CCSQA/FCSQA Newsletter

Northern Hemispheres

2010 Volume 1, Issue 1 Newsletter Date June, 2010

Message from the President

Inside this issue:

Special points of interest:

- *Annual Meeting Update from the SQA*
- *CVG meeting update*
- *Special Supplement Section: Questions and Answers regarding the new GLP Canadian Monitoring Program*

Dear CCSQA/FCSQA members.

This first half of 2010 has been a busy one for the CCSQA/FCSQA board. We have been meeting monthly to work on several projects to provide increased benefit to our membership.

One of our Directors, Joanne (Joe) Tyas, did a really fantastic job on creating a poster to showcase our chapter at the SQA annual meeting in Cincinnati, Ohio. I hope that some of you were able to stop by and say Hi! If not, there is a great summary of the meeting and our poster in this issue.

The board has also been furiously working on re-vamping our website. Thanks to Director, Irina Mosesova and Vice-President, Robert DiLonardo we are well on the way to having a fresh new look. In addition, the SQA has offered to take over webmaster responsibilities, so when our new site goes live we will be able to keep the site up-to-date. Any suggestions for the website are welcome. Send your comments/suggestions to websitecontent@ccsqa.org.

We are also continuing to monitor the progress Health Canada and Standards Council of Canada is making with respect to the roll-out of the GLP monitoring authority inspections for pharmaceutical and biotech product testing. Last November at the CCSQA/FCSQA annual meeting we were proud to have representatives on-site to discuss this program. The Q&A document prepared from that meeting is included in this issue of the newsletter.

The 2010 annual meeting committee (Sami Bassil, Robert Dilonardo and myself) is starting to plan for this year's meeting (our 8th annual), in which we will strive to continue the tradition of finding high-calibre presenters to speak on topics of interest to our members. If you have any ideas for topics or would like to present at our annual meeting, please send me an e-mail at janine.johnson@pfizer.com .

Well that's what we have been up to, if you have been up to something you think would be of interest to our membership, please do not hesitate to contact any of the board members, we would love to hear from you.

Have a Safe and Fun Summer!

Sincerely,
Janine

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

Meet your CCSQA/FCSQA Board

Janine Johnson: President

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

Robert DiLonardo: Vice-President

Principal Inspector, Quality Assurance, Charles River Preclinical Services, Senneville, Quebec. 4 years in Quality Assurance specializing in GLP regulations.

Andrew Graham: Past President

Senior Director, Operations, for LAB Research Inc., Laval, Quebec

26 years in pre-clinical experience including 20 years in Quality Assurance specializing in GLP regulations.

Ritta Jadeja: Secretary

Quality Assurance Associate.

Patheon, Mississauga, ONT. 18 years of Quality Assurance experience in GLP, GCP, and cGMP regulations.

Azadeh Abedian: Treasurer

Montreal, Quebec.

19 years in Pre-Clinical and Pharma industries including 12 years of QA experience in GLP and GMP regulations.

Irina Mosesova: Director

Senior Quality Assurance Inspector, Charles River Laboratories Preclinical Services Montreal.

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

Sami Bassil: Director

Senior Quality Assurance Inspector, Charles River Laboratories Preclinical Services Montreal.

3 years in Quality Assurance specializing in GLP regulations.

Tanja McAulay: Director

Quality Assurance and Systems Manager, CIRION Biopharma Research, Laval Quebec.

