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CANADIAN CHAPTER SOCIETY OF QUALITY ASSURANCE

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Summer 2018

NEWS LETTER

Your CCSQA Board

Inside this issue

SQA Board Liaison
Greg Furrow

WANT TO CONTRIBUTE?

CONTACT US:
info@ccsqa.org

Hello CCSQA Members!

While we are here midway through my year as CCSQA Board President, I am happy to reflect on all that we have accomplished over the last year and a half. Under Presidency of Julie Rousseau, we held an amazing one day annual meeting in Montreal back on October 26, 2017. Some great presentations were provided to our attendees, including a member of the Standards Council of Canada.

The start of this year saw two fantastic webinars Sponsored by the CCSQA, which allowed CCSQA members, SQA members, other Chapter or Specialty Section members to participate for FREE. Our first sponsored webinar was on March 22, 2018 on Data Integrity by Aaron Clarke of Quality and Compliance and our second was on May 31, 2018 on Quality by Design in Bioanalysis by Mitesh Pillai from Zydus Research Centre.

A CCSQA lunch was held for members and interested parties at the SQA Annual meeting in Anaheim California on Tuesday April 10, 2018. Approximately 20 members attended and was a great opportunity for members to meet face to face and learn about each other.

Thanks to the efforts of the CCSQA Board and especially Josee-Ann Dulude, our current Vice President of CCSQA, we have re-launched our CCSQA Newsletter which we are hoping to send out twice a year.

Lastly, for those of you that are on LinkedIn, please come check out and join our CCSQA group. Feel free to post questions or comments. The CCSQA Board will be trying to post regularly to keep you up to date on what we have going on.

As we move into the 2nd half of our year, we are diligently working on planning our upcoming CCSQA Annual meeting, tentatively scheduled for early November and are hoping to be able to raise Sponsorship to upgrade our website to make it new and exciting.

Speaking on behalf of the Board, we would like to encourage participation in our planned events and webinars. We are also always looking for feedback on what you, the members, want to see from us – what areas of training can we provide, who would you like to have present at our annual meeting, what can we do to support you in your QA needs in Canada?

Lastly, our CCSQA is only as strong as its members – we ask that you get involved, volunteer, help organize a webinar or many other countless ways you can help us make the best SQA chapter. Reach out to us at info@ccsqa.org.
We look forward to hearing from you!

Warmest regards,
Sherry Lee Dawson, 2018 CCSQA President

CCSQA BOARD OF DIRECTORS

The Board of Directors is composed of engaged and passionate volunteers with a desire to provide leadership in Quality and Education. We meet on a monthly basis to develop and provide educational programs and content that will reach our members and help advance current quality assurance standards. Feel free to contact any Board of Directors with questions/comments about the CCSQA and how you can take a more active role.

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MEET YOUR 2018 BOARD OF DIRECTORS

PAST PRESIDENT

JULIE ROUSSEAU

Julie Rousseau started her career in Quality Assurance in 1999 where she joined Anapharm, a CRO based in Quebec City and occupied various management positions and multisite oversight. As Director, Quality Assurance and Regulatory Compliance Julie is responsible for the maintaining of an overall quality system that meets the highest standards of the pharmaceutical industry and regulatory expectations in the field of GCP and GLP regulated activities. Involved in conducting various types of audits and have been hosting more than 40 regulatory inspections by various bodies around the world such as the FDA, Health Canada, EMA, ANVISA and hosting client audits in both GCP and GLP fields on a regular basis. Currently working at Syneos Health at the QA Direction for operations located in Canada, Julie is responsible for maintaining the quality program for Early Stage business unit as well as collaborating with wider quality group in Phase II-IV whose colleagues are located in multiple countries and supporting the annual audit program. I thus have opportunity for sharing ideas mostly in clinical research during the different development phases but also for non-clinical studies.

