opportunity to have a replacement submission every 30 days (i.e., six (6) postings within that period).
IV. Pay-period: 1 year	This option allows you to pay **$200.00 CAD** for a 1 year subscription with the opportunity to have a replacement submission every 30 days (i.e., twelve (12) postings).

FORMAT REQUIREMENTS

Microsoft Word™ file format (file will be converted to PDF prior to posting)

Images must be of High Resolution (at least 300dpi)

Submissions may be modified due to file size limitations.

Submitters will be notified and asked to approve any modifications, prior to publication.

SUBMISSION REQUIREMENTS

Complete *SUBMISSION REQUEST FORM* (send email to info@ccsqa.org to receive form)

Notify CCSQA of your submission request by e-mail (include request form and submission)

Mail payment and the original submission request to the CCSQA at the address on the form

The CCSQA board reserves the right to refuse a submission, based on the relevance of the content to its membership. Submitters will receive notification by e-mail and return of payment will be accompanied with an explanation of rationale for refusal.

PAYMENT

The above rates are for non-members. Career opportunity submissions for CCSQA members are free of charge if the job posting is relevant to our membership (i.e., QA, regulatory). Members will receive a 10% discount on all other types of submissions (i.e., marketing). All advertising rates are NET (i.e., tax included). There is no discount for advertising agencies or non-members to the CCSQA. Payment must be received by check or money order, made payable to the Canadian Chapter of the Society of Quality Assurance. A 25$ surcharge will be applied to returned checks. Submission will not be uploaded until we receive full payment, the time clock starts on the date the submission is posted on the website.