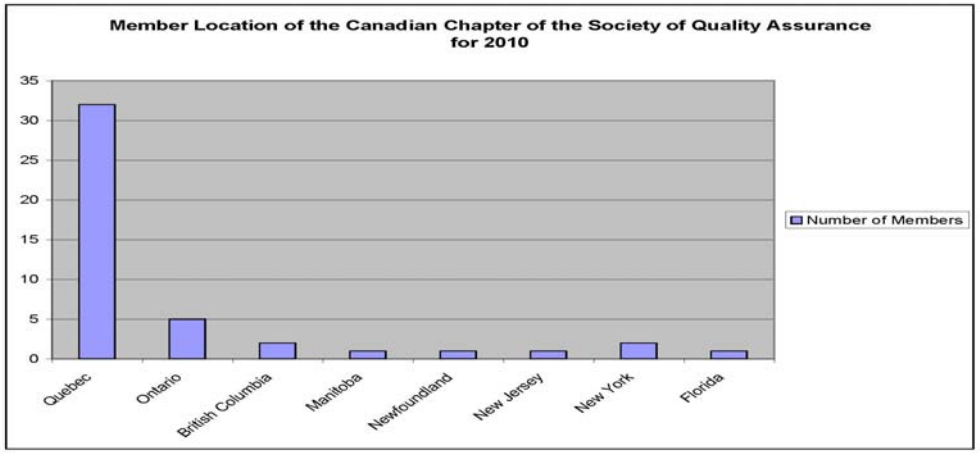
13 years of Quality Assurance specializing in GLP, GCP and GCLP.

Joanne (Joe) Tyas: Director

Director Quality Assurance, ITR Laboratories Canada Inc., Baie d Urfé, Quebec.

17 years of Quality Assurance experience specializing in GLP.

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



FCSQA/CCSQA Website is on the move!

The CCSQA board is happy to report that we have been working very hard in updating our website: making it more professional, useful, and interactive for our members. Working closely with our SQA colleagues, we will soon launch a brand new site which will include information and services to the general public; as well as, a link to a members-only section.

The general public will have access to useful regulatory links, information about the chapter, membership applications, upcoming events, and our past newsletters. In addition, we will encourage companies to post their current job openings in quality and regulatory affairs.

We are also very excited about the new members-only section that will be available in the near future. This section will allow members to discuss issues of interest, post their resumes, connect with fellow CCSQA members, and more. If you have any suggestions for the CCSQA website please contact us at websitecontent@ccsqa.com.

"Quality is never an accident; it is always the result of high intention, sincere effort, intelligent direction and skillful execution; it represents the wise choice of many alternatives" William Foster

Canadian Monitoring Authority Update

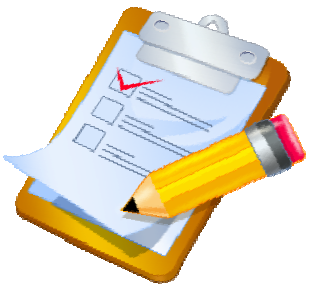
As was presented at the fall chapter meeting last year, Health Canada is moving ahead and developing a system for GLP monitoring for both pharmaceutical and biotech products.

The final guidance entitled "Non-Clinical Laboratory Study Data Supporting Drug Product Applications and Submissions: Adherence to Good Laboratory Practices"[1] was issued in April 2010. Health Canada will allow for a one year transition period for test facilities to gain SCC recognition.

This document would apply to all safety studies submitted in support of pharmaceuticals (including disinfectants), radiopharmaceuticals or biologic drugs that have been conducted in accordance with the principles of GLP.

The memorandum of understanding between Health Canada and the Standards Council of Canada (SCC) was signed in June of 2009.

1: Guidance Document Non-Clinical Laboratory Study Data Supporting Drug Product Applications and Submissions: Adherance to Good Laboratory Practice. Health Canada, April 30, 2010. http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodpharma/applic-demande/guide-ld/glp_bpl-eng.pdf.



"Quality means doing it right when no one is looking"
Henry Ford

Update on the Society of Quality Assurance 26TH Annual Meeting in Cincinnati, Ohio, 27-30 April, 2010: Joanne Tyas

From 27 to 30 April 2010, representatives of the Canadian Chapter of the Society of Quality Assurance attended the Society of Quality Assurance meeting in Cincinnati, Ohio, US. The Canadian Chapter was promoted during the poster sessions of the meeting.

In addition to displaying a poster, information on the Canadian Chapter membership and its benefits, the improvements to the CCSQA website and updates to the Canadian GLP monitoring authority were presented during the poster sessions.

There appeared to be quite a lot of interest with several attendees dropping by for discussions and to take a Canadian souvenir. There was also a raffle for a cute Canadian Moose stuffed toy which was won by an attendee from the US.

