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

Newsletter / Journal

Volume 3, Issue 2 December 2004

INSIDE THIS ISSUE

2005 CCSQA Board of Directors and Nominees

President - Anne Beaubien anneb@envirotest.com

Treasurer - Penny Kirsch penny_kirsch@yahoo.com

Director - Paul Sidney psidney@ctbr.com

Director - Michael Maddix Maddixm@wyeth.com

Past-President - Janine Johnson jjohnson@cato.com

BALLOTS DUE: 24 December 2004

Nominees:

Vice-President – Deborah Dragoon Dragood@wyeth.com

Director – David Grégoire dgregoir@pharmascience.com

Director – Shelley Antel santel@hill-top.com

Secretary- Joanne Tyas jtyas@itrlab.com

President's Message

CCSQA President – Janine Johnson

Well this is it…My last official presidential address. My year in office has been full of challenges and I hope that you all are as pleased with the results as I have been. To recap we had a great turnout at the SQA meeting in Reno, NV; the board met lots of members at the CCSQA lunch table and during our bowling-night-out. Our annual training and membership meeting in October was a smash success with a 38% registration increase over our first meeting. We had very interesting and knowledgeable speakers and great interaction among the attendees with differing interests.

This February at the SQA meeting in Florida we will be participating in the World Fair; poking some fun at our Canadianisms with a "Pin-the-Tail-on-the-Beaver" game and a Little Known Facts About Canada Trivia Contest. We will also have Maple Syrup candies and some nice prizes for the booth draw. I look forward to seeing you all at the booth and no, I will not be in an RCMP costume, but I might be persuaded!!!!

Thank you all for your continued support.

Janine

Financial Report 3rd and 4th Quarter 2004

***CCSQA Treasurer* – Penny Kirsch**

$1579.15 June 30, 2004 Balance

Income

$3355.00	October Meeting Registrations
$100.00	2005 Memberships
$3455.00	Total

Expenses

$48.43	Accutel Conferencing Systems (August)
$1552.72	Embassy West Conference
$135.61	Gifts for Conference Presenters
$1736.76	Total

$3297.39 December 20, 2004 Balance

What's New on the CCSQA WWW

We had 2330 Website visits since January 2004 with the most visits/hits occurring in June. The average hits per hour in December ranged from 1 to 26 and the average hits per day were between 27 and 55. According to the Web Page Statistics, the Canadian QA website links and career opportunities were some of the top links visited.

Please submit requests for Web Page content to Ms. Debbie Dragoon at **dragood@wyeth.com**.

Membership Committee Update

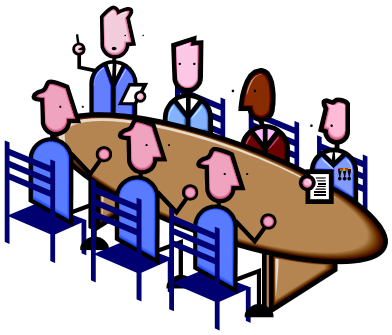
Membership by the Numbers: 64 members as of 20 December 2004 (25 new / 39 renewed)

Our goal, as in previous years, is 75 members. We need your help to reach our goal, please renew your membership or reach out to other QA professionals you know and tell them about the CCSQA.

WELCOME NEW MEMBERS for 2005

Jeanne Dunn – EMCH Medical Pipeline Testing

Helen Penny – Agriculture and Agri-Food Canada



WHERE ARE THEY NOW????

Nahid Bibak – Viridae Clinical Sciences

Michael Harvey – Xanthus Life Sciences

CANADIAN REGULATORY UPDATES

HPFB news can be found at *www.hc-sc.gc.ca/hpfb-gpsa/inspectorate/new_e.html*

PMRA news can be found at http://www.pmra-arla.gc.ca/english/main/new-e.html

BGTD news can be found at http://www.hc-sc.gc.ca/hpfb-dgpsa/bgtd-dpbtg/whatsnew_e.html

NHPD news can be found at http://www.hc-sc.gc.ca/hpfb-dgpsa/nhpd-dpsn/index_e.html#1

TPD news can be found at http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/whatsnew_e.html