PRESIDENT

SHERRY LEE DAWSON

Sherry Lee Dawson, is a Senior Quality Systems Project Manager at Charles River Laboratories Montreal ULC, a safety assessment site conducting GLP studies. In this role she oversees various projects, including Regulatory Inspections, Sponsor Audits, Vendor Audit program for her site, quality metrics and other internal cross site projects / initiatives. Her regulatory work experience of 19 years has covered FDA GLP and OECD Principles of GLP across Toxicology, Pathology and Laboratory Science focussed work. She is a Registered Quality Assurance Professional (RQAP) GLP since 2001. Sherry has served on the RQAP Board for 3 years, on the Canadian Chapter of Quality Assurance for 3 years (currently the President) and is current co-vice chair for the Bioanalytical Speciality Section of the Society of Quality Assurance. She holds a BSc in Biology from McGill University in Montreal, Quebec, Canada

VICE-PRESIDENT

JOSÉE ANN DULUDE

Josée Ann Dulude started her career in the pre-clinical research business as an animal technician at Bio Research (formerly known as Charles River Laboratories) back in 1997. Her need for new challenges helped her move to the Quality Assurance department where she first obtained a data reviewer position. Through the years she have acquired knowledge and expertise which led to becoming a senior inspector in 2008 at Citoxlab North America. Recognized for her expertise and my “out of the box thinking”, Josée Ann was promoted as Manager of Global Planning and Process Improvement in 2011 where she was in charge of the management of the archives, global planning and costing of studies. Still, her love for the regulations and her ability to bring Operation and QA together brought her back in Quality Assurance in 2013 as a QA Manager. Now acting as a QA Director at Citoxlab North America, Josée Ann has accumulated over 20 years of experience in the GLP industry. Her involvement covers a diversity of expertise including but not limited training, client/government audits, corporate harmonization of procedures, external audits and management. Josée Ann’s ability to communicate and her desire to always expand beyond her limit and the scope of her duties brought appreciation and true collaboration from her peers and superiors.

TREASURER

FRANCO MANCINI

Franco obtained a BSc in Biochemistry and Food Science in 2002/2005 from McGill University. He began his career as an GLP Quality Assurance Inspector at ITR Laboratories Canada Inc in 2005 and in 2016 was promoted to the position of GLP Quality Assurance Supervisor at ITR Laboratories Canada Inc. Franco has been a QA professional in the GLP for 13 years now. Franco has been a member of the CCSQA since 2007 and an SQA member since 2014. He is currently on the CCSQA board of directors as the Treasurer and held the position since 2014. Franco has obtain the RQAP-GLP designation from the SQA since 2009.

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Dimitra Copitas, Director

My career began in the clinical research business as an analyst at MDS Pharma Services back in 1998. My desire to learn more and progress further helped me move to the Quality Assurance department where I first obtained an auditor position. A few years later I acquired knowledge and expertise which led me to become a Senior Auditor in 2002 at MDS Pharma Services and a Senior Auditor at Biotrial Bioanalytical Services in 2003. In 2015, I was promoted to setting up the quality system at the Newark, USA, Biotrial clinical site supported by the Quality Assurance department in France. However my longing for knowledge and new challenges brought me over to the pre-clinical world, In 2017, I joined the QA department of Citoxlab North America, as Senior Auditor where I can share my 18 years of experience in the GLP and GCP industry. My background covers a range of expertise and my strong assets of organization communication and believing in myself provided exceptional relations with my peers and supervisors.

Nooshin Davani, Director

After 6 years working in a clinical microbiology lab in Iran, Nooshin joined Charles River Laboratories Montreal in 2004. She began her career in Quality and quickly moved through the ranks as a QA Auditor. During these years in addition to auditing variety of GLP studies and computer system validation (CSV), Nooshin actively took part in vendor audits and hosting sponsor and government audits. Currently Nooshin is a Regulatory and Compliance Manager at Charles River Lab and is a Registered Quality assurance Professional (RQAP) GLP since 2007. She has served 1 year at Canadian Chapter of quality Assurance (Director).Nooshin holds a Bachelor's degree in Science, with specialization in Microbiology from university of Isfahan, Iran.