A formal presentation was also provided during the meeting on Health Canada's initiative to establish a GLP Monitoring Authority. Health Canada expects that safety studies submitted in support of pharmaceuticals (including disinfectants), radiopharmaceuticals or biologic drugs have been conducted in accordance with the Principles of GLP.

In June 2009 Health Canada signed a memorandum of understanding with the Standards Council of Canada (SCC) to allow SCC to act as the monitoring authority for GLP compliance of test facilities in Canada.

The final guidance document "Non-Clinical Laboratory Study Data Supporting Drug Product Applications and Submissions: Adherence to Good Laboratory Practices"[1] was issued in April 2010. Health Canada will allow a one year transition period from the date of issue for test facilities to obtain SCC recognition.

The meeting was also attended by various US government regulatory officials and the following topics were presented by them:

- ✦ Good Laboratory Practice Program Update from FDA's Center for Devices and Radiological Health
- ✦ Electronic Records – Perspective from FDA and Industry
- ✦ Animal Health Regulatory Update
- ✦ The Regulation of Genetically Engineered Animals
- ✦ Clinical Regulatory Update
- ✦ FDA/EMEA GCP Initiative
- ✦ EPA/GLP Update.

Updates were provided by the speakers on the activities and findings from the Bioresearch Monitoring Program and the approaches taken by the agencies to inspect enough studies/sites to ensure the integrity of data.

During the presentations there was also some emphasis placed on the Sponsor and their responsibilities in the conduct of studies and in submitting quality data to the agency.

It was interesting to hear that as part of submission of data to regulatory authorities of certain OECD member countries, some US Sponsors have been asked to provide their GLP compliance certificates.

The speaker representing the EPA re-emphasized that unlike some of the other OECD member countries the US GLP monitoring authorities do not provide GLP compliance certificates.

The speaker confirmed that if a US laboratory has been inspected by the relevant US GLP monitoring authority for GLP compliance the data from that laboratory should be accepted by another OECD member country.

It was not surprising to hear that the proposal for updating the FDA rule 21 CFR Part 11 "Electronic Records, Electronic Signatures"[2] is still under discussion; however, there is an initiative to move this forward.

(continued next page)

As part of the initiative, the Centre for Drug Evaluation (CDER), intends to inspect selected companies from within industry for compliance with the rule and in light of the guidance document "Part 11, Electronic Records; Electronic Signatures – Scope and Application"[3] which was issued in 2003.

This initiative will allow the agency to evaluate industry's current compliance and understanding of 21 CFR Part 11. The results of the inspections will provide information which will assist the agency in re-evaluating 21 CFR Part 11.

In addition to the presentations by the Regulators, there were also many interesting posters and presentations by industry representatives some of whom were from Canada.

The meeting was opened by the key note speaker Kurt Weingand whose presentation was titled "Lessons in Leadership for Crisis Management". Kurt's presentation was very interesting and shared key experiential learnings from management of the 2007 pet food recall.

Many training sessions were offered at the meeting and provided an opportunity for the various specialty sections of SQA to hold their meetings.

The SQA annual meeting was however, not all about work and several social activities were also offered such as the opening reception, a trip to Newport Aquarium and the international networking reception and the jam house featuring SQA's own "Deviations".

The next SQA Annual Meeting will be held in San Antonio, TX, 27 March - 1 April 2011. More information can be found on the SQA website www.SQA.org

References:

1: Guidance Document Non-Clinical Laboratory Study Data Supporting Drug product Applications and Submissions: Adherence to Good Laboratory Practice. Health Canada, April 30, 2010. http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodpharma/applic-demande/guide-ld/glp_bpl-eng.pdf

2: 21 CFR Part 11 Electronic Records; Electronic Signatures; Final Rule, U.S. Department of Health and Human Services, March 20, 1997.

3: Guidance for Industry, Part 11, Electronic Records; Electronic Signatures – Scope and Application, U.S. Department of Health and Human Sciences, August 2003.

SQA's "Deviations" Playing at the International Networking Reception:

"It is easier to do a job right than to explain why you didn't"
Martin Van Buren

FDA and OECD News

The FDA has published a proposed ruling directly impacting Sponsors.