Environment Canada CEPA registry news can be found at http://www.ec.gc.ca/CEPARegistry/default.cfm

Health Protection and Food Branch Updates

- Summary Report of the Inspections of Clinical Trials Conducted in 2003 / 2004 (December 14, 2004)
- Guidelines for Temperature Control of Drug Products during Storage and Transportation - Draft (GUIDE-0069) (December 1st, 2004)
- Standard for the Fabrication, Control and Distribution of Antimicrobial Agents for Use on Environmental Surfaces and Certain Medical Devices (GUIDE-0049) (December 1st, 2004)
- Annex 3 to the Current Edition of the Good Manufacturing Practices Guidelines for Selected Category IV Monograph Drugs (December 1st, 2004)
- Summary Report of the Compliance Inspections of Canadian Pharmacy Sites Involved in the Sale of Prescription Drugs Via the Internet or Via Distance Dispensing (November 16, 2004)
- Letter to Stakeholders - Creation of a Regulatory Framework for the Implementation of Good Manufacturing Practices for Active Pharmaceutical Ingredients (October 28, 2004)
- Alternate Sample Retention Site Application Form (October 26, 2004)
- Guidance for Records Related to Clinical Trials (GUIDE-0068) (October 25, 2004)
- Companies that hold a Drug Establishment License (October 1, 2004)
- Mutual Recognition Agreements (MRAs) Updates (October 1, 2004)
- Letter to Stakeholders Regarding Proposed Amendments to the Medical Devices Regulations - Schedule 1426 (September 14, 2004)
- Guidance on the Processing and Distribution of Semen for Assisted Conception Regulations (GUIDE-0041) (September 1, 2004)
- Policy for the Importation or Sale of Active Pharmaceutical Ingredients for Veterinary Use (August 22, 2004)
- Validation Guidelines for Pharmaceutical Dosage Forms (GUIDE-0029) (August 15, 2004)
- Inspection Strategy for Post-Market Surveillance (POL-0041)(June 25, 2004)

- Risk Classification of Post-Market Surveillance Observations (GUI-0063) (June 25, 2004)

HPFB Electronic Review Initiative

- Call for Volunteers Members for a Working Group on Electronic Submissions
- Canadian DTD for ICH Module 1 eCTD now available
- CAPRA CTD/eCTD Symposium - June 1 & 2, 2004
- Guidance for Industry - Creation of the Canadian Module 1 eCTD Backbone File
- Guidance for Industry - Preparation of Drug Submissions in the eCTD Format
- Letter of Interest for an E-Submission and E-Review Solution

Pest Management Regulatory Agency Updates

- **December**

  Status of NAFTA Joint Reviews (JR) U.S. EPA, Canada PMRA, and Mexico CICOPLAFEST

- **November**

  Re-evaluation of Aluminum and Magnesium Phosphide (PACR2004-43)

  Chondrostereum purpureum Strain PFC2139 Cp-PFC2139 (Technical Grade of Active Ingredient); Chontrol Paste (End-use Product) (REG2004-09)

  Methoxyfenozide (REG2004-08)

  Isomate-P Pheromone for use in Orchards for Mating Disruption of the Peach Tree Borer (RDD2004-04)

  Formic Acid/NOD Formic Acid Pad and Mite-Away II™ Formic Acid Pad (PRDD2004-05)

  Capsaicin (RRD2004-30)

- **October**

  Draft Adverse Effect Reporting Forms

  Adverse Effects Reporting Regulations (October 23, 2004) - Canada Gazette, Part I, page 2952

  Re-evaluation of Sodium and Calcium Hypochlorite (PACR2004-42)

  Re-evaluation of Paraquat Dichloride (PACR2004-41)

  Re-evaluation of Acephate (PACR2004-40)

  Re-evaluation of 5-Chloro-2-methyl-3(2H)-isothiazolone and 2-Methyl-3(2H)-isothiazolone (PACR2004-39)

  Daminozide (RRD2004-29) and 3-Trifluoromethyl-4-nitrophenol (RRD2004-28)

  Florasulam EF-1343 Suspension Concentrate Herbicide (PRDD2004-04)