Maghi Borgi, Secretary

Maghi started working as a Histology technician, in a pre-clinical testing Facility formally known as Charles River Laboratories, moved on to the Hematology department, where she occupied an analyst position. Quickly moved to the QA department where she held an auditor position working with study directors and auditing different type of Toxicological preclinical studies. While looking for new challenges and opportunities, Maghi was employed at Biotrial Bioanalytical Services, started as a senior auditor then promoted to Lead QA auditor, where she took the initiative with quality assurance tasks and manage QA team. Implementing audit processes, defining QA methodology, monitoring trends, hosting in client /government audits; and part of the company-wide initiative Vendor and Supplier Quality Systems Committee. After 18 years in the business, Maghi is now a QA Manager at Citoxlab North America, where she manages a group of auditors, overseeing the Quality Assurance System. Her vision is to make a team of auditors where her encouragement to the team is very important and crucial to make a great team, she believes by the following saying from Henry Ford: "Coming together is a beginning. Keeping together is progress. Working together is success"

Sandra Chiovitti, Director

Sandra Chiovitti began her career in the pre-clinical research industry as a project coordinator in 2006 at the ProCure Quebec Biobank. Her experience with implementation and development of formalized quality systems shifted her focus to quality assurance. In 2008 she was hired as a Quality Assurance Associate at Genizon Biosciences Inc. assessing GLP and GCP systems and activities. As the current Quality Assurance Manager at InSymbiosis, her expertise has expanded to include GLP, GCP, and to a lesser extent GMP related activities. Her primary responsibilities are to maintain the internal quality management system and manage vendor/third-party qualification assessments. Sandra has been a member of the CCSQA and SQA since 2012 and has been designated as a RQAP-GLP professional since 2013. In 2017 she was elected as a CCSQA board member. Sandra holds a Master of Science degree in Biology from Concordia University, Quebec. She has recently returned to graduate school to pursue a PhD degree in Management to explore the underlying institutional logics within the pharmaceutical industry.

Andjica Tasic, Director

A versatile professional with over 20 years of experience in Clinical Research field managing the conduct of the phase I, II, III and bioequivalence/bioavailability studies. Certified Clinical Research Professional (SOCRA), Certified Quality Auditor, certificate and accreditations from American Society of Quality (CQA) and member of the General Clinical Research Support Service – Scientific Reviewer NIH. Expert in establishing overall company's Quality System, always ready to provide leadership support, training and guidance to all company personnel.Recognized by upper management for hard work and dedication as a company solo representative during regulatory body inspections. Hosted and prepared numerous Regulatory Inspections (FDA, Health Canada, EMA, ANVISA and OECD GLP). Performed over 40 supplier and vendor audits to assure compliance with GMP, GLP, GCP and other applicable regulations. Committed to the principles and practices that result in high quality product and services, satisfied customers and continual improvement. Received a company award for innovative training and team development initiative.

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WEBINAR

Did you know that the CCSQA has already hosted two webinars this year, one in February and one in May, as described below! These webinar are complimentary to CCSQA members, SQA members, and other Regional Chapter Members and FREE.

Nonmembers may register at $25 and will receive a 2018 CCSQA Membership.

You have missed your chance of attending!!!

We are now Calling for Webinar Presenters

DO NOT MISS YOUR CHANCE TO MAKE A DIFFERENCE!!!

CONTACT US: info@ccsqa.org

February CCSQA Webinar

"Manufacturing Data Integrity"

Speaker: Aaron Clarke, Quality and Compliance Services

Description: The accelerating pace of technology adoption continues to create the requirement for change within the pharmaceutical industry. The use of electronic systems to conduct regulated activities within pharmaceutical production facilities has a direct potential impact to patients from inaccurate or unreliable data. It is, therefore, mission-critical for your company to incorporate core Data Integrity concepts, and maintain effective quality systems governance at both system and record level, based on data use and importance. This presentation complements recent webinars by describing key concepts, provides examples of data risk, and identifies control processes associated with managing the integrity of data at your company.

May CCSQA Webinar

Quality by Design in Bioanalysis

Presented by

Mitesh Pillai, Zydus Research Centre

Bioanalysis plays a crucial role in deciding the outcome of the study in case of bioequivalence studies. Bio-analytical methods are developed and validated based on the scientific approach. There are many cases when a validated bioanalytical method does not perform during the study sample analysis even after successful validation. This may lead to much complication during the sample analysis.