The proposed rule would require Sponsors to report any information indicating that any person has, (or may have), engaged in the falsification of data in the course of reporting study results, or in the course of proposing, designing, performing, recording, supervising, or reviewing studies that involve human subjects or animal subjects conducted by or on behalf of a sponsor or relied on by a sponsor.

The published proposed rule may be viewed at:

http://edocket.access.gop.gov/2010/2010-3123.htm .

Comments were due 20 May 2010. Update to follow!

The OECD has published the following documents (taken from SQA website):

*Section 2: Effects on Biotic Systems
*Section 3: Degradation and accumulation
*Section 5: Other Test Guidelines

Updated Test Guidelines:

*Section 2: Effects on Biotic Systems
*Section 4: Health Effects
Corrected Test Guideline:
*Section 4: Health Effects
Updated Work Plan for the Test Guidelines Programme (TGP)

They also published the following new documents in the Series on Testing and Assessments:

*Retrospective Performance assessment of the TG 426
*Report of the Validation Peer Review for the Amphibian Metamorphosis Assay

*Report of the Validation Peer Review for the 21-Day Fish Endocrine Screening Assay DRP on Fish Life-Cycle Tests

*Guidance Document on Mammalian Reproductive Toxicity Testing and Assessment

*Background Review Document on the Hershberger Assay DRP on Metabolism

Further information is available at their website: http://www.oecd.org/department/0,3355,en_2649_34377_1_1_1_1_1,00.html

CCSQA at the SQA Poster Sessions:

The CCSQA was well represented with a poster prepared by Joanne Tyas to present the benefits of the CCSQA to the SQA

CCSQA/FCSQA Annual Meeting: Not to be Missed !

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 the fall 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 and beyond. News of this will be posted soon on our website an our next newsletter.

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.

Treasurer's Report

Community Checking Account - TD Canada Trust	
Beginning Balance (01 January 2009)	**$9,425.35**
Income:	
2009 Membership Dues (42 @ 20.00)*	$840.00
Annual Meeting	$7,464.24
US Dollar Exchange Credits	$2.60
Service fee overpayment credit	$4.95
Total Income:	**$8,311.79**
Expenses:	
Bell Teleconferencing	$602.65
Post Box and Postage	$141.09
2008 Annual Meeting (Check 31 carried over into 2009)	$2,509.57
2009 Annual Meeting	$6,012.10
Website Fees (Gate.com)	$167.00
Community Plus Bank fees not reimbursed in error	$9.90
Total Expenses:	**$9,442.31**
Ending Balance (31 December 2009)	**$8,294.83**
Report prepared by: Janine Johnson, CCSQA President,	April 18, 2010

Highlights from the CVG 4th Workshop on Recent Issues in Regulated Bioanalysis : By Manal Hantash ITR Laboratories

The Canadian LC-MS Group, a branch of the Calibration and Validation Group (CVG), held the "4th Workshop on Recent Issues in Regulated Bioanalysis" in Montreal on April 22 to 23, 2010.

A variety of speakers from Regulatory Agencies, Pharmaceutical Companies and Contract Research Organizations were present at the workshop.

Representatives from the Committee for Medical Products for Human Use (CHMP) of the European Medicines Agency (EMEA), UK Medicines and Healthcare Products Regulatory Agency (MHRA), Health Canada, US Food and Drug Administration (FDA) and the National Health Surveillance Agency (ANVISA) of Brazil presented in the workshop.

The focus was on bioanalysis and bioequivalence.

The EMEA and FDA guidance documents on method validation were discussed during the workshop.

The representative from the MHRA reminded attendees that May 31, 2010 is the deadline for providing comments on the EMEA draft guidance document "Guideline on Validation of Bioanalytical Methods", which was issued in November 2009.

The FDA representative indicated that the FDA intends to also update the FDA guidance document "Bioanalytical Method Validation".

It is estimated that the draft document will be available for internal consideration late 2010 and will be issued for a comment period in 2011.