  Re-evaluation of Phosmet (PACR2004-38)

- **September**

  1-methylcyclopropene (REG2004-07) and Strategic Plan 2003-2008

  Mitin FF (RRD2004-27)

  Re-evaluation of Triclopyr (PACR2004-37)

  Clothianidin Poncho 600 Seed Treatment Insecticide (REG2004-06)

  Re-evaluation of citronella oil and related active compounds for use as personal insect repellents (PACR2004-36)

  Soap Salts (RRD2004-26)

Biologics and Genetic Therapies Directorate

- **November**

  Revised Templates and Related Proposals for Summary Basis of Decision - Drugs

  Draft Guidance for Sponsors Lot Release Program for Schedule D (Biologic) Drugs

  Project Management in the Review Process - DRAFT Qs and As for Sponsors

  BIOTECanada and the Biologics and Genetic Therapies Directorate Draft Meeting Notes

- **October**

  Expert Advisory Committee on Blood Regulation: May 05-06, 2004 Record of Meeting

  NUCLEAR MEDICINE ALLIANCE (NMA) and the BIOLOGICS AND GENETIC THERAPIES DIRECTORATE (BGTD) Meeting notes

  Draft Guidance for Industry: Drug Name Review: Look-alike Sound-alike (LA/SA) Health Product Names

  Draft Guidance for Industry: Marketed Health Product Name Assessment: Look-alike Sound-alike (LA/SA) Health Product Names

Natural Health Products Directorate

- Compliance Message 2 - Priority 1 Substances Date: June 30, 2004 (updated July 13, 2004)
- Approach for Review of products containing NHP ingredients set out in the TPD Labelling Standard or Category IV Monographs Date: July 5, 2004
- Information concerning applications for DIN, received by TPD prior to December 31 st, 2003 where the classification of the product is affected by the Natural Health Products Regulations Date: June 24, 2004
- Natural Health Products on the Listing of Drugs Regulated as New Drugs (April 1999 edition) and their Compliance Priority Categories Date: June 16, 2004
- Compliance Message - Priority 1 Substances Date: June 4, 2004
- Amendment to the Natural Health Products Regulations concerning Health Canada's Special Access Programme (SAP) Date: June 2, 2004

Therapeutics Products Directorate

- **December**

  Food and Drug Regulations - Project 1445 - Schedule F Update

  Newsletter; Winter 2004

  Consultation; Draft Guidance for Industry - Private Label Medical Devices

  Association Meeting; Canada's Medical Device Technology Companies (MEDEC) - Minutes of Meeting

  Notices & Early Consultation; Food and Drug Regulations - Project 1434 - Schedule F Update

  Therapeutic Products Directorate (TPD) - 2004 Quarterly Drug Submission Performance Report - Part I

  Biologics and Radiopharmaceuticals Evaluation Centre (BREC) - 2004 Quarterly Drug Submission Performance Report - Part II

  Therapeutic Products Directorate (TPD) - 2004 Quarterly Drug Submission Performance Report by Bureaux- Part III

Therapeutics Products Directorate (continued)

- **November**

  Food and Drug Regulations - Project 1439 - Schedule F Update

  Summary of Submission Performance - Medical Devices 2003 - Report

  Submission Fee Application Form

  Revised Templates and Related Proposals for Summary Basis of Decision - Drugs

  Revised Templates and Related Proposals for Summary Basis of Decision - Devices

  Scientific Advisory Committee on Musculoskeletal Therapies - Terms of Reference

  Scientific Advisory Committee on Musculoskeletal Therapies - Nomination Call Letter