The quality by design approach can be implemented during the method development phase in the laboratory. This shall help in achieving the targeted method performance. This will also help the laboratory to avoid failures during the study sample analysis. Moreover, the same method can be used for multiple study sample analysis.

Quality by design shall help in building the quality parameters at the development of the methods.

The quality by design approach shall help in building confidence in the regulatory authorities about the method validity and building expected quality in the method development of the assay.

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ANNUAL MEETING

November 1, 2018

Courtyard Montreal Airport
7000 Place Robert-Jancas, Montréal
H4M 2Z5 Canada
(514)339-5333

The Board is finalizing the details of November 1, 2018 annual meeting which is a great occasion to meet, network, and start discussion with colleagues from the regulated research quality profession. Among all the guest speakers, there is always an open plenary for Questions & Answers. A 5 à 7 networking event will again be organized to allow members to get together in trendy close by location.

The CCSQA is NOW calling for presenters!!!

Please submit your abstract at info@ccsqa.org and make plans to attend to this November venue.

The CCSQA will consider all regulatory QA topics for presentation: clinical (GCPs), preclinical (GLPs) and manufacturing (GMPs).

****Other areas of interest include animal health, bioanalysis, biotechnology, computer validation, medical devices, pharmacovigilance, scientific archiving, university issues and much more!*

If interested, please send an email to info@ccsqa.org by September 14, 2018 with the following information:

- ***Brief presenter biography***
- ***Abstract (300 words maximum)***
- ***Time requested for presentation and Q&A (30, 45 or 60 minutes)***
- ***Indicate if the PowerPoint presentation will be provided to attending members***

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REGULATORY MILESTONE

February 2018 the OECD Good Laboratory Practice published a new edition of the frequently asked questions (FAQ)

http://www.oecd.org/chemicalsafety/testing/glp-frequently-asked-questions.htm

April 2018 the OECD advisory document #19 entitled "*Management Characterization and Use of Test Item*" was released

http://www.oecd.org/general/searchresults/?q=OECD advisory document#19 entitled "Management Characterization and Use of Test

May 2018 the Food and Drug Administration published the Bioanalytical Method Validation Guidance for Industry

https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070107.pdf

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CALLING FOR SPONSORSHIP

Be visible and benefit of the CCSQA Annual Meeting by supporting the event

CONTACT US: info@ccsqa.org

Corporate Sponsorship

Companies wishing to help coordinate activities and/or underwrite expenses of CCSQA are invited to join us as sponsors. A number of different commitment levels are available through direct or indirect (goods and services) contributions. The costs and benefits of each type of sponsorship are listed below.

Titanium Sponsor | CCSQA Chapter Meeting Host
Your company name is listed in meeting programs, meeting-specific and legacy sections of our website. Recognition by peers and/or potential customers.

Platinum Sponsor | $1000 or more
Your company name is listed in meeting programs, meeting-specific sections of our website and, when applicable, attributed to a sponsored portion of a CCSQA meeting. Recognition by peers and/or potential customers.

Gold Sponsor | $500 - $999
Your company name is listed in meeting programs, meeting-specific sections of our website and, when applicable, attributed to a sponsored portion of a CCSQA meeting. Recognition by peers and/or potential customers.

Silver Sponsor | $200 - $499
Your company name is listed in meeting programs and meeting-specific sections of our website. Recognition by peers and/or potential customers.

Chapter Meeting Supporter | Your company's promotional items
Opportunity to provide your company's promotional items to advertise to all attendees of the CCSQA Meeting. Given potential to find new customers and to have your company name listed as a Supporter within the meeting program.

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Dear Colleagues,

We are looking forward to hearing back from our members. Feel free to contact your CCSQA board at *info@ccsqa.org* if you would like to make a contribution to the newsletter. All quality topics and questions are welcome! .

We encourage all of you to become more involved with the Canadian Chapter and we hope to see you at our next meeting which will be help on *November 1, 2018 at the Courtyard Montreal Airport*

In addition to our usual events, this year CCSQA is exploring additional activities to engage members and we are always looking for members to help out with CCSQA activities. If you have any interest, please email us at *info@ccsqa.org*.

Sincerely,
Your CCSQA Board.