One of the major changes to the FDA guidance documents will be modifications to the section of ligand-binding assays (LBA) including its acceptance criteria.

Some differences between EMEA and FDA guidance documents on Validation of Bioanalytical Methods were highlighted during the workshop and are listed in the table below.

It was clear from the discussions during the workshop that the majority of the bioanalytical community felt the need to harmonize the EMEA and FDA requirements for bioanalytical method validation. (continued next page)

How many QA auditors does it take to change a light bulb???
None, we don't fix the problems, we just find them!

ITEM	EMEA	FDA
Reference Standards	Discusses isotopic purity expectations of labeled reference standards	No reference to expectations regarding labeled reference standards
Selectivity	Criteria provided	Criteria not provided
Selectivity	Includes test for possible metabolic back-conversion	No specific metabolite tests recommended
Recovery	Not included in the guidance	Included in the guidance
Carryover	Included in the guidance	Not included in the guidance (but required and enforced by FDA)
ISR	Included in the guidance and criteria provided	Not included in the guidance (but required and enforced by FDA)
Matrix effect	Discusses specifics of evaluation and criteria provided	General statement that it should be investigated (criteria not provided)
Stability	Criteria provided	Criteria not provided
Reanalysis of study samples due to pharmacokinetic reasons	Not acceptable	Allowed

Highlights from the CVG 4th Workshop on Recent Issues in Regulated Bioanalysis : By Manal Hantash ITR Laboratories (Continued)

It was also suggested during the workshop that such a harmonized guidance document should be science driven and include the rationale behind each requirement to prevent "box checking" by auditors.

An appeal for global harmonization of the guidance document was made by the different bioanalysis groups via an open letter.

The letter "Request for Global Harmonization of the Guidance for Bioanalytical Method Validation and Sample Analysis" was written by Philip Timmerman (EBF),Steve Lowes (AAPS), Douglas M. Fast (APA-BSAT), Fabio Garofolo (CVG) and was sent to the US FDA and EMEA in February 2010 .

It was proposed that the FDA and EMEA merge the guidance documents in order to create one unified document; this document can be presented to the decision makers of each country so that one harmonized document can be adopted worldwide.

As a result agencies can then harmonize their audit approach. The Health Canada representative indicated that Health Canada supports the idea of harmonizing the requirements for bioanalytical method validation but believes that it could be a long process. Health Canada suggested that this probably should be taken on by the ICH to get the regulator's buy in.

he workshop provided an open forum for discussion, exchange of knowledge and ideas on bioanalytical issues and regulatory challenges faced by the bioanalytical community.

One of the focuses at the moment by regulatory authorities is the effect of lipemia and hemolysis on study samples results. This was discussed during the workshop and how industry should deal with hemolyzed or lipemic samples.

For example, is it acceptable to classify results from these samples as "not reportable" values, should the method validation include additional testing for hemolysis or lipemia?

Currently there is no documented guidance on how to test for the effect of hemolysis and lipemia and questions were raised on what should be the maximum hemolysis or lipid level to test.

It was recommended during the workshop that a procedure should be implemented in laboratories outlining how to examine for sample hemolysis.

Once samples are received by the laboratory they should be examined upon receipt for hemolysis. Any affected study samples should be flagged in the bioanalytical data.

Given the knowledge that some drugs favor red blood cell binding, a test for the effect of hemolysis should be considered during method validation.

It is difficult to identify lipemic samples but general agreement was that under appropriate extraction methods, where lipids can be removed or if chromatographically they can be separated from the drug peak, lipemia should not be an issue.

Normally, a rugged validated method and the use of a stable - labeled internal standard should compensate for any variation caused by hemolysis or lipemia.

The discussion on this topic ended with no consensus. Some companies in industry prefer to test for hemolysis and lipemia effects in the method validation while others do not.

Therefore the conclusion was that further discussion is required during future meetings.

A white paper on CVG's "4th Workshop on Recent Issues in Regulated Bioanalysis" will be published in the January 2011 issue of the Bioanalysis Journal and will include all topics discussed during the workshop and the consensus achieved.