  Policy Guide for the Management of Advisory Committees in Health Canada

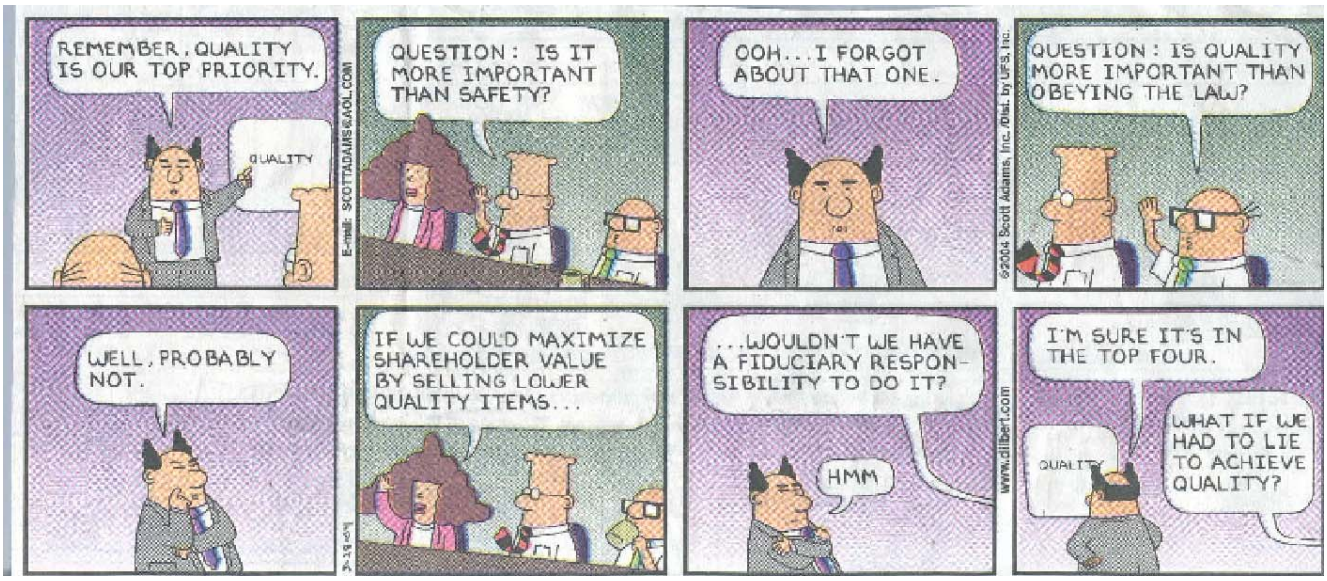
Environment Canada (CEPA Registry)

- Canadian Environmental Protection Act Review [2004-12-14]
- A Guide to Understanding the Canadian Environmental Protection Act, 1999 [2004-11-25]
- Government of Canada Proposes Improved Reporting Process for New Chemicals [2004-11-01]

Public Consultations

- New Substances Notification Regulations (Chemicals and Polymers) [2004/10/30 - 2004/12/29]
- New Substances Notification Regulations (Organisms) [2004/10/30 - 2004/12/29]
- Regulations Amending the New Substances Fees Regulations [2004/10/30 - 2004/12/29]
- Regulations Repealing the New Substances Notification Regulations [2004/10/30 - 2004/12/29]

DILBERT (copyright United Feature Syndicate and Scott Adams)



Upcoming Events

SQA's 21th Annual Membership Meeting and 1st International QA Conference

February 20-24, 2005
Orlando, FL USA

http://www.sqa.org/AM2002/Annual_mtgs_main.htm

If you are interested in participating in the planning of this historic meeting, please contact **Moira Bandoli (mbandoli@bioanalytical.com), 812/985-5900 x 121,** Chair of the 2004 Program Committee.

ENTER AND WIN - THE SQA PHOTO CONTEST!

SQA Historical Committee - **Victor I. Green, RQAP-GLP**

The SQA Historical Committee invites you to take pictures at this year's SQA-sponsored events, then submit them and/or any photos from past SQA events for entry in the SQA Photography Contest at the 21st SQA Annual Meeting and 1st International QA Conference in Orlando, FL in 2005.