The 5th CVG workshop will be held in Montreal from April 11 to 15, 2011 and it will include an update on the global harmonization for bioanalytical method validation.

Representatives from FDA (US), EMEA (EU), Health Canada, MHRA (UK), MEB (Netherlands), ANVISA (Brazil), SFDA (China), TGA (Australia), MHLW (Japan) and CDSCO (India) are expected to attend.

"If you don't have time to do it right, then you must have time to do it over!"

By: Unknown

NEWSLETTER: SUPPLEMENTAL SECTION

CCSQA/FCSQA ANNUAL MEETING 2009: PANEL DISCUSSION SUMMARY

DRAFT POLICY GUIDANCE on GLP RECOGNITION INSPECTIONS

19 November 2009

Health Canada (HC):

Mr. Jason Rancourt, Scientific Coordinator and Policy Advisor, Office of Science and Risk Management, Health Products and Food Branch

Ms. Alexandra Bray, Sr. Policy Analyst, Bureau of Policy, Science and Internal Programs,

Therapeutic Products Directorate

Standards Council of Canada (SCC):

Mr. Rassoulou Diallo, Sr. Program Officer, Laboratories, PALCAN Conformity Assessment

Mr. Gordon MacMillan, Sr. Program Officer, Laboratories, PALCAN Conformity Assessment

Industry (IND): Mr. Paul Sidney, Sr. Director QA and Regulatory Affairs, Charles River Laboratories, Preclinical Services Montreal

QUESTION AND ANSWERS:

Question 1:

Has the OECD/MHRA reviewed Canada's proposed monitoring program and agrees that it satisfies their concerns?

Answer:

HC: OECD has reviewed the policy guidance and indicated that it met the requirements of the mutual acceptance of data agreement.

IND: SCC has been "recognized" as Canada's monitoring authority by the OECD working group.

HC: MHRA has made a statement that Canadian studies are compliant if recognized by a monitoring authority.

SCC: OECD will be reassessing the program from time to time to ensure the SCC program meets the requirements for a monitoring authority.

Question 2:

Is it part of the SCC program to perform directed audits if requested?

Answer: **SCC:** yes

Question 3:

Is there grandfathering with respect to data submitted to the MHRA? Meaning some studies would have been performed prior to GLP recognition and some after.

Answer:

IND: No one here can speak for the MHRA, but if there is a claim of GLP compliance for a preclinical study within a regulatory submission and it was not performed after the GLP Monitoring Authority recognition of the facility, then it may be considered a false claim according to UK law. For example; If a UK study director claims compliance to the MHRA GLP statutory instrument and has a contribution from a test site in Canada who is not yet recognized to be in compliance with the OECD GLPs by

the SCC, the UK study director would have to list a compliance exception for the Canadian test site contribution to the study.

HC: Prior to recognition, one cannot claim compliance per Canadian monitoring authority but you can state how the data was collected and what inspections were performed to verify the data.

Question 4:

Is the plan to audit '*anyone*' contributing to a GLP study?

Answer:

SCC: Yes, if requested through a program application. If a 3rd party asks the SCC to do an inspection, this is also possible according to the SCC policy.

Question 5:

Is it possible for clinical laboratories to be audited by SCC and be recognized as a GLP laboratory?

Answer:

SCC: The GLP program is an ongoing process and expansion to the program will need to be discussed in a working group in the future. However, the SCC will assess each application and make sure it does not fall outside the scope of GLP. This type of inspection would also need to be recognized by Health Canada.

HC: These labs would not need a monitoring authority certificate for OECD GLP compliance, but the lab can apply for other laboratory accreditation through the SCC PALCAN program.

Question 6:

We need to submit safety studies for novel foods, should we be obtain OECD GLP recognition?

Answer:

HC: Novel foods are not currently covered under the initial pilot. You will need to look at if your data would fall within the regulatory framework for a country that you intend to submit data. If OECD GLP is a requirement in those countries then you may want to consider having GLP recognition.

Question 7:

How does the SCC pay for its monitoring program? Is it funded by Health Canada?

Answer:

SCC: All accreditation programs are cost recovery based.

HC: Health Canada cannot fund the program since the SCC must be independent from the regulatory authority.

Question 8:

What is the typical cost for a SCC Monitoring Authority Recognition audit?

Answer:

SCC: That depends on the scope and the size of the team. (Cost = Type of Audit + Travel Costs)

A cost estimate is provided to the applicant after the application is received to detail the annual yearly cost to maintain the accreditation. A fee schedule for the GLP program is available at: http://www.scc.ca/en/c/document_library/get_file?uuid=85e2b913-ed16-4b41-a32a-f8be490ff410&groupId=10817

NEWSLETTER: SUPPLEMENTAL SECTION

CCSQA/FCSQA ANNUAL MEETING 2009: PANEL DISCUSSION SUMMARY

DRAFT POLICY GUIDANCE on GLP RECOGNITION INSPECTIONS

19 November 2009

Question 9:

If the SCC recognizes a facility as being in-compliance with the OECD principles of GLP and then a problem is discovered. Is the SCC liable for the company's compliance?

Answer:

SCC: The SCC does not verify the company's overall compliance level. Having accreditation does not guarantee the quality of the work being done.

Question 10:

The FDA is the monitoring authority for the US and the US is a member of the OECD, so why does the FDA not provide accreditations?

Answer:

IND: Accreditation is not a required aspect of the GLP monitoring authority (MA) inspection process. Some GLP MAs have chosen to issue a certificate following annual or bi-annual reviews to detail the compliance status of the laboratory. Some countries choose not to issue a certificate. There is no obligation under the OECD principles to issue a certificate. The US law Title 21 CFR Part 58 GLP regulations do not require a site qualification audit by the US monitoring authority of a facility that makes claim to comply with GLPs. In addition, US law does not include the option to issue a certificate following a GLP audit. The US MA documents the scope of their audit and findings through an Establishment Inspection Report.

Question 11:

How many companies have requested to be audited?

Answer:

SCC: Two (2) officially; but, 20 queries have been received without submitting formal applications.

HC: A company does not have to wait for the policy guidance to be final to apply to SCC for inspection.

Question 12:

What happens if the final report goes to the regulatory authority (RA) for evaluation and is clearly not compliant? Does the RA contact the SCC to verify the data they are receiving if there is doubt of the GLP compliance? Does HC train their evaluators on what to look for with respect to GLP compliance?

Answer:

SCC: The HC inspectors are trained and qualified in GLP inspection techniques by the SCC. (This is in reference to the employees of HC who participate in GLP inspection audits as expert participants)

HC: The evaluators are quite thorough and should pick up on GLP compliance issues. In addition, part of the Memorandum of Understanding between the SCC and HC is to have an open communication. The details regarding inspections are openly provided to HC from SCC.

Question 13:

What kind of timelines are there between the GLP inspection and receiving accreditation?

Answer:

SCC: The SCC timelines depend on both the company and the SCC. The faster the company responds to the findings, the faster the process.

ABBREVIATIONS:

FDA: Food and Drug Administration

GLP: good laboratory practice

HC: Health Canada

IND: industry

MA: monitoring authority

MHRA: Medicines and Healthcare products Regulatory Agency

OECD: Organization for Economic Cooperation and Development

PALCAN: Program for the Accreditation of Laboratories in Canada

RA: regulatory authority

SCC: Standards Council of Canada

UK: United Kingdom

US: United States of America

LINKS:

Draft Guidance Document Non-Clinical Laboratory Study Data Supporting Clinical Trial Applications, New Drug Submissions and Drug Identification Number Applications: Adherence to Good Laboratory Practices.

http://www.hc-sc.gc.ca/dhp-mps/consultation/drug-medic/draft_ebauche_glp_bpl-eng.php

Medicines and Healthcare products Regulatory Agency http://www.mhra.gov.uk/index.htm

Organization for Economic Cooperation and Development GLPs

http://www.oecd.org/department/0,3355,en_2649_34381_1_1_1_1_1,00.html

SCC Program for the Accreditation of Laboratories in Canada

http://www.scc.ca/en/programs-services/laboratories

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 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.