Photo Contest Guidelines:

1. All photos must be taken during an SQA event: SQA Annual Meetings, SQA regional Chapter Meetings, SQA-sponsored training sessions or other SQA event.
2. Photos must be of SQA members attending the event.
3. Photos may be submitted in print format or in digital format recommended to be submitted in .jpeg format).
4. Type or legibly print your name and affiliation, phone number, names of individuals in the photograph, (left to right and front to back) on two small sticky labels. Also, include the name/ date/location of the SQA event (month and year are okay, if you do not know the full date). If the photo is submitted digitally, assemble the information and submit the label information with the digital image.
5. Secure one of the labels (from step 4) to the back of the photograph and submit the other label with the photograph. The extra label (or information submitted with digital photograph) will be used for display of the photograph.
6. Photos may be submitted via mail address to the attention of: Celeste Rose, RoseTECH Consulting, Inc., 1135 Dorothea Dr. Painesville, Ohio 44077. **Photos will not be returned, but will become part of the SQA Historical Photo archives.**
7. Digital photos may be sent via e-mail to Celeste Rose at crose@rosetechconsulting.com
8. The deadline for submission of photos via mail or e-mail is **January 15, 2005.**
9. Photos may also be submitted in a manila envelope to the SQA Historical Committee at the time of the Annual Meeting in Orlando, FL

Council on Professional Registration

The GLP Quality Assurance Professional Registry Examination has evolved with the Quality Assurance profession. Examinations given in 1997-2002 included questions based on FDA and EPA GLP regulations. Questions based on the OECD GLP principles were included in the 2003 examination and will be included in all future examinations. By including OECD GLP questions, the examination provides a well-rounded registration examination that represents the Quality Assurance profession for our US, Canadian, and International membership base, and for the Quality Assurance profession as a whole.

The GLP Quality Assurance Professional Registry Examination consists of 150 multiple-choice questions. Candidates are allowed three hours to complete the examination. Individuals passing the examination will be credentialed as Registered Quality Assurance Professionals in GLPs (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 the professional testing agency (Applied Measurement Professionals, AMP) that is contracted to assist SQA with development, administration, scoring, and analysis of the examination. The GLP Quality Assurance Professional Registry Examination is administered annually. For 2004, SQA has added an additional administration primarily for quality assurance professionals outside the United States. The examination schedule for 2004 and 2005 follows.

2005 Examination Schedule

Next Examination Date: Saturday, 19 February 2005

Application Postmark Deadline: Monday, 03 January 2005

Test Center Locations: Orlando, FL (SQA Annual Meeting); Chicago, IL; Philadelphia, PA; San Diego, CA

For Saturday examinations, examinees must report at 8:30 am. The examination begins at 9:00 am SQA reserves the right to cancel a test center due to insufficient registration. If SQA cancels a test center, the candidates who selected that center will be notified and may choose another test center or submit a written request for a full refund. The request for a refund must be sent to SQA Headquarters and be postmarked at least seven days prior to the administration of the examination.

Eligibility Requirements

To be eligible for the GLP Quality Assurance Professional Registry Examination, applicants must fulfill one of the two following requirements:

1. Have the equivalent of four years of full-time experience working as a quality assurance professional prior to the examination date; OR
2. Have a baccalaureate degree AND the equivalent of two years of full-time experience working as a quality assurance professional prior to the examination date.

Examination Fee: The examination fee in 2005 is $275 (USD).

For more information please visit the Professional Registration page on the SQA website: http://www.sqa.org/newsite/cpr/rqapglp-exam.asp

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OECD UPDATES

OECD SERIES ON PRINCIPLES OF GOOD LABORATORY PRACTICE AND COMPLIANCE MONITORING NUMBER 14 : The Application of the Principles of GLP to in vitro Studies.

Publication date(s): English 30 November 2004; French 01 December 2004

http://appli1.oecd.org/olis/2004doc.nsf/linkto/env-jm-mono(2004)26

GET NOTICED!!! Advertise HERE!

Advertisements are posted for 60 days on our webpage http://www.ccsqa.org/ and in each issue of our newsletter (average of 2 per year). The following rates are for non-members; members will receive a 25% discount off the published rates.

Full Page	(7in x 9 in)	150$
1/2 Page	(3.5in x 9in)	100$
Business Card	(3.5in x 2in)	50$

Newsletter only rates are as follows:

Full Page	(7in x 9 in)	75$
1/2 Page	(3.5in x 9in)	50$
Business Card	(3.5in x 2in)	25$

Webpage only rates:

30 days	25$
60 days (one update)	50$
90 days (two updates)	75$

All ads must conform to the dimensions listed in the rates. The publisher is not liable for advertisements printed from faulty ad materials. Advertisements may be modified due to size limitations on the webpage and electronic transfer to members. Submitters will be notified and asked to approve any modifications, prior to publication.

Newsletter Specifications: Arial, 10 point, normal font; Wordperfect or Microsoft Word file format

Webpage Specifications: Microsoft Word file format (The file will be converted to PDF prior to posting on the webpage) High Resolution (at least 300dpi)

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How to Hunt Elephants – **Anonymous Contributor**

How to Hunt Elephants -- Senior Management Style

Senior managers set broad elephant hunting policy based on the assumption that elephants are just like field mice, but with deeper voices.

How to Hunt Elephants -- Sales Style

Salespeople don't hunt elephants but spend their time selling elephants they haven't caught, for delivery two days before the season opens. Software salespeople ship the first thing they catch and write up an invoice for an elephant. Hardware salespeople catch rabbits, paint them gray, and sell them as "desktop elephants."

How to Hunt Elephants -- QA Style

Quality assurance inspectors ignore the elephants and look for mistakes the other hunters made when they were packing the jeep.

FDA Regulatory Updates

On 24 November 2004, the Food and Drug Administration (FDA) issued the final rule for **21 CFR Parts 16, 1270, and 1271, Current Good Tissue Practice for Human Cell, Tissue, and Cellular and Tissue-Based Product Establishments; Inspection and Enforcement.** This rule will become effective 25 May 2005.
The FDA is requiring human cell, tissue, and cellular and tissue-based product (HCT/P) establishments to follow current good tissue practice (CGTP), which governs the methods used in, and the facilities and controls used for, the manufacture of HCT/Ps; recordkeeping; and the establishment of a quality program.

For more information go to:

21 CFR Part 1270: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1270
21 CFR Part 1271: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=1271

EMPLOYMENT OPPORTUNITIES

CANTEST®

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

CANTEST has a 35 year history of providing professional services to a wide variety of private and public sector organizations. The company is 100% Canadian, employee owned and well positioned for growth. Due to it's continued growth; the company has the following opening:

QA AUDITOR

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

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

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

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

Quality Assurance Manager
Early Clinical Research (ECR)

Under the guidance of the Sr. Director, ECR Quality Assurance (QA), you will manage the day-to-day activities of the ECR QA team. You will ensure that the records, methods and practices are in compliance with company policies, procedures and regulatory requirements. As the primary site contact for ECR QA, you will interact with external clients during client audits as well as internal departments to ensure needs and deadlines are met. You will provide guidance and will ensure regulatory compliance for audits/inspections conducted under your responsibility. You will manage and motivate a team of QA Auditors.

To qualify, you must possess a B.Sc. in Science or a related field with a minimum 5 to 6 years experience in QA. You have sound knowledge of regulations (GCP's and Part11) and a good understanding of QA's role and functions. You should possess knowledge of the Clinical processes, Pharmacokinetics (PK) / Statistical methods as well as FDA and ICH regulations and guidelines. You have good leadership and communication skills, ability to keep calm and focused under pressure.

Company profile

Giving substance to knowledge. Translating mind into matter. Those principles are the very essence of MDS Pharma Services, one of the largest contract research organizations (CRO) in the world. With our unparalleled expertise and highly sophisticated technology, we provide analytical microbiological and bioanalytical services, as well as develop and validate research projects. In doing so, we take part today in the discovery of health products destined to revolutionize the world tomorrow. MDS Pharma Services is a recognized leader in Quebec for its expertise in Phase I Clinical Research as well as their bioequivalence studies and their Pharmacokinetics/Pharmacodynamics studies.

At the heart of our success are our employees. Their unwavering commitment helps us strive to create a unique work environment, where people can apply their intelligence and reach their full potential in a milieu that reflects the MDS Pharma Services core values: respect, trust, integrity and excellence.

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

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

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Comments & Contributions

Please forward any comments or contributions for the CCSQA Newsletter to Anne Beaubien:
(anneb@envirotest.com):

- GLP/GCP contributions.
- Regulatory questions.
- Advertisements or Job Posts.
- Upcoming events.